Abstract

Background

Public and patient involvement in healthcare research is increasing, but the impact of involvement on the individuals, on service delivery and on health outcomes, particularly in specialist population groups like critical care, remains unclear, as does the best way to involve people who have experienced critical illness.

Objectives

To explore former patients' and family members' views and experiences of involvement in critical care research and/or quality improvement.

Methods

Using a qualitative methodology, semi-structured telephone interviews were conducted with seven former intensive care unit patients and three close family members, across England. Data were analyzed using a standard process of inductive thematic analysis.

Results

Four key themes were identified: making it happen; overcoming hurdles; it helps; respect and value. Findings centre on the need for flexibility, inclusivity and transparency. They further highlight the particular challenges faced by critical illness survivors and their family members in relation to research involvement, the importance of individualised support and training and the vital role that project leads have in making people feel valued and equal partners in the process

Discussion

This is the first study to explore patients' experiences of involvement in critical care research. Despite the small, homogenous sample, the study provides valuable and important data, to guide

future practice. It highlights the need to enable and support people to make informed choices at a time when they are ready to do so. It further highlights the importance of gatekeepers, to avoid vulnerable people contributing before they are ready, a practice, which could negatively affect their heath status.

Key words (MeSH)

Critical care; Patient Participation; Qualitative research

1   **Patient and Family Member Experiences of Involvement in Critical Care Research and Quality**

2   **Improvement Projects**

3   As a result of policy drivers, such as those from the National Institute for Health Research (NIHR) in

4   England (Denegri, 2015), the importance and value of involving patients and the public in the design

5   and delivery of research is internationally acknowledged and commonplace in the United Kingdom

6   (Staniszewska et al., 2017; Staniszewska et al., 2018).

7   Public and patient involvement (PPI) is defined as when projects are carried out 'with' or 'by'

8   members of the public rather than 'to', 'about' or 'for' them, with different levels of involvement

9   described (Denegri, 2015). This means researchers working together with lay people, who have

10   personal experience of a condition or illness, to design and/or carry out research (Bench, 2019). PPI

11   is also relevant to quality improvement (QI), with experienced based co-design or other participatory

12   methods recommended to facilitate patient representatives, clinicians and researchers to work

13   together (Donetto et al., 2015). Research evidence suggests that PPI improves the quality, relevance

14   and impact of projects (for example, Barber et al., 2011; Boote et al., 2015; Brett et al., 2009, Brett

15   et al., 2014; Evans et al., 2015; Mockford et al., 2012).

16   Despite the growing body of evidence, the effects of involvement on individuals, on service delivery

17   and on health outcomes, particularly in specialist groups like critical care, remains unclear (Bench et

18   al., 2018; Staniszewska et al., 2018). Most published studies describe case examples with little

19   discussion of either the method of involvement or its effects on the individual (Bench et al., 2018;

20   Domecq et al., 2014). Where experiences are reported, they tend to focus on those of clinical staff or

21   researchers rather than the patient representatives (Bench et al., 2018).

22   Research to identify the best method by which to involve people who survive a critical illness is

23   clearly needed (Bench et al., 2018; Bench, 2019; Domecq et al., 2014; Menzies et al., 2016).

24   Guidance for involving people with mental health problems in the research process (Repper et al.,

25   2014) and reporting involvement more generally (Staniszewska et al., 2017) exists. Advice on generic

26   training and support is also available from INVOLVE, a national advisory group for public involvement

27   in research in England (Staley et al., 2012). Whilst these publications are likely to be to some extent

28   applicable, it is imperative that the particular needs of people with previous experience of critical

29   illness are addressed and that future PPI reflects their views and experiences.

30   **Materials and Methods**

31   The aim of this study was to explore former patients' and family members' views and experiences of

32   involvement in critical care research/QI. We employed a qualitative methodology using semi-

33   structured interviews. The research team included a critical care nurse researcher, two service user

34   researchers and a Professor of social science. We also invited trustees of ICUsteps, a Charity run by

35   former patients and family members, which provides support for people recovering from critical

36   illness, to comment on study proposal. Ethical approval was granted by a University (LRS-16/17-

37   4217) and informed consent obtained from all participants prior to data collection.

