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Stakeholder Requirements for an Ethical Framework to Sustain Multiple Research Projects in an Emerging Living Lab involving Older Adults

1 Introduction

Living Labs (LLs) are a phenomenon of increasing interest for both the public and private sector. They are defined by ENoLL "*as user-centred, open innovation ecosystems based on systematic user co-creation approach, integrating research and innovation processes in real life communities and settings*" (ENoLL, 2006). They were formally recognised by the European Commission in 2006 (EC, 2006) and in that same year the European Network of Living Labs (ENoLL) was established to create a network for European LLs and promote knowledge exchange. Despite this recognised status, the literature suggests LLs still lack formalised ethical guidelines for the design, development, and implementation of research projects, and for sustained user participation (Habibipour, Ståhlbröst, Georges, & Bergvall-Kåreborn, 2018; Pino et al., 2014; Sainz, 2012). This may be due in part, to the nature and characteristics of LLs and the heterogeneity in which LLs are conceptualised and implemented (Burbridge, 2017; Hossain, Leminen, & Westerlund, 2019; Müller & Sixsmith, 2008; Novitzky et al., 2015; Schuurman, De Marez, & Ballon, 2015; Yazdizadeh & Tavasoli, 2016). Irrespective of the context, LL researchers have the responsibility to ensure that users engage in LL research activities freely having fully understood what it means for them to take part (Perrault & Nazione, 2016), particularly on a medium to long term basis, as is often the case with LL projects.

Through this study, we sought to explore the ethical challenges involved in LL research, particularly when older adults are involved, through the experiences and views of a number of stakeholders who have been involved in LL activities. The study was part of a larger initiative called the Data Driven Research and Innovation (DDRI) Programme. Through the programme, Coventry University has been working in partnership with a specialist regional care organisation (later referred to as ‘Setting A’, this organisation offers day care, long-term residential and short-term respite care for older adults and people living with dementia), and a national housing association (later referred to as ‘Setting B’, this association offers independent living for adults over 55 years, and extra care where needed), as well as a number of other organisations on a series of research projects (see Table 1 for examples). The study described here was undertaken to explore the challenges associated with setting up DDRI as a novel LL within the two partner settings to support independent and healthy ageing for older adults through the development and use of technology.

INSERT TABLE 1 ABOUT HERE

The aim of the research was twofold: (1) to understand multi-stakeholder experiences and ethical issues related to user participation in LL research, (2) to propose an ‘ethical framework’ to guide the development and communication of future LLs projects. The research provides insight into the ethical considerations from a multi-focal perspective, taking into account the views of a range of stakeholders with an interest or concern in the LL or research outcomes. This includes the views of researchers and/or LL managers as experts (e.g. Habibipour et al., 2018), of family members, and critically the needs, expectations and overall concerns that users may have when engaging in LL research activities. In this LL context, users are the residents who provide information and act as testers, developers and designers to shape innovation within their daily living environment (Nyström et al., 2014). We also use the term participants in the paper in reference to the subjects taking part in this specific interview study.

The users in our LL are older adults, some of which may have cognitive or physical impairments. The involvement of adults with reducing cognitive and physical capacity poses specific ethical challenges, for example ensuring authentic informed consent, that users rights and well-being are taken into account, and appropriate involvement of family in making decisions about particpation and consent (Beattie & Buckwalter, 2007; Dunn, Alici, & Roberts, 2015; McDonald et al., 2016; McGuire, 2009). Researchers are guided by professional and national ethical codes of conduct for example, the International Ethical Guidelines for Health-related Research Involving Humans (CIOMS, 2016), the British Psychological Society code of conduct in the UK (BPS, 2009); or the Health code of conduct (NSW, 2015); etc.). Furthermore approval processes (for example in the UK the Integrated Research Application System for health and social care/community care research) are in place to protect participants and ensure research results in benefit and minimizes risk of harm. We argue that the range of available guidance can be a challenge to navigate and apply to complex applied and multi-disciplinary projects, and may sit outside of a researcher's usual disciplinary space. Through this research, we sought to inform the development of an ethical approach to guide the DDRI programme of projects, and in so doing form an early 'ethical framework' that to pave the way for the set-up, development and evaluation of future LL innovation activities.

2 Literature review

2.1 Framing the LL phenomenon

LLs bring together end users, researchers and industry to research, co-create and develop novel content for innovative products, services and practices within real life environments (ENoLL, 2006). Involvement of users in LLs is seen as a "*participative force for co-creating value*" (Pallot, Trousse, Senach, & Scapin, 2010, p. 2), and facilitating the creation of an innovation *ecosystem* based on a public-private-people partnership in the form of collaborative processes and knowledge sharing. This innovation process becomes user-centred (with user as subject) and participatory (with users as partners) to increase user-acceptance of new products, services or processes, and hence reduce the market failure rate (Dell'Era & Landoni, 2014; Habibipour, Padyab, Bergvall-Kåreborn, & Ståhlbröst, 2017). Innovation paradigms include 'Open Innovation' when the LL activities have clear goals with regard to processes of exploration, exploitation and retention, and 'User Innovation' where user involvement and user co-creation are central (Bergvall-Kåreborn & Ståhlbröst, 2009; Hossain et al., 2019; Leminen, Nyström, & Mika, 2019; Schuurman et al., 2015; Ståhlbröst & Bergvall-Kåreborn, 2011; Westerlund, Leminen, & Habib, 2018; Yazdizadeh & Tavasoli, 2016, Hossain et al., 2019; Schuurman et al., 2015).

