

This is an Open Access document downloaded from ORCA, Cardiff University's institutional repository:<https://orca.cardiff.ac.uk/id/eprint/134638/>

This is the author's version of a work that was submitted to / accepted for publication.

Citation for final published version:

Shepherd, Victoria , Sheehan, Mark, Hood, Kerenza , Griffith, Richard and Wood, Fiona 2020. Constructing authentic decisions: proxy decision making for research involving adults who lack capacity to consent. *Journal of Medical Ethics* 47 (12) , e42. 10.1136/medethics-2019-106042

Publishers page: <http://doi.org/10.1136/medethics-2019-106042>

Please note:

Changes made as a result of publishing processes such as copy-editing, formatting and page numbers may not be reflected in this version. For the definitive version of this publication, please refer to the published source. You are advised to consult the publisher's version if you wish to cite this paper.

This version is being made available in accordance with publisher policies. See <http://orca.cf.ac.uk/policies.html> for usage policies. Copyright and moral rights for publications made available in ORCA are retained by the copyright holders.



# Constructing authentic decisions: proxy decision-making for research involving adults who lack capacity to consent

Victoria Shepherd\*<sup>1</sup>, Mark Sheehan<sup>2</sup>, Kerenza Hood<sup>1</sup>, Richard Griffith<sup>3</sup>, Fiona Wood<sup>4</sup>

<sup>1</sup> Centre for Trials Research, Cardiff University, Cardiff UK

<sup>2</sup> Ethox Centre, University of Oxford, Oxford UK

<sup>3</sup> College of Human and Health Studies, Swansea University, Swansea UK

<sup>4</sup> Division of Population Medicine, Cardiff University, Cardiff UK

\*Corresponding author:

Victoria Shepherd

Centre for Trials Research, Cardiff University, 4<sup>th</sup> floor Neuadd Meirionnydd, Heath Park, Cardiff CF14 0GB

Tel: 02920687641

Email: [ShepherdVL1@cardiff.ac.uk](mailto:ShepherdVL1@cardiff.ac.uk)

Key words: Bioethics, research ethics, cognitive dysfunction, third party consent, decision making,

Word count: 4320

## **ABSTRACT**

Research involving adults who lack capacity to consent relies on proxy (or surrogate) decision-making. Proxy decisions about participation are ethically complex, with a disparity between normative accounts and empirical evidence. Concerns about the accuracy of proxies' decisions arise, in part, from the lack of an ethical framework which takes account of the complex and morally pluralistic world in which proxy decisions are situated. This qualitative study explored the experiences of family members who have acted as a research proxy in order to develop an understanding of the ethical concepts involved, and the interactions between those concepts. Proxies described a complex process of respecting the wishes and preferences of the person they represented, whilst integrating preferences with what they viewed as being in the interests of the person. They aimed to make a decision that was 'best' for the person and protected them from harm; they also aimed to make the 'right' decision, viewed as being authentic to the person's values and life. Decisions were underpinned by the relationship between the person and their proxy, in which both trust and trustworthiness were key. Proxies' decisions, based both on respect for the person and the need to protect their interests, arose out of their dual role as both proxy and carer. The findings raise questions about accounts which rely on existing normative assumptions with a focus on accuracy and discrepancy, and which fail to take account of the requirement for proxies to make authentic decisions that arise out of their caring obligations.

**Keywords:** Decision making capacity, research participation, informed consent, ethics

## **INTRODUCTION**

Obtaining informed consent is considered to be a fundamental ethical requirement for medical research [1, 2] derived from the principle of respect for autonomy [3]. Research involving adults who lack capacity to consent relies on decisions about their participation being made by proxies or surrogates on their behalf [4]. In England and Wales, there are legal provisions for a family member or friend to provide informed consent on behalf of an adult who lacks capacity to participate in a clinical trial [5] or, for other types of research studies, to provide advice about their likely wishes and feelings regarding the matter [6]. However, the consent or advice provided by the proxy can never be ethically equivalent to personal consent and, as a consequence, conducting research with those who lack decisional capacity is ethically complex [7]. One area of difficulty arises from the substantial variance between the normative standards of proxy decision-making and empirical research which describes the ways in which proxies actually make ethical decisions in practice [8].

### **Disjuncture between normative and empirical accounts**

Normative accounts of proxy decision-making have historically been based on an ethical framework that proposes a 'step-wise' approach which starts by first turning to the person's advanced directives or statements about their wishes or, in the absence of any such directive, a substituted judgment, asking what the patient would have wanted, lastly relying on the standard of best interests [9]. A number of flaws with this theoretical bioethical hierarchy have been identified [9] including its inconsistency with proxy decision-making for research in practice [10]. The involvement of those lacking decisional capacity in research is ethically problematic - it may neither satisfy the known wishes standard nor the substituted judgement standard, is hampered by the lack of a robust ethical framework [11].

The findings from a recent systematic review of empirical research exploring proxy decision-making for research challenged the accepted reductionist account of proxy decision-making [10]. It found that the normative accounts are largely unsupported by the empirical data on proxy decision making [10]. However, as the studies included in the review were predominantly hypothetical or scenario-based studies, further work to empirically explore proxy decisions about research participation in practice was required [10]. Understanding how proxies translate these ethical principles into practice is important as laws, policies, and research governance processes may rest on assumptions about proxy decision-making, such as the notion that proxies are able to decide based on substituted judgment, that are not manifested in practice [12].

