Strength of public preferences for endovascular or open aortic aneurysm repair: results of a telephone survey

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ABSTRACT

Background: This study evaluated public preferences for the treatment processes for abdominal aortic aneurysm repair in order to allow preferences to be incorporated into a cost-effectiveness analysis.

Method: A telephone survey using a trade-off method in UK resident adults (18 +) with no prior diagnosis of a vascular condition.

Results: 167 (79.9%) of 209 participants stated that they would prefer endovascular aneurysm repair (EVAR), 40 (19.1%) preferred open surgery, and two (1.0%) stated no preference. Participants preferred EVAR because of the less invasive nature of the intervention and quicker recovery times. Participants preferring open surgery cited reasons such as having a single follow-up appointment and a procedure that felt more permanent. When participants were asked to make a sacrifice in order to have their preferred treatment, 122 (58.4%) favoured EVAR, 18 (8.6%) favoured open surgery, and 69 (33%) had no preference. Those preferring EVAR were willing to give up a mean of 0.135 expected quality adjusted life years (QALYs) to have EVAR compared to a willingness to give up 0.033 expected QALYs among those preferring open repair.

Conclusion: These results indicate a clear preference for EVAR over open surgery, which is at odds with the recent recommendation by NICE that EVAR should not be recommended as a treatment option. The findings suggest that greater consideration be given to treatment process characteristics. By not explicitly incorporating such preferences into the decision-making process, NICE runs the risk of recommending treatment pathways which are contrary to the preferences of the UK population.

Introduction

The choice of surgical intervention for the repair of unruptured abdominal aortic aneurysm (AAA) is controversial[1]. Open surgery has been the standard care provided to patients, which involves a large abdominal incision to insert a prosthetic graft. The development of endovascular surgery allows a stent graft to be inserted under radiological control through a small incision in the groin. Clinical trials in patients with AAA have concluded that endovascular aneurysm repair (EVAR) is associated with fewer perioperative deaths but this survival advantage is not maintained in long-term follow-ups[2-6]. Currently both procedures are available for treatment[7].

Several studies evaluating the cost-effectiveness of EVAR compared to open surgery have found that open surgery is more cost-effective[8-10]. This is largely due to the additional device cost and the EVAR follow-up, which requires additional imaging and reinterventions[11]. Consequently, recently published draft guidelines by The National Institute for Health and Care Excellence (NICE) recommend the adoption of open surgery as the standard care for the repair of non-ruptured AAA[12]. However, this recommendation is not supported by patient preferences and clinical opinion, with EVAR currently being used for the majority of elective repairs in the UK[13, 14].

In formulating its guidance, NICE uses quality adjusted life years (QALYs) as the measure of benefit in cost-effectiveness analyses (CEA), implicitly assuming that improvements in health are the only thing of relevance to patients. However, there may be many other influences on patient preferences regarding the health care technologies[15-18]. Examples of such influences are patient autonomy, dignity, and the procedures patients have to undergo in order to achieve an improvement in health outcome[19-21]. The last of these is commonly referred to as 'process utility' and is the subject of this paper. Process utility can be defined as the utility that patients derive from the processes of health care consumption and is distinct from the utility derived from the outcome of that consumption. For example, a patient may prefer to have minimally invasive surgery rather than open surgery because of the less invasive process associated with the former. If the two types of surgery are compared in a standard CEA, then the patient's preference for the process of minimally invasive surgery will not be considered. The potential implications of omitting this preference will, of course, depend upon the strength of preference in relation to long-term health benefits. The importance of process preferences has been recognised by NICE[22], but economic evaluations do not routinely incorporate process utilities

into their analysis. As the UK government continues to promote patient choice and autonomy[23, 24], the need to include preferences for health care processes into cost-effectiveness studies is becoming increasingly important. The aim of this study is to quantify strength of preference for the processes of EVAR and open surgery, using a method that allows preferences to be incorporated into a cost-effectiveness analysis.

Methods

The method involved surveying members of the UK population, through individual telephone interviews, to elicit their preferences for EVAR and open surgery for the treatment of AAA. At the heart of the method is the notion of opportunity cost and how this relates to value. Fundamentally, something is only of value to an individual if s/he is willing to give up (or sacrifice) something in order to acquire what is being valued. Without sacrifice, there is no value. What respondents were asked to sacrifice in order to have their preferred treatment option was small changes in the chance of treatment being successful. From their responses it was possible to quantify their strength of preference in terms of a QALY equivalent which, in principle, would allow these preferences to be incorporated directly into a CEA.