Whilst the focus and approach may vary, there are key facets and characteristics that can be identified across existing LLs (Hossain et al., 2019). Firstly, this includes the use of real-life settings for the development of new products and services. This could range from a wide set of environments and contexts in which specifically the users are engaged, to the application of methodologies to identify and analyse user needs, preferences and expectations in these environments (Bergvall-Kåreborn, Ihlström Eriksson, Ståhlbröst, & Svensson, 2009; Dell'Era & Landoni, 2014; Følstad, 2008; Leminen, Westerlund, & Rajahonka, 2017). Secondly, LL research is characterised by the presence of multiple stakeholders. Multiple perspectives can contribute to the LL innovation process and outcomes (Habibipour, Padyab, et al., 2017; Pino et al., 2014; Ståhlbröst, 2012).. Multi-stakeholder collaboration and knowledge sharing is regarded as a critical factor to successful LLs (Almirall & Wareham, 2008; Buitendag, van der Walt, Malebane, & de Jager, 2012; Mulder et al., 2008; Voytenko, McCormick, Evans, & Schliwa, 2016; Wenger, McDermott, & Snyder, 2002).

Some authors have incorporated the role played by stakeholders in their conceptualisation of LLs. For example Bergvall-Kåreborn et al. (2009) propose the importance of 'openness', where multiple stakeholders cooperate and share their perspectives to foster innovation in LLs. Whereas McPhee et al. (2012) suggest that in LLs "*stakeholders form Public-Private-People-Partnerships (4Ps) of companies, public agencies, universities, users, and other stakeholders,* *all collaborating for creation, prototyping, validating, and testing of new technologies, services, products, and systems*" (p.3). Hossain et al. (2019) highlight LLs form a quadruple helix integrating collaborations between business, research and education, public administration, and civil society/users.

Activities conducted within LLs, include innovation testing, validation, experimentation and co-creation (Almirall & Wareham, 2008; Følstad, 2008; Hossain et al., 2019; Mulder et al., 2008; Schuurman, Mahr, De Marez, & Ballon, 2013). These activities could be grouped in terms of exploration and exploitation (Almirall & Wareham, 2011). Methodologically, ENoLL (2006) further state that LLs "*are both practice-driven organisations that facilitate and foster open, collaborative innovation*". LLs typically involve multi-method design-driven approaches (such as ethnography, qualitative and quantitative methods, etc), in which the co-design/co-creation criteria can depend on the degree of involvement and actual utilization of user feedback and suggestions (Bergvall-Kåreborn & Ståhlbröst, 2009; Hossain et al., 2019; Kanstrup, 2017; Schuurman et al., 2013). Finally, LL sustainability and the longevity of the related activities are an important defining characteristic (Dutilleul, Birrer, & Mensink, 2010; Gualandi & Leonardi, 2018; Habibipour, 2018; Kröse, Veenstra, Robben, & Kanis, 2012; Nyström, Leminen, Westerlund, & Kortelainen, 2014; van Geenhuizen, 2018).

2.2 Framing the ethical challenges in LLs

There has been some limited exploration of the ethical issues involved during the design, development, and implementation of research and development projects (Habibipour et al., 2018; Sainz, 2012). Whilst complex ethical issues are not confined to work in LL's this is one setting where the researchers do need to embrace reflexivity in order to process the "ethically important moments" that will occur during the research (Guillemin & Gillam, 2004).

Ethical awareness is also critical for projects where older adults and cognitively impaired adults are present and directly involved (Beattie & Buckwalter, 2007; Dunn et al., 2015; Pino et al., 2014; Sainz, 2012). Some key issues and concerns are covered by procedural ethics (e.g. obtaining approval form relevant ethics committees), and ethical codes of conduct (such as those noted above), that apply to research involving human participants. Guidance relates specifically to working with older adults, as well as those with physical and cognitive impairments (Finlay, 1998; Guillemin & Gillam, 2004; Holden et al., 2016; Mackin et al., 2009; McGuire, 2009; Ramcharan & Cutcliffe, 2001; Tinker, 2003; Waycott et al., 2015). For studies in the LL context, the issue of informed consent is important and the potential need to consider the renewal of that consent during a specific project as well as long-term participation in a research programme (Fields & Calvert, 2015; Mayo & Wallhagen, 2009; Pino et al., 2014; Ukamaka, 2009; West, Stuckelberger, Pautex, Staaks, & Gysels, 2017).

When undertaking research with people with cognitive impairments, the literature introduces the concepts of 'fluctuating consent', 'process consent' or 'rolling consent' (Dewing, 2007; Novitzky et al., 2015; Stirman, 2018) to ensure willing participation. These include (a) the necessity to repeat information on an iterative basis (i.e. not only when requested), and asking for consent during the various stages of the research development, (b) listening to the content and nuances of the speech and continuously assessing whether participation is voluntary and (c) communicating the possibility of opting-out or withdrawing from research at any given stage (Novitzky et al., 2015). In addition, the authors suggest '*judiciousness'* and a more comprehensive human-centred approach from both researchers and care-givers where research activity may involve long-term data gathering.

With the recent introduction of the General Data Protection Regulation (GDPR 2018) to regulate data protection and privacy for all individuals within the European Union (EU, 2016/679), the management of data and privacy will be brought more sharply into focus.

Researchers need to adhere to the seven principles of GDPR (2018) by ensuring their research is compliant with aspects of fairness and transparency, purpose, data minimisation, accuracy, storage limitation, integrity and confidentiality and accountability. Some of these aspects may prove challenging for LL research and will require careful consideration in the planning of the research. As LLs involve real life communities and settings, the boundaries between research as a defined activity and daily living can become blurred. Challenges are recognised in the protection of user data and privacy, particularly where there is necessity to obtain full, long term confidential information and filter from this information anything that the users do not wish to have released (Korman, Weiss, & Kizony, 2016; Sainz, 2012; van Wynsberghe & Robbins, 2014).