38   ***Sample and Recruitment***

39   We purposively recruited 10 adults (>18 years), seven former intensive care unit (ICU) patients and

40   three close family members (Table 1). The sample included four women and six men, aged 39-78

41   years from across England, all of whom identified as White British. All had previous experience of

42   being 'actively involved' in research or quality improvement projects; defined as contributing to the

43   design and/or delivery of a project, in contrast to being a research participant.

44   We contacted the lead investigators of projects identified to have PPI by email and asked them to

45   distribute an information sheet to any representatives on their projects. We identified these by

46   screening:

47   1.   Publications included in a published scoping review of PPI (Bench et al., 2018)

48   2.   Relevant critical care websites, e.g. European Society of Critical Care, Intensive Care Society

49   and Intensive Care National Audit and Research Centre.

50   In addition, organizations such as the ICUsteps Charity (www.icusteps.org.uk), contacts via

51   professional organizations and social media (twitter) helped promote the study.

52   Insert Table 1 here: *Participant Characteristics*

53   ***Data Collection Methods and Tools***

54   One to one audio-recorded semi structured interviews were conducted by a single researcher.

55   Interviews took place by telephone to ensure that geographical location and physical health status

56   were not barriers to participation. Following completion of a set of demographic questions, a topic

57   guide was used to explore participants' views and experiences. Questions were informed by a

58   scoping review of the literature (Bench et al. 2018) and focused on how people got involved, their

59   experience of involvement and suggestions for improving future practice. Interviews lasted 25-45

60   minutes and each participant was offered a £10 shopping voucher to compensate for their time.

61   ***Data Analysis***

62   Anonymised interview data were uploaded into $NVIVO_{11}$ and subjected to a standard process of

63   inductive thematic analysis, as described by Newell and Burnard (2011). The interviewer first coded

64   all transcripts and generated draft themes, which were reviewed by a second researcher. All

65   members of the research team agreed final themes using a consensus approach.

66   **Results**

67   Four final themes: making it happen; overcoming hurdles; it helps; respect and value, amalgamated

68   an initial 40 codes and a number of subthemes. (Table 2).

69   Insert Table 2 here: *Themes and Subthemes*

70   **Making it Happen**

71   *Nature of Involvement*

72   Experiences of involvement were wide ranging and included people being co-investigators or

73   members of research project steering or advisory groups; part of local quality improvement groups

74   and members of national committees. Some participants had also been involved in national priority

75   setting exercises and/or worked as volunteers within clinical areas. The number of patient

76   representatives on a project and the extent and length of their involvement varied enormously, with

77   some examples of extensive commitment, often undertaken on a voluntary basis.

78   Whilst most people described researcher or clinician led activities, there were also examples of

79   patient led or joint project work. The nature of involvement was constantly evolving. Participants

80   described a snowball effect, with one experience leading to other opportunities: *"We started*

81   *initially…helping to contribute towards research and also the process of improvement…then we're*

82   *going to move from there into the trauma research… and I've also explored communication with*

83   *patients who have got tracheostomies"* (Participant 2).

84   Most participants described their role as expert advisors, where they used their experiences to

85   comment on project ideas and draft documents. Some participants had no wish to be involved in

86   additional activities such as data collection, publications, attending conferences etc, whereas others

87   expressed a clear sense of pride in doing so, as illustrated by one man who said, *"If you read that*

88   *article…they were my comments on there".* (Participant 8). There was, however, a general feeling

89   that collecting data was not an appropriate role, highlighted by one lady who said "*I think patients*

90   *may be concerned about Data Protection breaches...I would be concerned. For me, personally, with*

91   *somebody without a clinical background managing my personal details about what happened in ICU,*

92   *I probably wouldn't give the information, to be honest*" (Participant 5).

93   *Inclusivity and Flexibility*

94   There was a consensus that people should be involved to whatever degree they wanted to and in

95   ways that suited them. One participant said, *"I would hate to exclude people who haven't had the*

96   *advantage of education...or if somebody is not very articulate, not to assume that they wouldn't be*

97   *interested and their views wouldn't be important"* (Participant 7). Including bereaved family

98   members was described as rare and potentially difficult for the individual, but the value of doing so

99   was highlighted: *"Aren't they of a greater asset because they lost loved ones?"* (Participant 5).

100   Another participant pointed out, however, that "*it can be difficult to approach relatives that have*

101   *just lost a loved one…"* (Participant 8).