Process utility interview procedures

Following some introductory information giving the background to the study, the respondent was taken through a simple diagram explaining the concepts of chance and probability (see Figure 1). An interview booklet which had been sent to respondents beforehand was used to illustrate the concepts using pictures. Once the respondent indicated they understood and were happy to proceed, the main interview began.

Respondents were first taken through descriptions of three health states labelled A, B and C (written descriptions of the health states were in the interview booklet and are reproduced in Appendix A). The health states comprised a typical health state experienced by someone with an AAA which was at significant risk of rupture (A), full health (B), and dead (C). They were asked to imagine they were experiencing health state A and to consider two possible treatment options. These were EVAR and open surgical repair (written descriptions were in the interview booklet and are reproduced in Appendix A). It was explained that in both cases successful treatment would result in them moving into health state B, but that there was a small chance that the treatment would be unsuccessful, in which case they would die (health state C).

Respondents were then told to assume that both treatments were available to them at their local hospital and that the chance of each treatment being successful was the same, and was equal to 95 in 100. They were then asked to state which treatment they would prefer if they had a choice, and to give a reason for their answer.

Respondents who said they would prefer EVAR were then asked if they would still prefer EVAR if the chance of a successful outcome was lower with EVAR than with open repair (that is, less than 95 in 100). Those who said they would still prefer EVAR were then asked a series of Yes/No questions to determine the lowest chance of a successful outcome at which they would still prefer EVAR over open repair. This was done by presenting respondents with different probabilities of success in a 'ping pong' fashion until the lowest chance of success was arrived at.

Respondents who stated a preference for open repair were taken through a similar exercise, with the difference being they were asked if they would still prefer open repair if the chance of a successful outcome was higher with EVAR than with open repair (that is, more than 95 in 100). Those who said they would still prefer open repair were taken through a similar 'ping pong' exercise to determine the highest chance of success with EVAR at which they would still prefer open repair over EVAR. It should be noted at this point that the survey data reported here were part of a larger survey investigating other aspects of vascular service provision in which respondents were asked to consider changes to the probability of EVAR being successful. It was felt that in order to minimise the cognitive burden on respondents, only the probability of EVAR being successful should be varied, with the corresponding probability for open repair remaining constant throughout. At the end of the interview, respondents were asked a number of socio-demographic questions.

Participants

Participants were 18 years of age or over, citizens of the United Kingdom and had no previous diagnosis of a vascular condition (self-assessed). The justification for sampling members of the public rather than patients lies in the context of how the values are likely to be used, namely to inform national health care priority setting. In this context, NICE states a preference for QALYs to be based upon general population values[22]. The total target sample size was 200, which is based on previous applications of similar techniques among members of the general public[25-27].

Recruitment and consent

Participants were recruited via 10 NHS trusts across the UK. A range of approaches were used to identify potential participants. These include approaching hospital visitors on site, having recruitment stands in dining halls, using posters around the trusts with study details and recruiting staff via blanket emails. When approaching potential participants, efforts were made to ensure the sample was representative of the general population with regard to age and gender. Contact details of potential participants were securely transferred to the research team, who then contacted these participants (between September 2017 and January 2018) to arrange a date and time for telephone interviews. Participants who agreed to be interviewed were sent an interview booklet approximately one week before interviews took place. They were advised to read the interview booklet prior to the interviews to familiarise themselves with information enclosed. Verbal consent was obtained over the phone prior to commencing the interview and was audio recorded. The use of verbal consent was accepted and approved by the South East Coast - Brighton & Sussex Research Ethics Committee.

Outcomes

Respondents' willingness to trade changes in the chance of success of EVAR in order to have their preferred treatment can be used to estimate the value of the treatment processes of both treatments. Specifically, for each treatment preference it is possible to estimate the maximum amount of expected QALYs respondents would be willing to sacrifice in order to have their preferred treatment.

In estimating QALYs, it is assumed that any health state can be assigned a number between 0 (dead) and 1 (full health). This study has three health states, the values for two of which are known - B is full health which is assigned a value of 1 and C is dead which is assigned a value of 0. The value of health state A is unknown and is represented by U(A). QALYs are calculated by multiplying the value assigned to a health state by the time spent in the health state.