In terms of developing and sustaining a LL project, another critical ethical issue regards maintain user interest and participation in projects or potential withdrawal during the lifetime of the LL project. Kang (2012) highlighted that finding the right people and keeping them, is one of the most critical factors to sustain LLs. User needs, (intrinsic/extrinsic) motivations and expectations can change over time, leading to drop-out from research activities prior to completion (Callari et al., 2019; Georges, Schuurman, & Vervoort, 2016; Habibipour & Bergvall-Kåreborn, 2016; Habibipour, Georges, Schuurman, & Bergvall-Kåreborn, 2017; Habibipour, Padyab, et al., 2017; Habibipour et al., 2018). Co-creation activities are an active method to fully engage LL users in the design of artefacts, beyond the more typical user requirement collection and evaluation phases (Schuurman et al., 2015).

The development of solutions through co-creation may raise ethical concerns in relation to the ownership of the emerging intellectual property (Draetta & Labarthe, 2010; Sharp & Salter, 2017; van Geenhuizen, 2014). The ‘ownership’ of the rights and profits of ‘collaborative’ outcome should be considered particularly when commercial partners are involved in the LLs, and where involvement of voluntary users in co-design activity produces outcomes that may be commercialised.

Building trust and operational transparency is critical to ensure successful and sustainable LL research initiatives (Kröse et al., 2012; Nyström et al., 2014; van Geenhuizen, 2018). Whilst the literature does highlight some ethical challenges and issues that may arise when projects and research are carried out (Barcenilla & Tijus, 2012; Sainz, 2012), there is still a lack of guidance and well documented ethical practice to support researchers in developing and sustaining LL research programmes (Dutilleul et al., 2010; Habibipour et al., 2018; Habibipour, Georges, et al., 2017; Habibipour et al., 2018).

3 Method

In order to investigate and explore ethical challenges involved in LL projects, a qualitative research approach was adopted with the use of semi-structured interviews (Blaikie, 2009; Ritchie, Lewis, Nicholls, & Ormston, 2014). This study was undertaken between April-December 2017. The study received ethical approval from the Coventry University Research Ethics Committee. A letter of support was provided by the residential partner organisations (i.e. Settings A and B). The principles of the British Psychological Society Code of Ethics and Conduct and UK Research Integrity Office's Code of Practice for Research guided the research.

3.1 Research participants

The study involved 26 participants. These included DDRI project stakeholders as well as experienced researchers with relevant LL/ethics experience. The DDRI programme involves researchers and experts working closely with staff and residents (i.e. users) at the two settings. This study therefore included staff, residents and families of the two partner living environments. Advertisement flyers were distributed internally in the two living environments to recruit staff and residents. Names of interested staff were passed on to the study lead researcher who then contacted the staff member to make an appointment. Residents were recruited via the recommendation of the staff team (e.g. at Setting A), or via coffee morning events advertised by a flyer at which the lead researcher gave an overview of the research to residents providing further information to those who wanted to take part (e.g. at Setting B). None of the interviewed residents had a diagnosed cognitive impairment. Family members were recruited through flyers left on the reception desk at Setting A. In total n=6 staff, n=6 residents and n=2 family members took part in the research (see Table 2).

INSERT TABLE 2 ABOUT HERE

In addition we were interested in the view of researchers working within the DDRI as well as others with previous LL related experience. The selection criteria included:

(1) researchers from Coventry University involved in DDRI
(2) researchers from other universities with experience in conducting research involving older adults and/or adults with cognitive impairments; and/or experience in projects in Living Labs (LLs), or Ambient Assisted Living (AAL); and/or expertise related to ethics.

Overall n=7 researchers and n=5 subject experts in related fields took part (see Table 3)

INSERT TABLE 3 ABOUT HERE

3.2 Procedure

The aim of the interviews was to investigate the way ethical issues are currently addressed and implemented in LL projects, particularly when older adults are involved, and to collect (user) requirements in relation to participation within DDRI and LLs. Four distinct interview schedules were developed for (1) the researchers and subject experts in related fields, and (2) staff in the 2 living environments, (3) residents as users and (4) family members of residents. The schedule for researchers and experts focused on the experience of working in a LL domain and concerns and/or propositions related to ethics. The schedules for staff, residents and families included probing questions to collect opinions (both positive feedback and concerns) about the ongoing DDRI projects in the two living environments (namely in Setting A and Setting B), and ethical issues and concerns about taking part in research. The average interview length was an hour. All participants were able to provide informed consent, after reading and understanding the participant information sheet.

3.3 Data collection and analysis

The interviews were audio recorded and then transcribed verbatim by an external provider. The transcripts were saved, coded and analysed using NVivo (v.11 Plus for Windows, ©QSR International) (Bazeley, 2007). The management of an NVivo project to record, code and analyse data provides traceability of the steps and milestones. A NVivo project (entitled 'DDRI-Driven Research and Innovation') was created, containing the research transcripts; selected literature articles; a memo journal keeping track of all activities and decision-making points agreed throughout the research; and the coding frame used to analyse the material. The project was secured with a password only known by the project team.

