



# Warranting the decision-maker, not the decision: How healthcare practitioners evaluate the legitimacy of patients' unprompted requests for risk-reducing mastectomy

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## ABSTRACT

**Objective:** Shared decision-making exists to reconcile healthcare practitioners' responsibilities to respect patients' autonomy whilst ensuring well-made decisions. Patients sometimes make unprompted requests for procedures that carry medical and other risks, such as risk-reducing mastectomy (RRM). Faced with pre-formed decisions into which they have had little input, it is unclear how practitioners can reconcile respecting autonomy with ensuring well-made decisions.

**Methods:** Qualitative study of linked patient–practitioner interviews in a breast unit in North-West England. We examined how 10 practitioners addressed 19 patients' unprompted requests for RRM.

**Results:** Practitioners empathised with patients' distress about cancer risk, regarded RRM as legitimate to help, but were wary of choices made 'emotionally'. Practitioners did not seek to establish whether choices were well-made but, instead, 'warranted' patients by satisfying themselves that patients were 'sensible' and 'informed' decision-makers, and thus their decisions could be trusted. Practitioners provided information, and tested patients' resolve by delaying decisions and presenting 'what if' scenarios depicting failure or harm from RRM.

**Conclusion:** Patients who present emotionally and with resolution can receive RRM without evidence of a well-made decision.

**Practice Implications:** Argumentation theory proposes an ethically robust and clinically practicable approach, whereby practitioners elicit, examine and, where appropriate, challenge arguments underpinning patients' decisions.

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## 1. Introduction

The idea that patients should influence their own care shapes expectations of medical practice [1], expressing a cultural ethic of autonomy and empowering patients to protect their interests against dangers of unfettered medical authority [2]. Shared decision-making (SDM) aims to marry patient participation with practitioners' need to ensure that patient choices are clinically reasonable [3]. As typically portrayed, practitioners present and explain options to patients. Patients develop preferences based on

their values and priorities, and negotiate with practitioners to achieve agreed outcomes [4].

Newer SDM approaches recognise limits on patients' capacity to make independent decisions [5]. Choices are often unfamiliar and technically complex, or made while emotionally distressed. Thus, preferences can be labile, weakly-held, or inconsistent with patients' values. Where patients do not make good decisions through careful integration of reasonable assumptions about relevant potential outcomes, arguably their autonomy is weakened because choices may not be linked to their values and priorities [6–8]. Hence, Cribb and Entwistle [5] claim that clinicians have responsibility to help patients make as good decisions as possible whilst minimising imposition of clinicians' own views.

In a context of medical consumerism [9] and online medical information [10], worried patients sometimes form preferences

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before consulting practitioners, from whom they request specific interventions [11]. This creates a dilemma for practitioners, who have been unable to follow the SDM process of selecting and explaining suitable options. Further, having been excluded from patients' decision-making they are less able to evaluate whether a decision has been well made [12]. Yet, practitioners must decide between moral risks of denying patients' well-chosen requests, and clinical risks of agreeing to interventions that patients have not chosen well.

A clinical problem that focuses this tension arises when women request risk reducing mastectomy (RRM), the irreversible surgical removal of healthy breasts to reduce breast cancer risk. RRM reduces risk of new cancer for most women [13,14], but reduces breast cancer mortality only in those with a high probability of BRCA1/2 gene mutation [15]. RRM is controversial in exposing healthy women to surgical risk and possible adverse effects on self-perceived appearance and sexuality [16]. In one study [17] of women requesting RRM after BC, almost all initiated the request, and almost none considered important factors such as the magnitude of cancer or surgical risk [see also 18,19].

In the present study, our immediate aim was to illuminate the dilemma that patients' unprompted requests for RRM present to practitioners; that is, how to balance respect for patients' requests with the need to ensure that decisions about whether to proceed to surgery are well-considered. Our overall aim was to identify implications for SDM theory.

## 2. Method

### 2.1. Design

We took the approach of Kleinman [20]: that a starting point for researching ethical dilemmas is to understand how actors routinely approach and negotiate them. We therefore interviewed patients and their practitioners about how each approached the decision about RRM and reached the final decision. Using a cross-linked design we could understand the perspective of each party [21]. As our aims were inductive, we used qualitative methods. We interpreted our findings in light of ethical and decision-making theories.