Taking those who prefer EVAR as an example, and using a time horizon of one year after treatment, the value of the EVAR treatment process is estimated as follows. Suppose the lowest probability of success that those preferring EVAR would be willing to accept and still choose EVAR is 0.92. In this case, the expected QALY gains associated with both treatment options can be estimated:

Open = [(1 x 0.95 + 0 x 0.05) – U(A)] x 1

EVAR = (1 x 0.92 + 0 x (0.08) – U(A)] x 1

The sacrifice in QALYs associated with EVAR = [(1 x 0.95 + 0 x 0.05) – U(A)] – [(1 x 0.92 + 0 x (0.08) – U(A)]

= (0.95 – 0.92)

= 0.03 QALYs

In this example, the respondents who prefer EVAR are willing to sacrifice 0.03 expected QALYs to have EVAR rather than open repair.

A similar calculation can be made for those preferring open repair.

Analysis

Descriptive statistics for public preferences and sociodemographic characteristics were calculated using frequencies and percentages for categorical variables and means, medians, and interquartile ranges for continuous variables. Group differences were explored using hypotheses tests, including the t-test, Mann-Whitney U test, and Chi-Square test as appropriate. Reasons for preferring EVAR or open surgery were coded into themes using NViVO version 12 software. All quantitative analyses were undertaken using SPSS version 24.

Public Involvement

In designing the study materials, the research team were cognisant of participants' likely unfamiliarity with vascular conditions and treatment options. They were also aware that participants needed to fully understand what was being asked of them and that risk (chance of success) in particular needed to be presented in a way that was understandable. The interview booklet, containing health states and treatment descriptions, was developed by the research team with extensive input from patients and clinicians familiar with the conditions and treatments concerned. Study materials were extensively tested with five members of the Sheffield Teaching hospitals NHS Foundation Trust Online Public Advisory Panel. Ten pilot telephone interviews, along with several peer review exercises, were also carried out. The overall aim was to test the language, structure and comprehension of the study materials in order to gather feedback and refine the survey. The feedback obtained included suggestions on the wording, design of study materials, and the need to present risk (percentages) in an understandable way. All of the feedback was incorporated into the final version of the study materials.

Results

A total of 209 participants completed the telephone questionnaire, giving a response rate of 64%. Two additional participants were interviewed but they were classified as "protesters" and were subsequently excluded from the study because they chose not to engage in the preference elicitation questions. Among the 209 participants missing, data were low and did not exceed 2%. To ensure quality, the interviewers checked whether the participants understood the concept of risk involved in undergoing surgery for AAA. A simple diagram explaining risk was presented to the participants, and when asked to interpret it, all participants stated that they fully understood the concept of chance of treatment success or failure. On average the interviews took 12.9 (SD 4) minutes to complete.

Characteristics of Study population

Of the 209 participants, 63.6% were female and the mean age of the sample was 52.3 years (Table 1). The majority of the sample (73.7%) were in paid employment, 22.5% were retired and 2.4% were unemployed. Most of the participants (67.5%) were married or cohabiting, and 16.7% of the sample lived alone. With respect to highest level of education, 64.6% had a college or university level qualification, 10% had attained A-level qualifications, 21.5% had achieved O level (GCSE) qualifications and the remaining 3.3 % had attended primary school. The average household size was 2.6 people. The participants were recruited from several counties in the UK, namely, Greater London, South Yorkshire, Kent, Staffordshire, Cambridgeshire, Essex, Cumbria and Northumberland.

General preference for type of surgery

In a ceteris paribus situation where treatments were provided at a local hospital with the same chances of treatment success, 167 (79.9%) participants said they would prefer EVAR, 40 (19.1%) said they would prefer open and two (1%) people said they had no preference for either treatment. Stated reasons for preferring EVAR included the less invasive nature of the procedure (i.e. smaller cut, smaller scar), quicker recovery, less pain, less time in hospital, choice of local anaesthetic, more monitoring because of the yearly follow-up, personal experience of having a keyhole operation for a different condition, and no stay in ICU (see Table 3). Stated reasons for preferring open surgery included a preference for having only one follow-up appointment after the surgery, finding the procedure more permanent without any leakage, a dislike of the EVAR surgery, knowing someone who had undergone open surgery, preferring general anaesthetic, and preferring the longer stay in hospital.