### **Developing a more empirically grounded account**

While empirical methods have support as a good way of grounding ethics, it is also important for ethical analysis to be grounded in the facts and reality of a situation [13]. We conducted a qualitative study to explore the experiences of family members in England and Wales who have acted as a research proxy [14], using a multiple-analytic approach to examine the data through multiple lenses. Pluralistic qualitative analyses have been found to be valuable in providing a multi-layered understanding of phenomena which possess ontological and epistemological multiplicity and multidimensionality [15]. This paper reports the use of a modified grounded theory (GT) approach to analyse the data and reflectively refine a previously proposed framework of ethical considerations in

proxy decision-making developed following a systematic review of empirical studies in predominantly hypothetical scenarios [10].

Empirical bioethics methodologies have been the subject of much vigorous debate in recent decades [16]. In line with Huxtable and Ives' framework of 'mapping, framing and shaping' phases of empirical bioethics research, the aim of this study is to explore specific areas of the previously mapped terrain that have been identified as being in need of deeper exploration [10] in order to develop an understanding of how these key issues are experienced (or 'framed') by relevant stakeholders [17]. Under this approach, the issues are framed by the lived experience of relevant stakeholders in order to reveal further unanswered questions, and indicate possible ways forward as part of future work [17]. The descriptive framework presented here is not intended to make direct, normative claims. Instead, the aim is to articulate the range of relevant concepts and considerations that proxies use to make decisions in practice in order to build an account that is grounded both empirically and theoretically [19].

## **METHODS**

Semi-structured interviews were conducted with family members who had acted as a research proxy for a person who lacks capacity. Potential participants were identified through condition-specific research networks, social media platforms, and research registries in England and Wales. The study was approved by Cardiff University Research Ethics Committee (Ref 17/54). Informed consent was given by each participant prior to conducting the interview.

### **Data collection**

Whilst data used for this study were collected primarily for a thematic analysis of the proxies' experiences of decision-making which has been previously reported [14, 20], the aim of the interviews was also to capture ethical concepts, critically examine the previously developed framework [10], and further refine it based on updated concepts identified from the data. Interviews were conducted either face-to-face or by telephone. A topic guide was developed (**Supplementary file 1**) which was informed by findings from a recent systematic review and the resulting the resulting framework of proxy decision-making [10]. The interviews were digitally audio-recorded with consent and transcribed verbatim.

### **Data analysis**

Grounded theory (GT) methods focus on building theory that is grounded in the data, with an emphasis on understanding processes and actions [21]. GT methods have been widely used by empirical researchers in bioethics [22] and legal research [23]. Using a modified grounded theory approach [24] data were coded iteratively with a particular focus on actions and processes rather than topics [25] to allow reconstruction of actions and facilitation of a theoretical framework development [24]. The wider research team discussed the categories and the proposed conceptual relationships between the categories, which then linked the categories into a coherent theoretical model [26].

## **RESULTS**

### **Participants**

Interviews were conducted with 17 family members who had acted as a research proxy for a relative who had impaired or absent capacity, predominantly someone living with dementia (**Table 1.**). Proxies included those who had agreed to research participation by the person they care for and those who had declined, and some had made decisions about more than one study. The types of research considered included clinical trials of investigational medicines, as well as observational and questionnaire or interview-based studies.

**Table 1. Characteristics of participants and interviews**

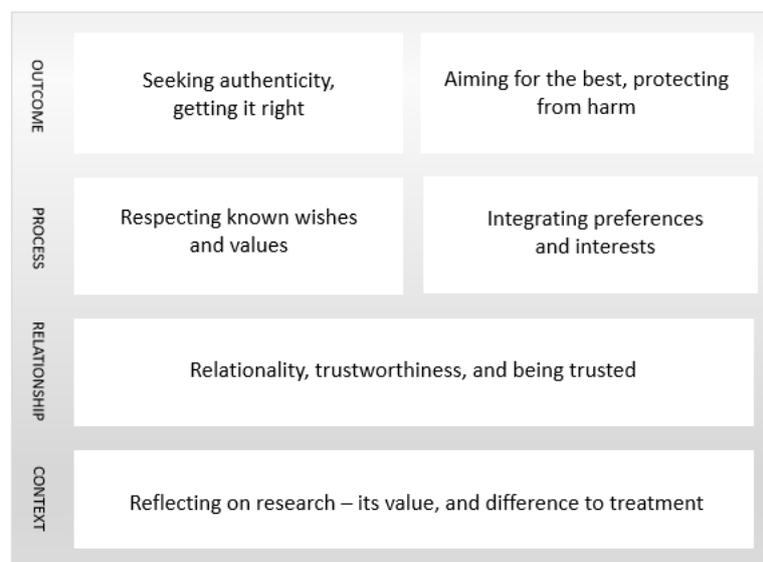
	Participants n (%)
Gender	
Male	4 (24%)
Female	13 (76%)
Relationship	
Adult son/daughter	12 (70%)
Spouse	3 (18%)
Other	2 (12%)
Daughter-in-law	1
Daughter and spouse*	1
Interview	
Face-to-face	
Participant's home	8 (47%)
Other location	4 (24%)
Via telephone	5 (29%)
Duration of interview	19-90 mins (mean 44 mins)

\*Participant was the spouse of a person with impaired capacity and also had a parent with impaired capacity

## Main findings

Six inter-related categories were identified which captured the relevant ethical concepts within proxy decision-making for research, consisting of a number of following principles set within the context of how research is viewed by proxies (**Figure 1. Framework of proxy decision-making for research**).