### 2.2. Setting

The study was in a university teaching hospital surgical unit that performs bilateral RRM (BRRM – excision of both breasts) and contralateral RRM (CRRM – removal of the contralateral breast in cancer survivors) and a linked clinical genetics unit. All patients were discussed by a multidisciplinary team including breast nurses, geneticists and surgeons, often after referral to the genetics unit for an opinion. Clinical responsibility for the final decision rested with a surgeon. BRRM and some CRRM candidates were externally referred to the clinic or genetics unit or seen as relatives of existing patients. Other CRRM candidates were BC patients treated by the surgical unit, who had discussed RRM with a practitioner during or after treatment. UK clinical guidance [22] specifies that women may be offered RRM if at high risk of a genetic mutation. There was no other institutional guidance.

### 2.3. Recruitment

Patients were recruited from October 2013 to March 2015. We sampled patients purposively from surgery lists to include BRRM and CRRM patients of varying ages, and CRRM patients with and without BRCA1/2 mutations. We tried to recruit patients who requested, but did not receive, RRM by asking practitioners to recall such consultations during the interview period. Practitioners

recalled none and, in their interviews, recalled few patients ever changing their minds. We interviewed the surgeon involved in RRM decisions for each patient and genetic counsellors (GCs) where appropriate. Two breast care nurses routinely saw all patients on the surgical unit but were without a specific role in patients' decision-making. Hence, they were interviewed once at the end of data collection where they reflected on their practice in general and on specific patients (Table 1).

### 2.4. Procedure

North-West England Research Ethics Service (13/NW/0421) approved the study. Patients participated in face-to-face semi-structured interviews as soon as possible after the consultation in which surgeons agreed to RRM. Interviews were in patients' homes or private spaces in the surgical unit, as each patient preferred. Interviewers had been previously trained in qualitative interviewing and were further trained by the investigators for this project. An interview guide prompted exploration of: how patients arrived at their preference for RRM; what they wanted from consultation; what they understood was the practitioner's role in the consultation; and their perspective on how the decision was reached. The interviewer used open questions, prompts and reflection to achieve a conversational style, probing as appropriate. We previously reported how patients arrived at their preferences [23]. Here we report their accounts of the consultation and decision.

**Table 1**

Patients linked to each practitioner, previous BC and whether genetic mutations have been identified, and practitioners' age, gender and years in practice.

| Patients                          |             |            |               |
|-----------------------------------|-------------|------------|---------------|
| Patient ID (linked practitioners) | Patient Age | Patient BC | Gene mutation |
| P2 (S1, GC3)*                     | 35–40       | No         | No            |
| P3 (S1, GC2)                      | 60–65       | Yes        | Yes           |
| P14 (S1)                          | 46–50       | No         | Yes           |
| P16 (S1)                          | 26–30       | No         | Yes           |
| P19 (S1)                          | 36–40       | Yes        | Yes           |
| P22 (S1, GC4)                     | 60–64       | Yes        | Yes           |
| P1 (S2)                           | 46–50       | Yes        | Yes           |
| P8 (S2)                           | 46–50       | Yes        | Yes           |
| P4 (S3, GC3)                      | 25–30       | Yes        | No            |
| P5 (S3)                           | 46–50       | Yes        | No            |
| P9 (S3)                           | 46–50       | Yes        | No            |
| P10 (S3)                          | 46–50       | Yes        | No            |
| P11 (S1, GC1)                     | 46–50       | Yes        | No            |
| P15 (S3)                          | 41–45       | Yes        | No            |
| P18 (S3)                          | 51–55       | Yes        | No            |
| P7 (S4)                           | 56–60       | Yes        | Yes           |
| P12 (S4)                          | 46–50       | Yes        | No            |
| P27 (S5)                          | 46–50       | No         | Yes           |
| P23 (S1, GC5)                     | 41–45       | Yes        | No            |

  

| Practitioners |                  |                     |                   |
|---------------|------------------|---------------------|-------------------|
| Practitioner  | Practitioner Age | Practitioner Gender | Years in Practice |
| S1            | 51–55            | M                   | 12                |
| S2            | 40–45            | F                   | 8                 |
| S3            | 61–65            | M                   | 20                |
| S4            | 41–45            | F                   | 15                |
| S5            | 51–55            | M                   | 18                |
| GC1           | 46–50            | F                   | 5                 |
| GC2           | 46–50            | F                   | 9                 |
| GC3           | 46–50            | F                   | 11                |
| GC4           | 51–55            | M                   | 25                |
| GC5           | 41–45            | F                   | 12                |
| N1**          | 56–60            | F                   | 30                |
| N2**          | 46–50            | F                   | 7                 |

\* P2 had a familial BC history but gene testing was uninformative. She was considered to have a high-risk of mutation.