102   Despite a desire for inclusivity, participants described repeatedly seeing the same people on projects

103   and some had themselves been involved on a number of occasions. Although the benefit of

104   experience was acknowledged, there was agreement that broader representation was required:

105   *"You don't want to have the same people constantly at all these different research projects, you want*

106   *to kind of, make sure you get a broader patient view rather than just one individual"* (Participant 4).

107   Whilst for most, the lack of financial reimbursement was not a barrier to participation, the offer

108   made people feel valued, particularly as *"everybody else in the room is [sic] being paid to be there"*

109   (Participant 7). It was also seen as a way of ensuring that everyone, regardless of their financial

110   status, had the opportunity to be involved, with one participant saying, *"then it doesn't sort of,*

111   *exclude them because they haven't got the finances available themselves"* (Participant 3).

112   *Providing Opportunity*

113   Using established connections, for example through critical care follow-up clinics run by clinicians,

114   with whom patients and relatives already had a relationship, was considered a good way of offering

115   the chance to be involved. Participants also described the benefits of being able to register their

116   interest on websites such as that of the ICUsteps Charity. There were also examples of people being

117   contacted directly by research teams and in some cases, people had been interviewed. As one

118   participant explained, "*Four or five people applied and I had a sort of interview. They didn't advertise*

119   *it as requiring an interview but it was really*" (Participant 6).

120   Participants stressed the need to reflect people's personal circumstances in the recruitment

121   strategy. As one person explained, *"Some people in the group will be very, very eager to*

122   *communicate and want to be very involved, others will take more of a back seat"* (Participant 3).

123   Whilst various timescales for approaching people, ranging from during the ICU stay up to five years

124   post hospital discharge were suggested, most agreed that there was no 'best time'. Participants

125   stressed the fact that, *"everybody's different…some people will be ready to share six months after*

126   *they've come out of ICU, somebody will be several years down the line"* (Participant 3). Participants

127   did agree, however, that providing information as early as possible could help people make an

128   informed choice about involvement.

129   Participants described the physical and emotional trauma associated with critical illness and

130   expressed concern that people might volunteer to be involved before they were ready. One former

131   patient said, *"People have such a desire to help, that they will put themselves forward and they will*

132   *volunteer before they're ready to and that could potentially end up damaging the*

133   *research…potentially the person himself"* (Participant 4). Participants considered gatekeepers,

134   defined as people or systems that offer protection for vulnerable individuals, important to mitigate

135   these potential risks. In most cases, these gatekeepers were clinicians. However, former patients and

136   relatives also undertook this role: "*A lot of people like to come through me…there's no pressure…you*

137   *would sort of be the intermediary between the research team and the group"* (Participant 3).

138   **Overcoming Hurdles**

139   *Meeting Logistics*

140   Participants stressed the importance of organizing meetings based on the convenience of patient

141   representatives and the need to consider peoples' time and travel constraints, carer responsibilities

142   and health status. As one former patient pointed out, *"The more constraints you put in...Then they*

143   *drop out"* (Participant 5).

144   Most participants expressed a preference for physical face-to-face meetings: *"I find it easier to talk*

145   *and discuss things with other people in a meeting...Anything that involves dealing with people, I find*

146   *it much better to do it face-to-face"* (Participant 9). Participants also felt that physical meetings

147   offered the additional social benefits that some people sought and avoided technical problems and

148   concerns about using the internet. However, participants acknowledged that local physical meetings

149   were not always possible or cost effective.

150   There was consensus that a flexible approach to meetings, adapted to purpose and agreed by all was

151   the best way forward, although the benefits of some discussion in patient specific groups was

152   highlighted. Describing his experience, one participant said: *"It all worked quite well in those small*

153   *working groups, and when the bigger group came together you were already into it and so it was*

154   *perfectly reasonable to participate in the bigger meeting as well at that stage"* (Participant 9).

155   Participants discussed the challenge of sustaining peoples' commitment levels over time, particularly

156   where there was a desire to establish longer-term quality improvement (QI) project groups. Talking

157   about involvement in research projects, one former patient also said *"You don't want people to lose*

158   *interest halfway through the study…Of all the people that must have attended in the beginning and*

159   *who applied to do the study, there's only actually two of us who go"* (Participant 5).