**Figure 1. Framework of proxy decision-making for research**



See **Table 2** for illustrated descriptions.

## Reflecting on research – its value, and difference from treatment or care

Proxies recognised that decisions about research were different to those about medical treatment. They viewed participating in research as having value, beyond any potential benefits to the person, which influenced their decisions about whether the person they cared for should participate. It was recognised that this value judgement was an important requirement for the proxy to make a decision about participation on behalf of another person.

## Relationality, trustworthiness, and being trusted

Trust and having a trusting relationship was a fundamental value underpinning proxy decision-making for research. Trust featured through both the trustworthiness of the proxy and the functions or roles it played in decision-making. Trustworthiness determined who was chosen to act as proxy. Trust provided the authority to make decisions on the person's behalf - where the proxy was trusted and so their decision was trusted by the person - and it also provided the conditions for making the proxy decision as it required the proxy decision-maker to make the right (or 'good') choice for the person.

**Table 2. Illustrated descriptions of categories**

<p><b><i>Reflecting on research – its value, and difference from treatment or care</i></b></p> <p><i>“And just recognising that it’s a good thing to do research” [08, adult daughter]</i></p> <p><i>“If you’re responsible for somebody who can’t make those decisions themselves, then you need to be sure that the thing that they’re getting involved with is worthwhile. And I think it’s the worthwhileness which is the important thing. If the carer doesn’t feel that the work is worthwhile, then I don’t see how you can make a decision to put somebody in for it.” [05, adult son]</i></p> <p>Underpinning the proxy decision is an assumption that the person would share the proxy's own view about the value of taking part in research. This may also mean the proxy 'projects' their views onto the person.</p> <p><i>“For the whole of society, because my mother, if research, if she were eligible, could assist people in the future, then that has got to be good hasn’t it?” [15, adult daughter]</i></p>
<p><b><i>Relationality, trustworthiness, and being trusted</i></b></p> <p><i>“You have to have the trust don’t you, to make a decision for somebody, you, they have to trust you and you have to trust them, they know you’re doing the right thing for them” [02, daughter-in-law]</i></p> <p>Trusting a family member was not necessarily task-specific, it may have applied to trusting them in all areas of the person's welfare, and some proxies act jointly or severally with other family members.</p> <p><i>“I actually signed here, but we’re of the same frame of mind anyway and I like just told her [referring to her sister]. Yeah, fine. We’ve both got the same thoughts on these little things. Yeah, we just trust one another” [11, adult daughter]</i></p> <p>Trust was considered to have moral weight by proxies, where the responsibility of being trusted was felt by proxies, it was viewed as a heavy burden at times, but it was also considered an honour.</p> <p><i>“It’s quite onerous sometimes ...I mean it is quite a thing to make somebody else’s decisions for them a lot of the time isn’t it?” [08, adult daughter]</i></p> <p>Trust was transitive in nature, which had particular relevance when those involved in approaching the proxy regarding participation were known and trusted by them, or in cases where trusted care home staff introduced researchers they trusted to the proxies.</p>

*"It was well going down the lines and if the person you trust trusts that other person, you trust that person as well. Yes and I trust this home completely ...and they trust [name of researcher] ... so I trust [name of researcher]." [10, adult daughter]*

### **Respecting known wishes**

*"He may not now make his decision what to do but I know from what he's said in the past that he would do anything to help. Knowing what his previous thoughts were, and knowing that he actually said, and I'm not sure he didn't write it down" [07, female spouse]*

*"For her science is important and it always was, though she was an artist she studied science and she did a lot of abstract paintings about science." [04, adult daughter]*

Proxies also used what they knew about the person's values and virtues when deciding on their behalf, particularly whether the person was altruistic or willing to help others. They knew whether the person would wish to 'do good' generally, even if they did not know their specific wishes about research participation.

*"I think knowing my mum and [name of husband], they would both be helpful to everybody. You know, they've not led lives where they've been set away from society, they've always joined in with society if you see what I mean. I see it as a moral issue. Um that sort of being a good citizen sort of." [14, female spouse]*

Some proxies acted intuitively when making a decision, rather than deliberating over the relative factors. In these cases decisions were considered to be easy and were made quickly or automatically, perhaps because they knew the person well and so could come to a decision relatively effortlessly.

*"I think that because I know him so well, we've been married for thirty years. Because I know him really well, we know each other really well." [14, female spouse]*

### **Integrating preferences and interests**

Proxies integrated the person's known wishes and preferences and what is in their current and future interests, whilst seeking to respect both. Some proxies viewed this entirely from the person's perspective, where they tried to consider what the person's assessment about their own interests would be.

*"I think they sort of go hand in hand really because if you put yourself in their shoes then you know what they think would be best for them, so you're sort of reading what they're going to be doing themselves and you can more or less sort of read what they're thinking and I think it goes hand in hand. Knowing what he would want and what he would think is best for him." [10, adult daughter]*

The process of weighing up and deciding necessarily takes into account new information that wasn't available at the time of any expressed wishes, particularly where the significance has changed given the change in situation and therefore context.