\*\* N1 or N2 saw all patients individually, usually before GCs and surgeons.

Practitioners provided one face-to-face semi-structured interview about each of their study patients, in private offices in the clinic as soon as possible after the interview with the relevant patient (breast-care nurses were interviewed once). In the first interview with each practitioner, we explored their general approach to RRM decisions, allowing them to talk freely while seeking to anchor discussion in specific cases and experiences to avoid over-generalized or idealized accounts. An interview guide prompted the interviewer to explore: how practitioners found that RRM arose in consultations; how they responded to patients' requests for RRM and what influenced their response; whether and in what ways they were concerned with, or tried to assess or influence, how patients formed their preferences; and how the final decision was reached. Then, for surgeons and GCs, discussion of specific study patients was informed by the interviewer's preliminary listening to the recording, or reading the transcript, of the patient's account. Practitioners were asked about how they approached the decision, how they understood and responded to the patient's position, and how the final decision was reached. In interviewing practitioners, we protected the confidentiality of what their patients had told us by ensuring that we did not disclose any element of the patient's account. Where necessary, practitioners were interviewed repeatedly as further patients became available.

### 2.5. Data analysis

Analysis drew on a pluralist approach, in which we sought 'methodological integrity' by adopting practices that ensured fidelity to data and utility for the research question [24,25]. To examine the linked accounts of patients and practitioners, we used the method we described previously [21]. Initially, we worked at the level of each case, reading the linked accounts and developing a narrative synthesis of the case. We produced an evolving summary, modified after examining each case sequentially, and referring back as necessary to previously analysed cases, highlighting areas of consistency and inconsistency between and within cases, and elaborating, organizing and linking the emerging analytic categories so that the analysis developed iteratively, following a constant comparative approach [26]. We used Microsoft Word to label and organize text using evolving inductive headings [27].

SB led the analysis, reading all scripts and developing initial analytic categories. The analysis was discussed regularly amongst SB, PSalmon and PSaini, who also read all transcripts, and periodically amongst all authors, who read selected extracts. Analysis started descriptively but became more interpretative as, in analysing participants' statements, we took account of the context provided by the rest of their interview, by the other party's relevant interview, and by the developing analysis. We attended to possible functions of what was said, including the possibility that accounts contained justifications and rationalisations, or forgetting or deliberate deletion of information. We were alert to possible sources of heterogeneity in analysis, particularly between patients who had and had not been diagnosed with BC, and between practitioners with different professional roles and responsibilities. As analysis proceeded, we continually judged it according to consensus validity (through debate, it should satisfy all authors [28]), reflexive validity (it should change authors' initial and subsequent views [28]), catalytic validity (it should have potential practice implications [28,29]), and theoretical validity (it should inform theory [28]). Analysis ended when further discussion and reference to data did not appreciably change it ('theoretical saturation').

Key findings are illustrated by italicised quotes, with ellipses (...) indicating omitted text, and explanatory comments in square brackets. The requested procedure is noted in ellipses after each patient, as is any known BRCA mutation.

## 3. Results

### 3.1. Overview

All patients reported resolutely wanting RRM, whilst practitioners described being cautious because of its severity and questionable clinical benefit for some patients. Patients presented emotive cases for RRM, and practitioners empathised with their distress. However, practitioners faced a paradox; they wanted to ease patients' distress but were concerned about the validity of patients' 'emotional' decision-making. Practitioners' solution was to warrant the *patient* as 'sensible' and 'informed' rather than assessing the merits of the *decision*.