Qualitative Content Analysis (QCA) was used to make sense of the data (Schreier, 2012). The coding frame, agreed by all co-authors, followed a deductive approach (Saldana, 2012; Schreier, 2012) and was informed by the research objectives and a comprehensive literature review. It included nodes to reflect relevant research themes e.g. Informed Consent; Data Protection & Privacy; Involving Others; etc. Coding was performed by two researchers and the outcome shared and collectively discussed to address any disagreements. A 'Framework Matrix' was run to analyse the views and elicit requirements of the different sets of LL users /

participant groups (i.e. (A) researchers and experts; (B) staff; (C) residents; (D) families). The emerging requirements were annotated in red bold within each cell in the grid, and then aggregated to respond to the study research questions, whilst quotes were highlighted in blue. See Figure 1 below for an overview of the ‘Framework Matrix’ structure used to highlight the emerging requirements.

FIGURE 1: ILLUSTRATIVE ‘FRAMEWORK MATRIX’ IN THE NVIVO DDRI PROJECT

4 Results

The results bring together the views of a range of stakeholders. Issues raised by researchers and experts working in the context have been considered alongside those of staff, residents, and family members. The main themes are presented below.

4.1 Ethical review and approval

The ethical review and approval processes for LL-based research were considered. Both researchers and experts agreed that an ethical approach should take into account the distinctive characteristics within LLs, such as significant collaboration with users and stakeholders, the development and promotion of co-designed services and products into the market; and collaboration with organisations outside the LLs.

Researchers and experts acknowledged that there is variation in approach to ethical approval within different countries and organisations, and between research disciplines. This may be critical to those LLs promoting cross-country (e.g. USA and Europe) and cross-disciplinary collaboration:

> “*I think there are differences per country and per institutions. In the first case, it is true that most of the countries follow the European regulations in terms of ethics, but still there are different regulations, so it’s more about a general framework. In*

> *the second case, I have found really very big differences between one institution and another, depending for example on the ethics committees of e.g. a hospital or a university. Each of them has set up their own committees and their own procedures and they are very different not in terms of what is required to meet the regulations/norms, but in the set-up of the ethics documentation and the procedures*". [Expert]

Different bodies are in place to provide approval depending on the location and nature of the research, with potentially different terms of reference depending on the history of involving human participants (for example, between Psychology, Medicine, Engineering, Design etc.). Some of the residents interviewed noted that formal consideration of ethical conduct is much higher than in the past:

> *"With us oldies we have lived through a time that was less pc, an unrestricted era, there was no political correctness, we relied on discretion. Now it seems to be in more detail and you have to be very careful what you say...but it's our age, we are not sensitive at all".* [Resident]

4.2 Working with older adults, and adults with disabilities

Researchers and experts raised personal concerns about their experience of working with older adults, and adults with cognitive and/or physical impairments, and as such understanding and adapting to their needs (for example during consent processes, data collection and sharing results). These concerns also related to working with older adults to develop and evaluate innovative technology. Resident responses to research participation were also explored. One resident cautioned about potential reactions from adults suffering from underlying healthcare issues that may impact on the way they respond to research activities:

> "*You see, there are people with slight irritable problems, get het up very quickly, the sight of a piece of paper that they have to listen to and do anything with it is beyond them... You know, it's how much they can cope with and you don't know whether it's because of their underlying illness or not, you just accept them as they are and then just work around them*". [Resident]

Further, if research involves adults with cognitive/physical impairments (e.g. Dementia, Parkinson's, or sight decline issues), additional ethical challenges are posed, as also highlighted by family members who showed concerns for their parents' declining cognitive capacity and communication ability:

> "*The only thing that I think that would be difficult is if you were to spend an extended period of time with her to get her to do one single thing because of her concentration levels, she'd get tired very quickly. So it should be a gently, gently approach really*". [Family]

> "*You need to explain things to the older people - you know - they may read but it doesn't go in, you have to explain. It's no good just giving them a piece of paper*". [Family]

Suggestions were made by residents as to how research may be positioned to encourage participation. Older adults may have ambivalent attitudes towards being contacted for 'research purposes'. This could be affected by the personal background/ past experience. Consideration of language and alternative expressions such as "We want your views" may be important during participant recruitment:

> “[To take part in research] *Yeah well I think we should, yes. I’m quite happy about it. But then it depends on the background of the person, they wouldn’t normally. They’ve just never heard of it? or and like what it’s all about?*”. [Resident]

> “*I feel that as soon as you say research they’ll say “Oh no-- I’m not interested, thank you”. I think so because they think of researchers are really going inside you”.* [Resident]

The interviews considered the provision of information to potential LL users. Issues such as content, size of font, format e.g. written and audio were discussed. Exemplars were given and received positive feedback. The need to adapt information to individual resident needs was emphasised:

> “*Sight and hearing are important. We all look normal enough but everyone’s got some kind of underlying problem. For the people who are partly blind or blind, it could be read out to them. You would have here a few with sight problems*”. [Resident]

Informed consent processes are critical, but can be complex aspect in LL participation. Both researchers and experts commented that it could bring additional challenges due to research participation on a medium-long term basis, involvement in a number of varied projects in a residential space, and when participant capacity to consent may fluctuate to cognitive decline:

> “*LL participants are living in a place where data is collected about them on a daily basis, stored and then made accessible to researchers. This in my mind would require a much more explicit and clear consent process*”. [Expert]

A clear understanding of the research context was recognised to be important. This may include users participating in a number of different research projects on an ongoing basis:

> "*Well, because here we are dealing with residents living within these LL research environments, we need to make sure that they know the purpose of our research, what we are doing with the data, implications to their home privacy, security, and whether they are able to make the decision themselves, or they need a relative to help them make the decision, etc.*" [Researcher]

It was noted that participants/users may change their mind and attitude towards a specific type or stage of research, and consequently may modify the terms of involvement, or decide to opt out from the research during a project:

> "*People should be able to kind of refresh their consent or be made aware again of how things are being done. But I don't see that as particularly problematic as long as it is done in that very kind of open and often discussed way on a regular basis. This could happen in review meetings or whatever else was going on in the selected living environment*". [Expert]

The significance of the informed consent process was noted. This is important to all users in LL research activities, and may be also regarded as a 'psychological contract' and commitment to the ongoing research activities and partnership:

> "*It's a framework collaboration…It's like building an agreement about the way we work*". [Researcher]

Informed consent may also relate to the ownership and usage of the research output, and possible future initiatives that may follow from the current one, especially where co-creation and technology development is the focus. Additional consent processes should be in place for participants unable to consent, or with fluctuating ability to consent. When independent informed consent is not possible this may be given by a consultee (under the Mental Capacity Act):

> "*Currently, if adults with cognitive impairments are involved in specific clinical trial experiments, if they are not able to provide consent and/or participate in any type of activity, we refer to their legal representatives. The other way that we are experiencing this is to assess the capability of the person with some test, initial test, and see if they are able to either participate or not ...that's how we are doing it right now*". [Expert]

Family members were confident of their ability to gauge whether their parent would be willing to take part in a specific research project:

> "*If you were to go and meet Mum now what I would do is before you came into the room, I'd go and explain to Mum this is a lady that I've been speaking to and she'd like to do this and I'd explain everything to her first and then I'd introduce you and then I'd tell her what you'd like to do etc. and she would automatically say it's up to him, she would point to me because she's put the trust in me and she's got faith in me because of the decisions that I've made since she's been unable to make them herself so I think that would be the right approach to go through the relative. But if she did not want to do something, she'd make it known like physically she'd wave or be waving her finger and you'd certainly know that no she doesn't want to do that*". [Family]

The researcher and expert participants agreed that special consideration should be applied to ongoing consent when older adults, and/or adults with cognitive impairments are involved:

> "[…] *using little reminders – like watching people, considering how they're interacting, what the conversation is about and how engaged they are, how much understanding they're showing of what we're doing, just to make sure that they are present*". [Expert]

Residents agreed that it is important that researchers keep checking at regular intervals the current interest of resident as users in being part of the LL research project and refresh informed consent:

> "*It does make sense to me, because you know lots of things can happen to you, so you may feel that you don't want to get involved anymore*". [Resident]

4.3 The role of the 'care network'

Researchers and experts acknowledged the critical role of family members in a residential LL involving older adults, as well as others involved in the 'care network' (e.g. health professionals). This is needed during the implementation and running of LL research initiatives from recruitment and consent through to dissemination. Researchers and experts confirmed that when older adults are engaged in research activities in LLs, family members and / or carers should be kept informed.

> *"Involving family and carers as much as possible so that they are aware of what their relatives think about research and what their opinions are on research. Therefore they can give kind of informed views later on if there is a new research project".* [Expert]

> "*We will get the family member involved if the participants agree to it. If the person is quite sick or frail then the family member is most likely going to be involved. You know, we've had situations in the past where we've had the older person agreeing to take part in the project but their family still unsure of what's going on in the research. So they might be ringing you because they've found your number on the information sheet and saying "what's this?", etc. We would always say to the*

> *person that they should let their family member know or discuss it with them directly their involvement*". [Researcher]

One expert suggested that facilitating the older adult to share their research attitude and intentions to all members of the care network from the outset would be beneficial. This should then be followed up with an outline of the research scope, progress updates, and open communication and sharing of concerns. Residents confirmed that involving their family is important but they did raise issues in terms of the availability of their family members for decisions that they perceive as not being critical:

> "*I don't know my family is fairly well scattered around the country, there's none of them that are local. But they are already aware of different aspects concerning my health, so this involves not only this project*". [Resident]

> "*Well I think it's fair enough but I mean for my own personal thing, my daughter and my son both have quite high-powered jobs and I wouldn't want them being you know, having to do extra, sort of thing*". [Resident]

4.4 Multi-stakeholder and user participation

LLs typically involve multiple stakeholders with differing needs and expectations. To facilitate collaborative working between groups, researchers and experts pointed to the need to create a shared expectation and understanding. It was suggested that an induction training or guidance is required prior to a project running to cover key issues such as ethics, key information for working in the specific environment, needs and expectations that may differ among the involved stakeholders:

> "*We do need a very clear induction about ethics, about going to the care homes or the Living Lab, whatever it is, just to observe, to try and immerse themselves into*

> *the sort of different culture and way of doing things and they really need a whole week on ethics, they need some training*". [Researcher]

> "*[...] depending on who the client is or thinking about for example a start-up or some entrepreneur that had a wonderful idea for a product, but they don't' know anything about ethics, regulations and the market, I won't say training but at least some guidance of what is needed for them in order to comply with all is needed".* [Expert]

Researchers and experts agree that each LL research initiative should specify and/or clarify the different roles the LL multi-stakeholders (including researchers, companies, family members, gatekeepers, carers, staff, managers) will play before, during and after project completion to manage expectations.

> "*With robotic technology there are frequently commercial companies involved in research. A motivating factor might be that a company could want the data or extra data that could be used elsewhere. What are they allowed to record? What would they sell as a result? Should people have control over this? I think concerns would be similar in elder care sector*". [Expert]

> "*In terms of expectations there are two things here. One is the expectations of the end users or the users participating in the different activities in the LLs, and the other one is the expectations of the LLs themselves when they are working with a particular company or a particular organisation. You have to be very clear about the research objective, what it is about, when it begins and when it will end and what will happen afterwards, because you get engaged with different users and different needs. Good communication at all levels throughout the research initiative is essential!"* [Expert]

Participant motivation to take part in LL studies was largely intrinsic and indicated to be strongest when projects were linked to health. It was argued by residents, family and staff that they were most motivated by projects which could have a positive and/or negative impact on the residents' health, and enabling them to contribute to finding solutions to their current problems. Discussion around the individual exemplar projects provided an opportunity for the residents to bring examples from their personal experience, and demonstrated that they considered the project goals to gauge their own interest in taking part.