*"The only issue I would have with those is these days giving blood tends to hurt her a little bit. I don't know why, it never did before, but it does now. So, yeah. Whether pain is a different thing. She usually doesn't tell you if she's in pain, but giving blood does hurt." [11, adult daughter]*

Respecting the person's values or preferences, even if they were strongly committed to them, could be overridden if the proxy considered it would be against their interests to participate. The change in their circumstances meant that some of the person's preferences were now considered in light of the need to protect their welfare.

*"He's always been a bit of a risk taker. But at this stage, where before it would've been risk-taking, now I see it as not risk-taking. I would see it as ... it's all about his welfare now, you know." [09, female spouse]*

Proxies recognised that considering either interests or preferences may direct them to a decision that directly conflicts with the other. They used a process of balancing or integrating both preferences and interests to a greater or lesser extent, although concern for one aspect may emerge as a priority.

*"The primary thing that I have to look at is quality of life for mum. A secondary thing is the benefits to other people, you know, [that is why she would want] to do it in the first place..... But undoubtedly on anything it's got to be the quality of life for her" [06, adult daughter]*

### **Aiming for the best and protecting from harm**

Proxies sought to make decisions that were the 'best' for the person involved, or more broadly because they felt it was 'for the best'.

*"I am doing it because I think that's the best. I do think it's the best that he takes part in the trial and if he is ... if it will help in the future I think it's a good thing." [01, adult daughter]*

While the proxy might have anticipated some benefit from research participation, or at least a neutral impact, when it came to the possibility of any harm or risk or a negative experience, they put the person's welfare as uppermost. This same approach was used when making all decisions on the person's behalf.

*"With [name of husband] it's all about his welfare now, you know. Hopefully I can just make his life a little bit better from the miserable existence he's been landed with really. So it is definitely on a basis of his welfare first and foremost" [09, female spouse]*

The proxy acts as a substitute for protecting the person's interests, where the need for protection was viewed as arising out of their perceived vulnerability.

*"I mean obviously I don't want to put him at any further risk. He's got limited time, now ... because he's quite frail, and so I wouldn't want to put him into any form of danger. Lumbar puncture does carry a risk. I'd probably say no, it would be because he could do without the complications of anything going wrong." [13, adult son]*

However, a protective role may also have harms associated with it through denying them the benefit that comes from participating in research, either in terms of directly improving their health and wellbeing, as well as from 'doing good'.

*"It's difficult because you're scared of what they could ... scared might not be the right word, but you're worried that you make the wrong decision ... and actually am I taking away an opportunity for her to be better than she is now?" [06, adult daughter]*

The responsibility for decision-making is viewed by proxies as part of their role, arising out of their responsibility to care for the person. So for some proxies, considering if the person would benefit from research fell under their aim of looking after the person and maximising their health and welfare.

*"If there was an indication of benefit to my mother, then it's different, because then you're seeing it as part of your caring role. Because if you can make somebody's life better as a result of becoming involved in a research thing, then that's obviously quite different, because there you see it as part and parcel of providing care" [05, adult son]*

### **Seeking authenticity – getting it 'right'**

Proxies also aimed for the decision to be the right decision, which meant one that would be consistent with what the person would want or would have decided, rather than seeing it as being a replica of the person's decision.

*"I would be pretty sure that the decision that I made, would be in line with what she would have wanted." [15, adult daughter]*

For some, this was a process of making a decision for the person and *then* comparing the person's decision with it; others used what they thought would be the person's decision and tried to approximate it, as a way of making sure the decision was authentic to the person.

*"I think of what my mum might have wanted when she was ... you know, what decisions she would have made prior to this disease taking over. And you know if I really thought she would want to do this then I would do it. But you know with the head that she had prior to this she'd look at this and ... I'm sure she would make the same decisions that I'm making on her behalf about that research"* [06, adult daughter]

In order to make a decision, some proxies described a process of consciously trying to stand in the person's shoes and attempting to make the decision that they think the person would have wanted to make, or wanted them to make, sought to involve the person themselves in the decision.

*"So you have to sometimes keep reminding yourself this isn't about me, this is about them and actually trying to remember to come back to that and sometimes reminding yourself to do that. It's very easy to get carried away sometimes and think you're doing it because you want to do it. That doesn't count."* [08, adult daughter]

*"I kind of get a feeling from her I think, but it would depend how she said it, I think, because I know her, if there was enough feeling in it, 'no I wouldn't want to do that, no', then I'd be like well you know, she doesn't want to do that, it's just judging her at that, at that time."* [15, adult daughter]

## Respecting known wishes

Proxies used what they knew about the person and their wishes and preferences about taking part in research as part of their decision, sometimes using the person's biographical narrative as the primary source for knowing what they would wish. Some proxies had had specific conversations with the person they represented, or they were aware of written statements about the person's wishes to take part in research. Some proxies knew about the person's previous participation in research and used this as a guide to knowing their likely wishes about taking part in the particular research study under consideration.