The characteristics of participants choosing EVAR or OPEN were similar, with no statistically significant differences in age, marital status or educational level (Table 2). However, there was a significant association between gender and the type of surgery that the participants preferred ($x^2(1) = 12.695$, $p<0.001$). Among females 88% preferred EVAR compared to 67.6% of males and 32.4% of males preferred OPEN compared to 12% of females. Subgroup analyses of free text comments show that males prefer OPEN because of the more permanent surgery with less likelihood of leakages whereas females prefer EVAR surgery because it is less invasive, and the recovery time is quicker. Similarly, there was a statistically significant association between employment status and choice of surgery (x^2 (1) = 7.707, p=0.006). Among those who were employed 85% preferred EVAR compared to 67.3% of people who were not employed and 32.7% of those who were not employed preferred open compared to 15% of those who were employed. Subgroup analyses of free text comments show that those who were employed preferred the quicker recovery and less invasive attributes of EVAR surgery.

Strength of preference for type of surgery

While the majority of respondents stated a preference for EVAR over open surgery (167 vs 40), it is important to value the strength of those preferences. Value is measured by the maximum sacrifice of expected QALYs individuals were willing to make in order to have their preferred method.

Among the 167 respondents who stated a preference for EVAR, when asked if they would still prefer EVAR if the chance of success was lower than that with open, 45 indicated they would not, and instead would switch their preference to open surgery. In other words, they were not willing to give up any expected QALYs to have EVAR despite having stated a preference for it. In terms of the specified definition of value (i.e. something is only of value if an individual is willing to give up something in order to acquire it), these 45 respondents do not value EVAR any more highly than they value open surgery. Thus, their stated preference for EVAR over open repair can be regarded as an extremely weak preference. This leaves 122 respondents who were willing to sacrifice expected QALYs to have EVAR instead of open.

Similarly, among the 40 participants who stated a preference for open surgery, when asked to consider their preference if the chance of success with EVAR was higher than with open repair, 22 indicated they would switch their preference to EVAR. Thus, these 22 respondents do not

value open surgery any more highly than EVAR, leaving 18 individuals who were willing to sacrifice expected QALYs to have open surgery instead of EVAR.

The relative strengths of preference among the 122 and 18 participants who had a positive value for EVAR and open surgery, respectively, are presented in Table 4 which shows the mean, median and total expected QALYs individuals were willing to give up in order to have their preferred surgical method. The mean expected QALY sacrifice among the EVAR group is significantly higher than that in the open group (0.135 vs 0.033, $p<0.001$). A similar result is found when median values are compared between the EVAR and open groups (0.1 vs 0.035, $p=0.001$). Aggregating the QALY sacrifices within the two preference groups reveals that those preferring EVAR were willing to give up 16.48 expected QALYs to have their preferred treatment compared to 0.59 QALYs among those preferring open surgery.

Discussion

Principal findings

This study conducted telephone interviews with 209 members of the general public to elicit their stated preferences for elective treatment of an AAA with either EVAR or open surgical repair. When considering simple direction of preference, 167 (79.9%) of this sample stated they would prefer EVAR, 40 (19.1%) indicated a preference for open surgery, and two people (1.0%) said they had no preference for either treatment. Consideration of strength of preference (measured in terms of a willingness to give up expected QALYs) revealed that 45 of the 167 respondents who stated they preferred EVAR and 22 of those stating a preference for open repair were not willing to make any sacrifice to have their preferred treatment, which was taken to mean that these preferences were so weak as to be commensurate with not preferring one treatment over the other. Thus, the revised number of respondents who preferred one or other treatment (defined in terms of their strength of preference) were 122 (58.4%) in favour of EVAR, 18 (8.6%) in favour of open surgery, and 69 (33%) having no preference. Those preferring EVAR were willing to give up a mean average of 0.135 expected QALYS to have EVAR compared to a willingness to give up 0.033 expected QALYs among those preferring open repair. These results indicate a clear preference for EVAR over open surgery among the participants interviewed.