> "*I recognize the importance of hydration, and my general health dictates that I do have a good intake of water [...] I've got severe heart problems and hydration is quite serious for me because, if I have too much fluid, it affects the heart working properly [...] but research into it is wonderful*." [Resident]

> "*Well, this is another one [taking about the "Applied sleep interventions for elderly residents in a care home setting" project] that's right in my area of concern*. [...] *I have a big problem getting off to sleep. I notice you've got three separate ideas, the milky drink, I'm sensitive to, to milk and any dairy, cheese or anything of that sort so that rules that out for me but I get the tryptophan from bananas and dates, dried dates*." [Resident]

In the case of DDRI projects, the involvement of staff in Setting A and B is critical to effectively support a smooth run of projects, by liaising with both researchers and users during the development of the research activities. The staff interviewed recognised their critical role as an intermediary between researchers and residents in communicating and sharing information about the research, and helping the research team develop useable information sheets and respond to questions.

> "*We would need to know how it works. We would need to know all the details so that if any of the residents who are trialling it came to us with any kind of problems, we would have some idea of what to do or who to go to*". [Staff]

The staff in both settings positively approached the DDRI research initiatives and commented that they viewed the initiatives as beneficial for the residents. The staff showed no concerns about resident involvement in research and were keen to support research so long as there was potential benefit.

> "*As long as they were happy to do it, it would be absolutely fine, they are more than capable of making an assessment and testing things out*". [Staff]

> "*The people here all enjoy doing it because it will give them a meaning -- a lot of them are looking for a meaning a purpose of something to do and I think this will give them, which will be good*". [Staff]

Staff did not raise concerns about the presence of DDRI researchers for data collection, but gave recommendations on conduct for example in being flexible, giving plenty of notice about plans and fitting around the staff and care requirements. The major concern raised by staff was the impact of projects on their own time and workload. Their work is varied and unpredictable, liaising with residents and supporting their needs all day. They argue that supporting residents in interacting and dealing with novel project issues could be time consuming.

> "*... my only concern because we are extremely busy, people get allocated their time slot so in-between they don't really have much time*". [Staff]

> "*Our jobs are very sort of busy and there's never enough hours and things so it's just how much involvement we have to have. Obviously we welcome it because it's going to make the resident lives better and for the future sort of thing, it would be fantastic if someone was to come in and do it all with the residents and we didn't*

> *have any necessary involvement, but it's just how much we'd have to be involved that concerns me*". [Staff]

In addition changes to work activity (for example introducing new projects, and/or asking for support for research activities) may raise some concerns:

> "*I think some people are a bit worried about change so it's like getting them to adapt to new concepts, but I think when everything's explained properly they'd take it well*". [Staff]

4.5 Participation in research activities

The residents that were interviewed (perhaps biased by willingness to participate in the interviews) were positive about participating in LL research projects. The residents (all from Setting B) when showed information on exemplar DDRI projects were keen to explore their views on the projects:

> "*Personally I like to get involved with these sort of things because I think it keeps my brain working*". [Resident]

They also showed interest in technology related projects and showed literacy in IT technologies (e.g., use of iPads, or smartphones).

We asked questions about incentivization of participation. Although during the recruitment process the staff suggested that rewards can be used (like vouchers, or reimburse expenses to compensate for time, or as a gesture of appreciation for participation) to motivate residents to participate, both residents and family members argued that participation in LL research should happen without the need for rewards. Indeed, residents agreed that as long as projects have clear outcomes, and will produce benefits to a larger group, no rewards and/or incentives are required to motivate participation in research initiatives.

> "*Well if I were told by doing research that I were likely to get better, have better sleep I should be taking part. And even if I didn't, it would help somebody somewhere*". [Resident]

> "*We should all do our bit and not expect a reward*". [Resident]

> "*No. No rewards. That drives the wrong behaviour doesn't it?*" {Family]

> "*It's just nice to think that you've helped somebody you don't necessarily need a reward*". [Family]

They did highlight the importance of effective and ongoing information about the studies to encourage participation and maintained involvement. Residents as users and participants, and family members, expect to receive information about the outcomes the project has achieved, and how it will be built upon in the future:

> "*You know having participated in that little bit of research, it obviously links into something else and it could be nice if you can hear about it and think: "well I feel quite proud of that because I helped*". [Resident]

> "*Being involved in research you expect to hear what the results are maybe with a short note that thank you for co-operating with the research, etc. People need to know what the output is, a thank you never goes amiss*". [Family]

Staff did note that based on previous experiences, research initiatives can lack feedback on results or follow through regarding proposed projects. This past trend has led some residents to question whether to get involved in research initiatives, and this trend should change if LLs are to grow.