Where there had not been previous discussions or statement that the proxy could use to determine what the person would decide, they used other factors as the basis for their decision. These were based on knowing the person's previous occupations and interests, which indicates to the proxy whether they would have wanted to participate or not. The weight given to these interests was dependent on how committed to them the person was, for example they may have had a lifelong interest in science or medicine. Proxies used these examples to provide justification for their decision. Proxies also used what they knew about the person's values and virtues when deciding on their behalf, particularly whether the person was altruistic or willing to help others, even if they did not know their specific wishes about research participation.

## Integrating preferences and interests

The proxy considered a number of factors when making a decision about research participation, which for some involved balancing or integrating the person's known wishes and preferences and what was considered to be in their current and future interests, whilst seeking to respect both. Some proxies viewed this entirely from the person's perspective, where they tried to consider what the person's assessment about their own interests and wishes would be. However, the proxy could override

respecting the person's values or preferences, even if they were strongly committed to them, if they considered it would be against their interests to participate.

### Aiming for the best and protecting from harm

Proxies sought to make decisions that were the 'best' for the person involved, understood in its broadest sense rather than viewed as making a decision that was in their 'best interests'. This might be in terms of achieving the best outcome, where the person's health or welfare could be improved through participation, or where there was no detriment to them but they may have a positive experience. Proxies may also view it as 'best' in terms of being a standard to achieve the best possible decision, which may be heavily influenced by the proxy's perception about the value of participating in research. The aim to make a good decision rested on a value judgement by the proxy that contributing to research is a good thing, and so the proxy having a positive disposition or attitude towards research alters how the proxy views research participation for the person and whether it is 'for the best'.

The proxy acts as a substitute for protecting the person's interests, where the need for protection was viewed as arising out of their perceived vulnerability. Caring for the person involved protecting them from 'threats' which could be from a number of directions, including: protecting them from invasion of bodily integrity (where research may be seen as potentially invasive); protecting them from any burden or negative impact from research; protecting them from the effects of the illness; and protecting the integrity or continuity of the person's self through upholding their previous wishes or the values they previously held.

The responsibility for decision-making, and the obligation to make good decisions, is viewed by proxies as part of their role, arising out of their responsibility to care for the person. The proxy's role as carer meant that they were looking after them (rather than just acting as their proxy) so for some proxies considering if the person would benefit from research fell under their objective of looking after the person and maximising their health and welfare.

### Seeking authenticity – getting it 'right'

Proxies also aimed for the decision to be the right decision, which meant one that would be consistent with what the person would want or would have decided, rather than seeing it as being an accurate or 'correct' replica of the person's decision. For some, this was a process of making a decision for the person and *then* comparing the person's decision with it; others used what they thought would be the person's decision and tried to approximate it. All proxies appeared to use what they knew about the person and the values, wishes, and goals that were important to them, as a way of making sure the decision was authentic<sup>1</sup> to the person. Although participants did not use the term 'authenticity', they

---

<sup>1</sup> Whilst the concept of 'authenticity' is the subject of much debate which is beyond the scope of this paper, it is considered here to be the value of being a particular self, a distinctive individual. Whilst often conflated with 'substituted judgement', authenticity can be distinguished from concepts of autonomy (or self-determination) and best interests. Indeed, at times a person's best interests might be considered to be at odds with their authenticity [Brudney D. "Choosing for Another: Beyond Autonomy and Best Interests," Hastings Center Report 39, no. 2 (2009): 31-37].

drew on the biographical narrative and long-held prior beliefs and values of the person they represented to make a decision that reflected a kind of resonance with that individual's life<sup>2</sup>.

As part of seeking authenticity, some proxies consulted with other people who also knew the person well and who may have knowledge that they didn't have, although more often it was just informing them rather than involving them in the decision itself. Another form of seeking authenticity was proxies involving the person themselves in the decision, irrespective of their ability to comprehend. Proxies respected their personhood and actively sought their participation in the decision and to incorporate their views, though this may mean seeking an emotional rather than necessarily a cognitive response. However, their assent, or any sign that they objected, was only sought if the proxy was already inclined to agree to their participation.

## **DISCUSSION**

This study reveals how proxies' decision-making for research is ethically complex in terms of the underpinning concepts, the processes and principles followed by proxies, and the outcomes the proxies are aiming to achieve. The study showed that, rather than the type of research involved or nature of the decision being made (providing consent for a clinical trial or advice for other types of research), of greater significance was whether participating would advance or harm the interests of the person they represented, and whether the decision would be authentic to the person and their values.

### **Enhancing the initial framework**

The set of concepts, processes and principles used here was developed with reference to a previously published framework [10]. The refinements are reflective of the methodological differences between the empirical studies that contributed to the initial framework and this study, and the broader range of contexts explored including across different types of studies, thus providing a richer account of the concepts identified in the initial framework. The initial framework is not prescriptive and so is not intended to determine the way in which proxies should make decisions on behalf of others. It is intended to articulate the range of relevant concepts and considerations that proxies can and do use to make decisions, and thus provide an empirically-informed and grounded account of proxy decision-making. The data presented here functions to enhance that account.