160   ***Health Status***

161   Participants highlighted that physical health status affected people's ability to be involved. In

162   particular, mobility problems were common in the early period after hospital discharge: *"I was on*

163 *walking sticks for a while and then crutches…it was quite a military ordeal for them to get me into*

164 *car and get me into the seat and, you know, on the train, that kind of thing"* (Participant 2).

165 In addition, participants described difficulties having to recall their experience; due to having little or

166 no memory of their time in ICU and/or the emotional trauma related to remembering. One former

167 patient said: *"I suppose the difficulty is constantly kind of, facing the emotional impact of the*

168 *trauma…we're sort of finding it difficult to keep going over that if you like…I sort of went through*

169 *post-traumatic stress and everything and I had to be counselled as well"* (Participant 2).

170 **It Helps**

171 ***Personal Benefits***

172 On an individual level, involvement was described as therapeutic, something which could provide a

173 renewed sense of purpose and value. As one woman said, *"I would say, 'Try it because it helps your*

174 *recovery. I think it helps you mentally... It feels good to help others"* (Participant 5). It was also seen

175 as an opportunity for social engagement: *"There's one gentleman that's lost his wife and he's very*

176 *grateful and happy to be part of the group actually because he, for one thing, it gets him out, he's*

177 *socializing...so he's happy to be there too, for the social side"* (Participant 1). Patient participants

178 further explained that involvement had helped them better understand not only their own

179 experience, but also that of their family and friends. In addition, people saw involvement as an

180 opportunity to find out about future critical care innovations.

181 ***Wider Effects***

182 Participants discussed the unique knowledge and insights that they brought to projects, drawn from

183 their critical illness experience. One participant said, *"Quite often when we're in these meetings with*

184 *the professionals, they'll turn around and say, 'I've never thought of that before, I haven't been a*

185 *patient'"* (Participant 8). Participants believed that their contributions, amongst other things, helped

186 focus project ideas and plans, refined research questions, determined inclusion and exclusion

187 criteria for studies, and facilitated the development of data collection tools. For example, one

188 participant said, *"There was a questionnaire that was going to be sent out to over 200 patients. I*

189 *raised a question – 'What kind of feedback would you expect to get from somebody who was in an*

190 *induced coma?'…sometimes, clinicians only see…their side of it, as opposed to somebody like myself*

191 *who has actually experienced it firsthand"* (Participant 5).

192 The opportunity to give something back was a key driver for involvement. One patient participant

193 explained that, *"We want other patients to be, you know, not go through the same things we did, so*

194 *we are constantly helping in that way"* (Participant 2). Many interviewees had refused offers of

195 financial reimbursement, had given the money to charity and/or had only accepted what they

196 required to cover their expenses. The need to 'give back' was particularly evident during an

197 interview with one family member who said "*If somebody gave me a million pounds, it wouldn't be*

198 *enough for what, you know, they saved xxx's life and his life is so precious, so anything I can do that*

199 *will make a difference"* (Participant 3). This desire to turn something negative into something

200 positive was reflected in most of the interviews and for some, was viewed as a moral obligation:

201 *"When you've been through something so life altering, life threatening, it's the desire to do*

202 *something to repay what you feel is a debt of gratitude"* (Participant 4).

203 **Respect and Value**

204 ***Support, Encouragement and Feedback***

205 The importance of providing a supportive environment was emphasized and participants considered

206 effective chairing of meetings vital, highlighting the need to take time to *"understand, to make them*

207 *feel an equal part of the team"* (Participant 4). There was agreement that the ability to express views

208 and opinions in a group setting was important; however, some described the process as daunting.

209 Where people felt encouraged and supported, they felt more able to contribute, as explained by one

210   participant who said, *"I was a little bit nervous at first but then they put us quite at ease and it was*

211   *fine. No problem at all"* (Participant 5). In contrast, during another meeting, not feeling valued had

212   affected her willingness to participate: "*Somebody came back and just thought that it was a*

213   *platform to take the mickey out of a Scouse accent [strong local accent held by people living in*

214   *Liverpool, England]...it got a bit annoying and a little bit offensive then. It put me off*" (Participant 5).