> "*We've had so many ...we've had people from XXX University, we've had people from XXX University, we've done the XXX project, a lot of them have done it and*

> *got involved but like I said we get no feedback, they just disappear onto the horizon and that's it. [...] I think they'd just like to know what happens, if it's made a difference, you know things like that*". [Staff]

Participants were asked for their views about withdrawal from research. Participants felt they would be able to step away from a study if they wished. The only concern raised was withdrawal in the event of a deterioration of personal physical and/or mental health. This was also highlighted by family members:

> "*That's part of the thing -- if this is no longer suitable for my Dad's condition or somebody else's condition, we just need to step outside the trial please*". [Family]

> "*Unless you just get fed up of taking part and they don't want to do it anymore, I don't see any issue*". [Resident]

> "*So again you've got to let people know that they can withdraw at any time just as you wish or because of a particular situation*". [Family]

5 Discussion

The DDRI LL emerged through a collaboration and shared interest between the involved stakeholders enabling development of a research programme benefitting from a range of disciplinary perspectives. It was driven from a user-centred perspective, rather than a strong methodological standpoint, with openness to a range of disciplinary approaches.

This study was undertaken to explore the ethical challenges involved in LL research activities. We have identified a paucity of research specifically exploring ethical issues in the context of living labs and guiding the set-up and running of new projects, or indeed new LL initiatives. This is confirmed by the ENoLL community, which urges further research to address certain key ethical challenges (e.g. privacy and use of users' data, nature of participation, ownership, etc) (ENoLL, 2018a, 2018b). With the recent introduction of GDPR (EU, 2016/679), there is some uncertainty amongst researchers in how to marry ethical and legal procedures around data collection, storage and disposal across a range of disciplines. Researcher confidence will grow over time, but as demonstrated by the participant views, it is perceived as complex in a LL environment. In a LL, research is undertaken in "*real-life communities and settings*" (ENoLL, 2006), and may involve participants in different activities, forms of data collection and involving a variety of partners who may foresee using the data for a range of purposes over time. There is a need for further knowledge and understanding of the ethical and legal requirements and how these fit with those traditionally stipulated in the ethical procedures and approval processes of specific disciplines.

In response to this, we have undertaken an explorative qualitative study to collect multi-stakeholder views on key ethical issues for an emerging LL environment involving older adults. Informed consent was raised in this study as a complex issue where research participation overlaps with residency within a living environment. Both researchers and experts regard informed consent as a critical element, and a potential challenge when research participation may be on medium-long time basis, may involve varied projects and when participant capacity to consent may change due to cognitive decline. Given the medium to long-term partnerships that characterise LL research initiatives, it becomes fundamental that informed consent is 'refreshed' periodically, and can cater to changes in the form of user participation. The provision of well-designed information in a number of formats (e.g. written, verbal, video) that meets the needs of older adults is key to ensuring consent is informed.

The possible inclusion of LL users with cognitive impairment or deteriorating capabilities should be taken into account when designing related informed consent information and processes. This user group potentially have a lot to gain from LL research and so their participation should be appropriately enabled. Literature in the field has addressed how an informed consent form for adults affected by cognitive impairments should be designed (Fields & Calvert, 2015; Ukamaka, 2009), and involve consultees as appropriate. Dewing (2007) argues that for people living with dementia, informed consent becomes increasingly redundant and consequently exclusionary to them as individuals. Using ‘rolling’ informed consent involves the implicit understanding that this is not the result in a single-event legal act but rather a “communicative process between the relevant parties” (Novitzky et al., 2015, p. 758), so that continuous assessment of the choices made by the vulnerable person can be made. Training of researchers is needed to ensure they are equipped to work with, and obtain consent appropriately in this context. A framework to guide the type of research for which it may be suitable to recruit users with reduced or fluctuating capacity to consent may be appropriate (Folstein, Folstein, & McHugh, 1975; Mitchell, Shukla, Ajumal, Stubbs, & Tahir, 2014).

The role of stakeholders and family members and carers in LL research is critical. Supporting open involvement, and regular communication in appropriate media supports team working and research design, through to participant recruitment, project delivery and dissemination. LLs are reliant on a network, or collaboration of stakeholders that are engaged and committed to the underlying ethos. The conduct of LL research initiatives may pose issues in maintaining multi-stakeholder motivation and willingness to take part in the research on a long-term basis. Critically, the literature suggests user attention, motivation and expectation seem to decrease over time, and users tend to drop out from the research and development activities (Habibipour & Bergvall-Kåreborn, 2016; Habibipour, Georges, et al., 2017), with significant (negative) impact on project time and cost efficiency, quality assurance, overall loss of trust with users and stakeholders (Habibipour, Georges, et al., 2017). Leveraging participant intrinsic (e.g. meeting the actual real needs) or extrinsic (e.g. rewarding) factors may sustain better LL research initiatives outcomes (Habibipour & Bergvall-Kåreborn, 2016). Indeed, we acknowledge that for longer studies maintaining participation can be a challenge and may require incentivising (Habibipour, Georges, et al., 2017). Furthermore, as users in LLs are actively involved in co-design and co-creation activities to produce value, there should be rewards in place that secure pay-back to all the actors involved, and therefore may also act as an incentive to finish the given assignments (Dutilleul et al., 2010; Georges et al., 2016). However, in our DDRI context and through this study we have found that participants are intrinsically motivated to participate to improve their own health, or that of others rather than driven by rewards. This is in line with other LL research on user motivation (Habibipour et al., 2018; Lievens, Baccarne, Veeckman, Logghe, & Schuurman, 2014; Ståhlbröst & Bergvall-Kåreborn, 2011, 2013) which showed the importance of "nurturing the users'" personal interests and enabling users/participants to contribute to finding solutions to their problems. This is an area we feel warrants further investigation in different types of LL research.

For project and LL programme sustainability, the communication of research advancements, expected outcomes and impacts should be part of an ongoing communication strategy addressing LL multi-stakeholders and particularly users. Arguable all the processes, milestones addressed, correction to the workplan undertaken, etc. should be documented, to enable everyone involved to monitor the development of the initiative. This will help sustain a 'fertile' environment of collaboration, knowledge exchange, and trust in the LL initiative and in everyone taking part in it. Critically, DDRI makes use of staffed residencies to create a LL environment. The potential impact of research on similar such environments should be acknowledged and carefully planned. Whilst there may be organisational commitment to research participation, the impact and varying workload for staff needs modelling and planning as part of a project's study design. This may also include the time family members need to provide during the research participatory activities.