### **Integration of interests and preferences**

Proxy decision-making in practice does not reflect the normative accounts of a hierarchical or 'step wise' approach, a finding which is supported by previous studies [27]. However, findings from previous studies which suggest that proxies use a combination of best interests and substituted judgment [28] or an approach that also considers the interests of others [29], or that there is a continuum between

---

<sup>2</sup> Authentic decisions, as described by Welie, are those considered to be in accordance with the individual's personal values, dispositions, attitudes, and intentions. Unlike autonomy, authenticity is attentive to the temporality of human life which cannot be reduced to a series of present decisions and actions [Welie, J. 1994. Authenticity as a foundational principle of medical ethics. *Theoretical Medicine* 15:1211—225].

substituted judgement and known wishes [8], are not well reflected in the pluralistic approach identified in this study.

Integration is distinct from authenticity as it is not limited to the way it captures the person's view. Proxies described a process of integrating both their family member's preferences and interests into a decision about research participation, that took account of what would be best for the person and would be in line with what they themselves would have wanted. In some instances, the proxy considered that they would agree to participation in a study that might result in some harm if that is what the person would have decided, and in other circumstances the proxy would reject a proposal that might lead to any negative impact on the person despite knowing that the person's decision would have been to proceed. This varied according to a number of contextual features (e.g study design, ability to withdraw, convenience of study visits), which are determinants of research participation more broadly [30], or may change over time where the proxy considered the person to have been in an increasing precarious condition. This integration may represent family members' attempts to reconcile their dual caring and representation roles. The challenging nature of attempting to make what they perceive to be a 'good' decision that is best for the person they care for is partly reflected in the uncertainty expressed by proxies, and may contribute to the emotional and decisional burden they experience [14].

However, even where there was a potential for their family member to derive some benefit from participation (either a health or psychosocial benefit), or they felt that they would have wanted to participate and help others, if the perceived risks were too great then proxies would decline participation. The reverse was also found, where even if there were more-than-minimal risks to the person's health, their long-standing altruistic values or willingness to accept risk led the proxy to agree to participation on their behalf. These findings suggest that proxy decision-making may be affected by a magnetism that draws the proxy to consider one or more factors which have a decisive influence on the determination of the decision-making process. The concept of a 'magnetic factor' appears in a number of court judgments concerning adults lacking capacity [31, 32]. Rather than meaning that an element is given particular weight in the 'balance sheet' of options, a factor that has 'magnetic importance' pulls the evaluation of all elements in a specific direction and thus determines the outcome of the case [33]. For proxies, this may have been the importance of maintaining the person's quality of life, or the primacy of respecting their preferences and values such as altruism, or some other factor such as the overriding value of scientific advancement.

### **Focus on authenticity rather than decision accuracy**

Proxies attempted to make a decision that was authentic to the person they represented, rather than attempting to determine what would be in their best interests or attempting to make a substituted judgement. Authenticity has been described as considering what the person *would want* done in the current circumstances, or deciding what the person *would choose*, based on having lived a life that expressed their individuality [34]. It is recognised that this is a hypothetical choice, made in the absence of autonomous decision-making capacity and any sufficiently clear expression of the person's actual choice [34]. Authenticity has been described as a sustained achievement that is exercised over time, in comparison to agency which is considered a momentary one [35], and through the legal concept of 'consistency' [6].

Authenticity can be viewed as operating at two levels in proxy decision-making. On one view, proxies might seek to make a decision that replicates the decision the person themselves would have made, and so the 'correctness' of their decisions could be straightforwardly measured through accuracy. However, it was clear that proxies in this study were not aiming at this 'replica' account of authenticity. Proxies alternatively described attempting to make decisions that were coherent with the values and wishes of the person, which drew on a sense of authenticity as genuineness. Here, proxies attempted to make a decision that was genuine to the person and their life and their values, and so sought to make the 'right' decision. Importantly, whilst there is some affinity between these accounts, the disconnect between proxies attempting to make right (cf. correct) decisions, emphasises the connections to much broader questions seen through the 'genuineness' versus accuracy (replica) model of authenticity.

Seeking authenticity, rather than making a substituted judgement, underlines that the proxy is not morally neutral, and is not merely acting as an empty 'conduit' passing on the person's known wishes [36]. Acting as the decision-maker involves some transfer of responsibility to the proxy as a moral agent [37]. This concept is supported by proxies' views about having responsibility for decision-making that arises out of their caring relationship with the person they represent and care for [14]. The legal frameworks reflect that the person is selected to act as proxy by virtue of their relationship with the person [5] as they are engaged in caring for them and interested in their welfare [6]. Their dual role as both a proxy and carer result in a dual moral responsibility to represent the person's preferences whilst promoting their interests. An authentic decision is one which is informed by knowledge of the person's values and is motivated by respect for the person [38]. These moral responsibilities, and proxies' own reports of both respecting the person's values and promoting their interests, are consistent with the intention of informed consent, which seeks to both respect an individuals' autonomy and advance their welfare or well-being [39].