215   Another participant pointed out, however, that: "*Those people who are patronizing you soon listen*

216   *when you start to put your ideas forward and so they start to respect you...People get used to you*

217   *and understand that you know more than they do about the patient experience"* (Participant 8).

218   Although some participants believed that professionals are willing to listen and take note of patient

219   voices, others described their involvement as a '*tick box*' exercise. Furthermore, a number of

220   participants had no knowledge of how their contributions had affected project outcomes, despite

221   explaining that such feedback was more important to them than being paid.

222   ***Training***

223   Few participants had received any formal training. There was a general view that it was not

224   necessary, but acknowledgment that it was very individual: *"I would think in some cases, maybe*

225   *people would like a bit of training, in my case I don't think so…"* (Participant 3). Participants stressed

226   the need to make clear peoples' roles at the start of a project: *"As a patient you sort of want to know*

227   *what your areas of responsibility are, certainly, and as to what you're contributing towards"*

228   (Participant 2). Others described the value of hearing previous patient representatives' experiences

229   and acknowledged the benefit of information sent prior to meetings. For example, one person said,

230   "*what the agenda is yeah…so you know exactly what we are going to be talking about"* (Participant

231   10). Another participant also suggested *"almost a kind of, underground map of the different stages*

232   *explaining…where we're at, where you'll be involved, where you get on, where you get off and clearly*

233   *to just kind of help just help visualize the view from the patient's involvement"* (Participant 4).

234   *Shared Language*

235   Paying insufficient attention to unfamiliar language/terminology used by professionals made people

236   feel less able to contribute. Describing her experience, one participant said, *"To be honest, it was*

237   *way over my head and I had to say, 'I don't understand at least 50% of this'…somebody like myself*

238   *who can't understand the medical terms and phraseology, it would put people off"* (Participant 5).

239   Another participant also expressed the opinion that *"There are times when maybe jargon could be*

240   *less…I mean, so definitely abbreviations …there's something about wherever possible speaking*

241   *ordinary language"* (Participant 7). This gentleman went on to share his view about the role of

242   research/project leads saying, *"One of the researchers in the room will occasionally pull us to one*

243   *side, say 'what this means is…' and I find that helpful...I like it when she does that"* (Participant 7).

244   **Discussion**

245   The aim of this study was to explore the views and experiences of people with previous critical

246   illness experiences about their active involvement in research or QI projects. The following sections

247   discuss the findings in the context of existing literature and propose recommendations for future

248   policy, practice and research.

249   *Involvement Methods*

250   Our study supports that a flexible and individualized approach, both to recruiting and retaining

251   people in PPI is important, findings congruent with those of a systematic review of patient

252   engagement by Domecq et al. (2014) and a scoping review specific to critical care (Bench et al.,

253   2018). Commonly, identifying patient representatives uses an approach similar to non-probability

254   convenience sampling (Elfil & Negida, 2017). Our participants, however, expressed a desire for wider

255   representation and greater inclusivity. Domecq et al. (2014) suggest that the use of volunteers,

256   particularly the same ones for a number of projects, can lead to the involvement of people that are

257 not truly representative of the targeted population. In contrast, others argue that the focus should

258 be on how best to capture the collective sharing of experiences, views and values rather than

259 worrying about achieving representation (Bench et al., 2018). Previous studies report that academics

260 and professionals are more concerned about representation than the individuals that are involved

261 (e.g. Martin, 2008; Renedo & Marston, 2011), however, the participants we interviewed also raised

262 this as an issue. In addition, whilst acknowledging the challenges, our findings suggest that further

263 involvement of under-represented groups is a desirable goal.

264 Considering and facilitating individual preferences for involvement at the earliest stage possible is

265 vital, as is the importance of agreeing roles at the start of a project (Dudley et al., 2015; Liabo et al.,

266 2018). Recognizing that all styles of meeting have value (i.e. face-to-face, virtual etc) is also likely to

267 promote inclusiveness and increase people's desire to continue their involvement. In our study,

268 although people were involved in many different ways, as reported by others (Domecq et al., 2014;

269 Liabo et al., 2018), the most common and accepted form of engagement was as 'experts by

270 experience' on a study steering or advisory group. The growing number of additional roles that

271 people are taking on, such as writing for publication is also worthy of note. The fact that some of our

272 participants reported undertaking patient/joint-led work and acting as gatekeepers for accessing

273 other patient representatives, as well as the more 'usual' clinician-led activities is encouraging, but

274 requires future analysis both in terms of the support needed and associated ethical issues.