Comparison with other studies

There is only one other study which has elicited stated preferences for EVAR and open surgery for the elective treatment of AAAs[14]. In this study, the authors conducted telephone interviews with patients who were undergoing periodic ultrasound scan surveillance for known AAAs in two UK hospitals. Prior to the interviews, patients were sent written information on the two procedures summarising the care pathways for both, with particular emphasis being given to features which differ between the two methods. In total, 56 patients took part in the study. Of these, 47 (84%) stated a preference for EVAR, 7 (13%) said they preferred open, and 2 (3%) had no preference. These results are very similar to those in this study, where the percentages preferring EVAR, open surgery and no preference were 79.9%, 19.1% and 1.0%, respectively.

Strengths and limitations of the study

The main strength of this study is that not only was the direction of stated preferences for EVAR and open surgery elicited, but the strength of those preferences has also been quantified. Information on strength of preference is more useful for decision making purposes as it provides a more comprehensive picture of underlying preferences. This is clearly illustrated by the stated preferences of 67 members of the sample being reclassified from preferring one or other intervention to having no preference once consideration was taken of strength of preference.

Another strength of this study is that, unlike many previous studies in other areas which have attempted to measure process utilities using alternative numeraires such as money[16, 28], this study has quantified strength of preference in terms of QALYs. This means that the value attached to process utility can be readily and explicitly incorporated into the type of cost-effectiveness analyses favoured by NICE, in which interventions are compared in terms of incremental cost per QALY ratios. As stated earlier, this study forms part of a larger body of research focusing on the evaluation of vascular services more generally, and these results will be incorporated into cost-effectiveness models evaluating the efficiency of vascular services provision in the UK.

Arguably, the biggest limitation to this study is the sample. The team deliberately chose to interview members of the public rather than patients in order to adhere to NICE's preference for values upon which QALYs are based to be those of the general population.[22] However, surveying members of the public presents a number of challenges and potential limitations.

Chief among these is that the approach relies upon participants being able to digest and understand the information presented to them and to go on and imagine themselves in a scenario where they are experiencing ill health and are faced with a choice between treatments. This is no easy task, and every effort was made to help the participants with their understanding and engagement with the exercise. Despite this, several participants remarked that they found it very difficult to imagine how they would react if they were faced with the kind of choices presented to them in a real-life situation. Having said that, the similarity between these results and those of Winterborn et al. (2009) whose sample comprised patients with an AAA is reassuring. Furthermore, the sample was not representative of the UK population, and as such the generalisability of these results may be limited. For example, AAAs are a condition which predominantly affect men, yet around two thirds of this sample were female. Despite attempts to address this by asking the trusts to recruit more males, the gender imbalance persisted as more women than men agreed to be interviewed. Nevertheless, several studies have reported an increase in ruptured AAA in women[29-31], and as such, the findings may be applicable to this subgroup.

Another limitation is the use of changes in risk to value people's strength of preference. Risk is a difficult concept for people to understand, yet the validity of these results rely upon people being able to comprehend risk and probability. To mitigate this, a carefully constructed exercise was designed in which people were introduced to the concept of risk and how it would be used in the interview. The team explicitly asked if people felt comfortable with the concept before proceeding with the interview, but nevertheless it may have been the case that some members of the sample did not fully understand this concept, thus calling into question the validity of their responses.

Another limitation is the decision to only vary the probability of success of EVAR whilst holding constant the probability of success of open surgery. As explained earlier, this was done to minimise the cognitive burden on respondents from only having to consider variation in one risk. However, this introduced a limitation when eliciting values from those who stated a preference for open surgery. For these individuals, their willingness to sacrifice expected QALYs in order to have their preferred treatment was measured by asking them to consider increases in the probability of successful treatment with EVAR. This was constrained to values between 95% and 100%. This contrasts with the process that was adopted with those people who stated a preference for EVAR. Here, their willingness to sacrifice QALYs was measured

by asking them to consider reductions in the probability of successful treatment with EVAR. The range of values which could be considered here was between 95% and 0%, which was larger than that for the group preferring open repair, and thus afforded the EVAR group the opportunity to express a greater strength of preference.

A final limitation of the study is the short time horizon over which expected QALYs were estimated. In principle, the time horizon can be extended beyond one year to cover remaining life expectancy. This would require estimation of the lifetime health profiles of patients following treatment with EVAR and open repair, and would produce larger estimates of the expected QALY sacrifices. While such an approach was beyond the scope of this study, it should be noted that adopting a lifetime perspective would result in the preferences for EVAR over open surgery being even more pronounced.