In this research we have highlighted potential variation in how ethical issues are approached in different organisations and between subject disciplines (e.g. BPS, 2009; NSW, 2013). It is argued therefore that a LL research project framework is of value to align approaches and provide overarching guidance and signposting. This should operate across disciplines and map critical project development milestones and ethical approval pathways to researchers and other organisations that are engaged in the LL activities. Clearer guidelines and standards would ensure harmonisation of practice across universities, research centres, organisations and across Europe.

6 Best Practices

Through this exploration within the context of an emerging LL (DDRI), we have developed an early framework to guide research design with ethical conduct as a guiding principle. This seeks to embed key elements that GDPR emphasises in respect to data protection and privacy. The framework illustrated a high level below, includes key points made by the study stakeholders during the interviews, and therefore it is meant to provide ‘user centric’ guidelines to support future LL research and development activity. The framework has been conceptualised as a project life-cycle process (Khang & Moe, 2008; Pinto & Slevin, 1988) with a design phase, a kick-off to the project, an implementation phase, and a conclusion of the research activities. A number of practice recommendations are made through the framework. These will be further expanded upon with supporting resources through ongoing work:

(1) Design phase

- Take into account the needs of the organisations involved, the approval bodies and key legal requirements e.g. GDPR when developing study protocols and related ethical applications
- Clarify, define and document the roles of the multi-stakeholders and users participating in the LL research project and wider programme to create a shared understanding.

- Consider informed consent as a 'psychological contract' to support working together that includes the different roles the LL multi-stakeholders hold.
- The involvement of users and family members should be planned into the process. It is important to understand and plan for specific user capabilities when launching new research activities (e.g. when working with older adults, and/or adults with cognitive impairment).

(2) Kick-off phase

- Induction of all involved stakeholders to the LL project activities and related ethical issues is important.
- The way in which the project is presented, labelled and initiative or interventions are described should be tailored to the context and users.
- Activities should be clearly explained to all users involved in the research to ensure that participation and the study design and related implications are well understood.
- Information requirements should be informed by the specific needs of users, and designed accordingly (e.g. font, coloured images, plain language etc.).
- Third parties (such as family members) benefit from and appreciate regular and relevant communication regarding individual studies and the wider LL programme.
- Informed consent would be provided ahead of the project starting and refreshed periodically. The process should take in to account user needs (e.g. capacity to consent, information needs etc). Audio-video (A-V) recording of consent process could be considered.

(3) Implementation phase

- Research outcomes should be shared during the conduct of LL research initiatives, to reinforce user commitment. These should be communicated in a way agreed by the users.

- Researchers should maintain regular contact with users, so that they feel that they are part of ‘the same project and goal’.
- Researchers should provide a safe and comfortable research environment in which all users feel free to opt in and/or out from research and take part in the research activities.
- Users should always be reminded of their rights and choices throughout the research development and implementation.
- Regard ‘*judiciousness*’ and respect as core values for researchers/experts when engaging users during data collection. Users as participants are collaborators and co-creators, and not ‘subjects’ of research.

(4) Conclusion phase

- Consider a range of dissemination methods and events in collaboration with users. The findings from each project should be disseminated to users, in a way that is ‘meaningful’ to them.
- Dissemination should highlight the benefits that have been received, and/or impact achieved from LL participation, as both active actors and residential members of the LL setting.
- Enable long-term follow-up and updates on progress beyond the time of direct participation, especially where the benefits and impact may be delayed.

FIGURE 2: EMERGING ETHICAL FRAMEWORK

7 Research Agenda

There is a lack of research exploring the ethical challenges and stakeholder needs in the living lab (LL) context. This study has explored ethical issues of consideration when setting up a new residential LL, involving older adults. This has been an exploratory study involving 26 stakeholders, to collect views and experiences. There is scope for more extensive exploration in this space to define the key issues and processes and be able to generalise the findings over the wide range of LL formats that currently exist. LLs are heterogeneous and there are country, contextual, methodological and disciplinary differences that warrant further consideration.

Whilst an initial framework has been proposed based on the interview findings, there is additional development work being undertaken to support this with further guiding resources. Ongoing research by the authors employs co-creation methodologies to further develop collaborative working practices, processes and guiding materials.

Rewards for LL participation is an issue warranting further investigation. We have found interest from multi-stakeholders on this topic and a desire to enable effective collaboration we well as collective realisation of commercial benefits emerging from LL work. The findings have highlighted the importance of regular communication and progress updates for users and wider stakeholder. Striking the balance between too much and too little communication and the level of detail can be challenging to foster engagement and motivation. It may be that this needs to be determined on a study by study, or at the user group level.

Finally, this study explored the perspectives of family members of LL residents, particularly in reference to parents with cognitive impairments. Our sample size was limited and wider consideration is requirement. Future research could also consider the role of family members whose children (aged under 18 or 16) are (unwittingly) involved in LL research.

8 Educational Implications

The contribution of this paper lies mainly in voicing and deepening multi-stakeholder (i.e. researchers, experts in the sector, and staff, residents as users and family members of two partner living environments) views, experiences and concerns in relation to LLs research and related ethical issues. It also provides and renews the necessary vocabulary related to this phenomenon allowing all involved stakeholders to better understand and be engaged in future LL collaborations and initiatives.

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