## **Fundamental role of trust**

Participants spoke about trust as being a fundamental element in a number of different forms, including the nature of the relationship between them and the person they represent, and their qualities of trustworthiness as being the reason they were trusted to act as proxy. Proxies often cited examples of being trusted by the person, perhaps using these qualities of trustworthiness as a justification for being trusted to act as proxy, although this level of trust can inevitably only be presented from the proxy's perspective. The functions of trust relationships in the context of informed consent and research have previously been analysed, including awareness of entrustment being an important component in decision making [40]. Similarly, characteristics of trustworthiness play a role in decision-making, where a person can be characterised as trustworthy when she 'acknowledges the value of the trust that is invested in [her, and] uses that to help [her] rationally decide how to act'[41]. In this study proxies also spoke about the transitive properties of trust between themselves, the organisation or individuals caring for their family member, and the research team. Other studies have previously highlighted the role of trust between the proxy and the investigators, although they did not identify the trust between the person and their proxy [28]. However, the relationship between the proxy and the person they represent is fundamentally different in nature to that between the person, their professional carers, and researchers. Alternatively the concept of reliance, which can be understood as a form of dependence that does not necessarily feature the emotive relationship

necessary for trust between parties, or obligations of professional integrity, may differentiate these particular relationships [40].

## **Strengths and limitations**

The study built upon a previous systematic review and provided an opportunity to further develop an initial framework that was based on studies exploring predominantly hypothetical proxy decisions [10] whilst this study explored experiential accounts. Participants included those who had agreed, as well as declined, to a family member's participation in a range of different types of research.

Limitations include self-reported views from a relatively small sample of family members, almost all of whom represented someone with dementia and who therefore experienced a progressive change to their role in decision-making. Their views may not be representative of proxy decision-making in different contexts, such as during an acute life-threatening medical event. The majority of participants held some form of Power of Attorney for the person they represented. Although Lasting Power of Attorney for health and welfare does not include decisions about research [20], family members who are a legally designated attorney may have differing experiences of making proxy decisions. Other family members may also have a less positive attitude towards research than those who participated. The study should also be viewed within the context of a broader debate about the role of social sciences and empirical research in (bio)ethics, and the accompanying methodological challenges and limitations [42].

## **CONCLUSIONS**

Following analysis of family members' experiences regarding making decisions about research participation on behalf of someone who lacked capacity to provide consent, an account of proxy decision-making for research has been developed. An illustrated account has been provided of the way in which proxies make decisions that pay attention to the person's preferences and interests, whilst seeking to achieve a decision that is authentic to the person. Existing accounts of proxy decision-making which focus on accuracy and discrepancy, and the subsequent development of interventions to 'improve accuracy', fails to acknowledge the requirement for proxies to make authentic decisions that arise out of their caring obligations. Understanding how, in practice, proxies can construct their reasoning in terms of a full range of ethical concepts and principles may open up the space for future exploration of whether the legal frameworks and research governance processes reflect the ethical practice of proxy decision-making, as well as the normative accounts previously described. Further exploration is needed to explore whether it contributes an account of proxy decision-making for research that better reflects the duality of proxies' roles and how ethical decisions are made in practice.

## **STATEMENTS**

### **Funding**

This study forms part of an NIHR Doctoral Research Fellowship, funded by the Welsh Government through Health and Care Research Wales (NIHR-FS-16). MS is supported by the NIHR Oxford Biomedical Research Centre, grant BRC-1215-20008 to the Oxford University Hospitals NHS Foundation Trust and the University of Oxford. The views expressed are those of the authors and not necessarily those of the NHS, the NIHR, or the Department of Health and Social Care.

### **Acknowledgements**

The authors are very grateful to the participants who kindly gave their valuable time to take part in the study.

### **Competing interests**

None declared.

### **Ethics approval statement**

Ethical approval for the study was provided by the School of Medicine Research Ethics Committee, Cardiff University (SMREC Reference Number 17/54).

### **Contributors**

This study forms part of a doctoral research fellowship held by VS, and supervised by FW, KH, RG, and MS. VS, FW, KH, RG, and MS conceived the study. VS conducted the qualitative interviews and led the data analysis. All authors were involved with the development of the initial framework and interpretation of the data. The further development of this framework was led by VS and MS. VS drafted the article, and all authors critically revised the article and subsequent revisions.

## REFERENCES

1. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2). 2016.
2. World Medical Association. WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects. 2013.
3. Childress JF, Beauchamp TL. Principles of biomedical ethics. Oxford University Press, USA; 2013.
4. Saks ER, Dunn LB, Wimer J, Gonzales M, Kim S. Proxy consent to research: the legal landscape. *Yale Journal of Health Policy, Law, and Ethics*. 2008;8:37–92.
5. The Medicines for Human Use (Clinical Trials) Regulations 2004.
6. Mental Capacity Act. 2005.
7. Westra AE, De Beaufort I. Improving the Helsinki Declaration’s guidance on research in incompetent subjects. *Journal of Medical Ethics*. 2015;41:278–80.
8. Berger JT, DeRenzo EG, Schwartz J. Surrogate decision making: Reconciling ethical theory and clinical practice. *Annals of Internal Medicine*. 2008;149:25–48.
9. Torke AM, Alexander GC, Lantos J. Substituted judgment: the limitations of autonomy in surrogate decision making. *Journal of General Internal Medicine*. 2008;23:1514–7.
10. Shepherd V, Hood K, Sheehan M, Griffith R, Jordan A, Wood F. Ethical understandings of proxy decision making for research involving adults lacking capacity: A systematic review (framework synthesis) of empirical research. *AJOB Empirical Bioethics*. 2018;:1–20.
11. Berger JT. Is best interests a relevant decision making standard for enrolling non-capacitated subjects into clinical research? *Journal of Medical Ethics*. 2011;37:45–9.
12. Dunn LB, Fisher SR, Hantke M, Appelbaum PS, Dohan D, Young JP, et al. “Thinking about it for somebody else”: Alzheimer’s disease research and proxy decision makers’ translation of ethical principles into practice. *American Journal of Geriatric Psychiatry*. 2012;21:337–45.
13. McMillan J. Grounded ethical analysis. *Journal of Medical Ethics*. 2019;45:1–2.
14. Shepherd V, Hood K, Sheehan M, Griffith R, Wood F. ‘It’s a tough decision’: A qualitative study of proxy decision-making for research involving adults who lack capacity to consent in UK. *Age and Ageing*. 2019;:1–7.
15. Frost NA, Nolas S-M. Exploring and Expanding on Pluralism in Qualitative Research in Psychology. *Qualitative Research in Psychology*. 2011;8:115–9.
16. Ives J, Dunn M, Cribb A. *Empirical Bioethics: Theoretical and Practical Perspectives*. Cambridge: Cambridge University Press; 2016.