275 Our findings support that survivors of critical illness and their families want to be involved and the

276 benefits of involvement. In addition to the altruistic aspects, involvement offers social engagement

277 opportunities, which can be therapeutic to the individual. Feelings of boredom, loneliness and

278 isolation are common after ICU discharge (Hashem et al., 2016) and PPI may contribute to effective

279 critical illness rehabilitation. This study also highlights wider benefits, such as increasing peoples'

280 knowledge, insight and research/improvement skills, factors important to creating people-centered

281 health research, which is trusted and valued by the wider public (Wellcome Trust, 2018).

282 ***Value and Respect***

283 A common concern identified in both our study and those of others (Bench et al., 2018; Domecq et

284 al., 2014) is that patient engagement in research or QI can be tokenistic. Whilst many or our

285 participants had a positive experience, there were examples of this occurring and a clear sense that

286 it was detrimental to achieving shared goals. Not feeling valued might also affect people's desire to

287 remain involved. Sustaining peoples' commitment longer-term is a well-documented challenge (for

288 example, Barry, 2005; Plano Clark et al., 2015). Our findings suggest that a greater focus on making

289 people feel valued might help address this issue.

290 There was a powerful sense of peoples' need to give something back. Despite acknowledgement of

291 its ability to enable equal opportunity for participation and to provide the resources required to

292 support involvement (Staley et al., 2012), payment was of limited importance to those we

293 interviewed. The issue of payment to patients and public for their involvement in activities is a

294 contentious area that has been the subject of much debate (South et al., 2014). In our study, most

295 participants did not want paying for their involvement; instead they wanted to give something back,

296 or '*get something out of it*', further highlighting the need to feel valued.

297 There was little perceived need for generic training. In contrast, there was a strongly expressed need

298 to feel valued, to be heard and to feel equal. The use of shared language is important to achieving

299 this and critical to collaboration of any sort, particularly in situations where people come from

300 different disciplines or backgrounds (Thomas & McDonagh, 2013).

301 ***Risks and Benefits***

302 Our findings support that, if done well, PPI in critical care offers significant gains for all, including the

303 patient representatives, the researchers, clinicians, future patients and policy makers looking to

304 deliver effective and efficient healthcare services. However, the need for gatekeepers to protect

305   recovering critical illness survivors from harm is an important finding. Post Intensive Care Syndrome

306   (PICS) or PICS (F) for family members are terms used to collectively describe the long-lasting physical

307   and psycho-social problems, which can affect people's quality of life after a critical illness (Davidson

308   et al., 2012; NICE, 2009; Rawal et al., 2017). PICS or PICS (F) can persist for several years after

309   hospital discharge, with many survivors and some of their family members requiring ongoing

310   healthcare service support with significant cost implications (NICE, 2009).

311   Researchers and health care professionals have an ethical obligation to protect people from harm. In

312   our study, physical health status and/or the problem of recall clearly affected peoples' capacity to be

313   involved. These issues present a dilemma around knowing when and how best to approach people:

314   too long afterwards might present recall difficulties; too soon afterwards could have negative

315   emotional effects and could reignite emotional trauma.

316   The concerns expressed about patients collecting data from fellow patients are important to

317   acknowledge. Garfield et al. (2015) involved lay people in collecting observational data in clinical

318   areas. Although the lay members described it as an interesting and informative experience, the

319   research team reported a number of challenges, for example, understanding research procedures

320   such as consent and navigating access requirements. These findings warrant further exploration.

321   **Limitations and Strengths**

322   This study interviewed a small sample of exclusively white British participants and reports only the

323   experiences of people located within a single geographically defined healthcare system. There may

324   also be differences between the views of patients and family members, which we did not uncover

325   due to the small sample. However, overall there was a clear sense of data saturation, supporting

326   that our findings may have wider relevance and applicability.

327   Whilst the service user researchers on our project group do not have direct critical care experience,

328   they live with long-term health difficulties and have significant experience of 'user-led' research.

329   Reflecting on our collective experiences, the project team highlighted the important distinctive

330   contributions that each person brought to the design of the study and analysis of its findings. Our

331   reflections support the need for continued development of PPI in critical care research and QI work.