Conclusion

By quantifying public preferences for the treatment processes associated with EVAR and open surgery in the treatment of AAAs, the results of this study strongly suggest that there is a clear preference among the sample for EVAR. This is at odds with the recent recommendation by NICE that EVAR should no longer be a recommended as a treatment option for this condition. These findings suggest that greater consideration should be given to the value that is placed on the relative process utilities of EVAR and open surgery in the elective treatment of AAAs. Those who expressed a preference for EVAR preferred the quicker recovery times and less invasive attributes of EVAR surgery. By not explicitly incorporating such preferences into their decision-making process, NICE runs the risk of recommending treatment pathways which are contrary to the preferences of the UK population.

Tables

Table1: Socio-economic characteristics of the sample

Characteristic	**Study sample - No. (%)**	**England & Wales population (From ONS, 2011)[32] – No in millions (%)**
Sex		
Male	76 (36.4)	27,600 (42)
Female	133 (63.6)	28,500 (44)
Employment status		
In paid-employment	144 (68.9)	15,816 (55.2)
Self-employed	10 (4.8)	3,988 (13.9)
Unemployed	5 (2.4)	1,800 (6.3)
Retired	47 (22.5)	Can't find
Student	1 (0.5)	1,410 (4.9)
Marital status		
Married	116 (55.5)	21,197(46.6)
Living with partner	25 (12)	Not measured
Widowed	7 (3.3)	3170 (7)
Divorced	14 (6.7)	4099 (9)
Single	46 (22)	15,730 (34.6)
Highest level of Education		
Primary	7 (3.3)	10307 (22.7)
O/level/GCSE	45 (21.5)	12985 (28.6)
A/level	21 (10)	5,618 (12.3)
College/University	135 (64.6)	12383 (27.2)
	Mean (SD) [range]	
Age, y	52.28 (15.57) [19-82]	39
Household size	2.55 (1.20) [1-7]	2.4

Table 2: Group Differences based on demographics

Characteristic	**Prefer EVAR**	**Prefer OPEN**	**P Value**
	Mean (SD)		
Age, y	51.51(14.94)	55.25 (17.27)	0.17
	No. (%)		
Sex			
Male	50 (67.6)	24 (32.4)	<0.001
Female	117(88)	16(12)	
Employment status^			
In paid-employment	122(85.3)	21(14.7)	0.006
Self-employed	8(80)	2(20)	
Unemployed	3(60)	2(40)	
Retired	31(67.4)	15(32.6)	
Student	1(100)	0(0)	
Marital status^			
Married	91 (79.8)	23(20)	0.71
Living with partner	22 (88)	3(12)	
Widowed	5 (71.4)	2(28.6)	
Divorced	12 (85.7)	2(14.3)	
Single	36 (78.3)	10(21.7)	
Highest level of education^			
Primary	6(85.7)	1(14.3)	0.118
O/level/GCSE	29(67.4)	14(32.6)	
A/level	18(85.7)	3(14.3)	
College/University	113(83.7)	22(16.3)	

^Some levels were collapsed to run the chi-square test because of small cell counts (i.e. expected counts were greater than 20%)

Table 3: Reasons for preferring EVAR or open surgery

Reasons for preferring EVAR	Frequency	Reason for preferring Open	Frequency
less invasive	105	One follow-up appointment	23
quicker recovery	96	Surgery feels permanent without any leakage	17
less pain	22	a dislike of the EVAR surgery	4
less time in hospital	18	knowing someone who had undergone open surgery	2
choice of local anaesthetic	12	prefer general anaesthetic	1
yearly follow-up reassuring	10	prefer the longer stay in hospital	1
Previous experience with keyhole surgery	7		
no stay in ICU	4		

Table 4: Quality Adjusted Life Years for EVAR vs open treatment

	n	mean (SD)	median (IQR)	Total
QALY sacrifice for EVAR	122	0.135 (0.104)	0.1 (0.05, 0.2)	16.48
QALY sacrifice for OPEN	18	0.033 (0.017)	0.035 (0.01, 0.05)	0.59

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Ethical approval: The study received ethical approval by the South East Coast - Brighton & Sussex Research Ethics Committee, Health Research Authority (REC Number: 16/LO/0943) on 20.4.2017. An amendment to the interview documents was submitted and approved on 02.05.2017. Each participant provided Verbal consent.

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