17. Huxtable R, Ives J. Mapping, framing, shaping: a framework for empirical bioethics research projects. *BMC Medical Ethics*. 2019;20:86.
18. Ives J, Draper H. Appropriate Methodologies for Empirical Bioethics: It's All Relative. *Bioethics*. 2009;23:249–58.
19. Goldkuhl G, Cronholm S. Adding Theoretical Grounding to Grounded Theory: Toward Multi-Grounded Theory. *International Journal of Qualitative Methods*. 2010; 9 (2).
20. Shepherd V, Griffith R, Hood K, Sheehan M, Wood F. "There's more to life than money and health": Family caregivers' views on the role of Power of Attorney in proxy decisions about research participation for people living with dementia. *Dementia (London)*. 2019;:1471301219884426.
21. Clarke Victoria, Braun Virginia. *Successful qualitative research : a practical guide for beginners*. SAGE; 2013.
22. Wangmo T, Provoost V. The use of empirical research in bioethics: a survey of researchers in twelve European countries. *BMC Medical Ethics* 18 (17)
23. Webley L. *Qualitative Approaches to Empirical Legal Research*. Oxford University Press; 2010.
24. Charmaz K. *Constructing Grounded Theory*. 2nd edition. Sage; 2014.
25. Silverman D, editor. *Qualitative research*. 3rd edition. London: SAGE; 2011.
26. Glaser BG, Strauss AL. *The discovery of grounded theory : strategies for qualitative research*. 1999.
27. Burns KEA, Prats CJ, Maione M, Lanceta M, Zubrinich C, Jeffs L, et al. The experience of surrogate decision makers on being approached for consent for patient participation in research: A multicenter study. *Annals of the American Thoracic Society*. 2017;14:238–45.
28. Karlawish JHT, Casarett D, Klocinski J, Sankar P. How do AD patients and their caregivers decide whether to enroll in a clinical trial? *Neurology*. 2001;56:789–92.
29. Black BS, Wechsler M, Fogarty L. Decision making for participation in dementia research. [*]*. *American Journal of Geriatric Psychiatry*. 2012;19.
30. Sheridan R, Martin-Kerry J, Hudson J, Parker A, Bower P, Knapp P. Why do patients take part in research? An overview of systematic reviews of psychosocial barriers and facilitators. *Trials*. 2020;21:259.
31. *White v White* [1999] Fam. 304. 1999.
32. *W v M and others* [2011] EWHC 2443 (Fam). 2011.
33. Szerletics A. *Best interests decision-making under the Mental Capacity Act*. 2011.
34. Brudney D. *Choosing for another: beyond autonomy and best interests*. The Hastings Center report. 2009.
35. Brudney D, Lantos J. Agency and authenticity: Which value grounds patient choice? *Theoretical Medicine and Bioethics*. 2011.

36. Kirk TW, Jennings B. Hospice ethics : policy and practice in palliative care. Oxford: Oxford University Press; 2014.
37. Devettere RJ. Practical decision making in health care ethics: Cases and concepts. Third edition. Washington: Georgetown University Press; 2010.
38. Scheunemann LP, Arnold RM, White DB. The facilitated values history: helping surrogates make authentic decisions for incapacitated patients with advanced illness. *American Journal of Respiratory and Critical Care Medicine*. 2012;186:480–6.
39. Wertheimer A. (Why) should we require consent to participation in research? *Journal of Law and the Biosciences*. 2014;1:137–82.
40. Kerasidou A. Trust me, I'm a researcher!: The role of trust in biomedical research. *Medicine, Health Care and Philosophy*. 2017;20:43–50.
41. Wright S. Trust and Trustworthiness. *Philosophia*. 2010;38:615–27.
42. Mertz M, Schildmann J. Beyond integrating social sciences: Reflecting on the place of life sciences in empirical bioethics methodologies. *Medicine, Health Care and Philosophy*. 2018;21:207–14.

**Table 1. Characteristics of participants and interviews**

Participant demographic data and characteristics of interviews conducted

**Table 2. Illustrated descriptions of categories**

Description of categories identified from data analysis, illustrated with participant quotes

**Figure 1. Framework of proxy decision-making for research**

Framework depicting the ethical elements of proxy decision-making for research set within the context of how research is viewed by proxies