332   **Policy, Practice and Research recommendations**

333   Table 3 details our key recommendations for PPI within critical care. Our findings support that it is

334   'ok to ask' (NIHR, 2014b) and that researchers should not assume that people do not want to be, or

335   are not able to be involved, as either participants or project members. Health care staff should offer

336   information about involvement throughout the critical illness trajectory and details of how people

337   can register their interest. ICU staff should incorporate this information into the standard resources

338   provided to patients and their families on admission, with follow up discussions at appropriate time

339   points, for example, whilst still in hospital, at outpatient clinic appointments and within primary care

340   services. Time dedicated to developing trusting, reciprocal relationships and mutual respect is key to

341   success, with clear expectations of what is required from the outset also vital. To avoid people

342   volunteering to become involved 'too soon' than is good for them and to protect their ongoing

343   interests, we recommend that an appropriately qualified health care professional, with a specific

344   remit to 'protect' participants, should be affiliated to all critical care research/projects.

345   Further research with a larger and more widely representative sample is required to inform future

346   guidelines for international practice. Despite potential similarities with other population groups (e.g.

347   NIHR, 2014a), it is important that future guidance for involving critical care survivors in research

348   and/or QI considers their physical and emotional vulnerability and ways in which these risks can be

349   mitigated. In the meantime, we strongly recommend the consistent use of the reporting guidelines

350   published by Staniszewska et al. (2017) to help further our understanding about those who are

351   involved, and their related experiences. Such reporting will enable us to identify under-represented

352   groups, where further investigation is required. It will also facilitate an evaluation of the effects of

353   PPI on enrolment and attrition in research studies (Domecq et al., 2014) and help determine

354   whether patient involvement helps disseminate findings in a more meaningful and understandable

355   way.

356   Insert Table 3 here: *Key Recommendations for PPI in Critical Care*

357   **Conclusion**

358   To our knowledge, this is the first published interview study exploring PPI from the perspective of

359   critical illness survivors and their families. As such, despite the small, homogenous sample, it

360   provides valuable and important data, to guide future practice. In particular, it highlights the need to

361   enable and support people to make informed choices at a time when they are ready to do so. Our

362   findings center on the need for flexibility, inclusivity and transparency. They further highlight the

363   particular challenges faced by critical illness survivors and their family members in relation to

364   research involvement, the importance of individualized support and training and the vital role that

365   project leads have in making people feel valued and equal partners in the process.

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469

470   **Figure Legends**

471   Table 1: Participant Characteristics

1	Female	45	Married	Housewife	Secondary education	Staffordshire
2	Male	39	Married	Full time employed	Post graduate	Staffordshire
3	Female	53	Married	Full time carer	Post graduate	Middlesborough
4	Male	47	Married	Full time	Secondary	Milton Keynes

				employed	education	
5	Female	50	Single	Full time employed	Secondary education	Liverpool
6	Male	Unknown	Married	Full time employed	Post graduate	Liverpool
7	Male	59	Single	Self employed	Doctorate	Liverpool
8	Male	70	Married	Retired	Degree	Surrey
9	Male	78	Married	Retired	Post graduate	Berkshire
10	Female	60	Unknown	Unknown	None	Newcastle

472

473   Table 2: Themes and Subthemes

Nature of involvement	Meeting logistics	Personal Benefits	Support, encouragement and feedback
Inclusivity and flexibility	Health status	Wider impact	Training needs
Providing opportunity			Shared language

474

475   Table 3: Key Recommendations for PPI in Critical Care

- PPI arrangements should be considered at the earliest stage of project development
- Health care professionals should offer information about involvement throughout the critical illness trajectory and provide people with details of how they can register their interest
- Recruitment should be flexible and individualized with consideration to:
  - the timescale for approaching ICU patients and their family members
  - participant preferences
  - wide representation
- An appropriately qualified health care professional, with a specific remit to 'protect' participants, should be assigned to all critical care projects
- Language/terminology that is familiar to/accessible for lay participants should be used at all times
- Project leads should consider a range of meeting styles (ie face to face, online etc.) to suit individual

needs

- Payments should be offered for involvement activities

- Time should be dedicated to developing trusting, reciprocal relationships and mutual respect

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