### 3.2. Patients were resolute in wanting RRM, but practitioners were cautious

Patients' accounts were characterised by their resolve for RRM. Before consultation all had decided they wanted RRM, and none described considering a change of mind at any point during the consultation or since. For example, P18 (CRRM) found recovery from mastectomy painful, but her determination to obtain RRM was unaffected: *'I am still as determined, I want it done. I have not changed my decision in any way. Even after the [mastectomy] surgery, I was concerned that it was going to be that horrible that I wouldn't, you know, want to go through that again, but I would rather go through that than chemo and be vomiting.'* Patients described being resolute in consultations with practitioners. P11 (CRRM) described needing to be determined to overcome perceived staff inertia or resistance: *'Yeah, it was always me kind of pushing for things, yeah, because I'm just like that . . . I don't think I would have been offered it at all. I don't think it would have been discussed.'*

By contrast, practitioners explained that RRM is a major procedure with significant risks of harm, which requires careful justification. Several cited clinical guidance [22] that RRM be offered only to women at high genetic risk. Talking about P11, S1 stated: *'it's (RRM) not without its risks, and I think if you are going outside very clear, prescriptive guidelines, those guidelines are there for good reason, at the end of the day, this is healthy tissue you know that is being removed.'*

### 3.3. Practitioners empathised with patients' distress, but were concerned about their 'emotional' decision-making

In interviews, patients explained their pursuit of RRM by describing their worry about future BC. They freely described trying to convey the intensity of these feelings to practitioners when they discussed RRM: *'I think for, for someone who doesn't know what my family history is and, and how much worry I've had throughout my whole life about it . . . Some people I don't really think they understand . . . and it's quite hard trying to explain to someone without being dramatic that, you know, it, it is for a really good reason.'*(P16, BRRM, BRCA+).

In turn, every practitioner empathised with patients' worry as a reason for seeking RRM. For example, N1 described a non-study patient who *'has had a really traumatic time, mother's died when they were quite young, they've been through it all and they would see that breast cancer in any shape or form as being the absolute thing to be avoided at all costs'*. Similarly, S2 described his reaction to P1 who wanted RRM because of her anxiety during appointments for mammography screening; *'I was empathic with her situation, that she was very young, she's got a young family and she did struggle quite significantly with her treatment . . . I think some people, not particularly this patient, find it very difficult to come back from mammograms . . . they worry a lot about having a mammogram and then having biopsies again, and that kind of takes over their ability to have quite a quality of life'*.

**Box 1.** Discrepant cases Two practitioners referred to clinical guidance in rejecting emotionally-motivated requests.

N1 recounted a patient (not in the study) who wanted RRM but did not meet guidance criteria\*, describing the emotional ‘effort’ of resisting the request: *‘We haven’t got a system that allows me to say “OK, that’s fine, I think it’s fine for you to have your breast tissue removed for that level of risk” . . . But emotionally then, you can feel a bit wrung out at the end of a session when somebody’s wanting something desperately and you’re not going to give it to them and you’re trying to say “Well, you know, the chances of you getting breast cancer at this level”, that doesn’t really mean anything when in their head that’s the worst possible outcome’*(N1).

GC3 described reluctance to refer patients to the multi-disciplinary team who did not meet guidance. Nevertheless she differed from N1 in that she made some exceptions, *‘If there are people that are really, really, really struggling, and I think I have only done it a couple of times, I will take their notes and discuss them at the clinic. But I have done that rarely because I think it is just undue pressure [on surgeons to offer RRM].’*(GC3).

\* Clinical guidance (CG164 [22]) in the UK recommends that RRM be offered only to women with high risk of BRCA1/2 mutations. This guidance is less explicit for women who are not high risk of BRCA1/2 mutations.

Although two practitioners consistently rejected requests that lay outside clinical guidance (Box 1), most regarded distress as a reason to agree to RRM, even where guidance criteria were unmet. GC4, for example, was explicit that RRM could resolve patients’ continuing sense of vulnerability after BC: *‘I certainly believe in holistic medicine in terms of, it’s not just a risk, it’s impact, it’s living with it, it’s perception of risk’.*

However, all practitioners mistrusted decisions that they regarded as having been made ‘emotionally’ rather than ‘rationally’. For example, S3 described how personal or family experiences with BC, and their emotional impact, could be more important in patients’ decisions than information from practitioners: *‘It’s [having BC] a very powerful experience . . . It’s more powerful than me saying “The percentage is this, the percentage is that.”’*(S3). S3 continued, explaining that many patients do not decide rationally: *‘I think a lot of the decision-making that goes on is much more emotional than we think. There is this whole thing of, I mean the current paradigm within the NHS, and modern society, is that we have a whole load of logical people, logical, rational, well-informed, intelligent people who make logical, rational, well-informed intelligent decisions. Mostly that’s not true. You know mostly we have a load of scared, worried, ill-informed people who don’t understand the pathology, don’t understand the risks’* (S3).

Similarly, GC3 described her difficulty with women who: ‘are so fixed in their view it is difficult to have a useful conversation with them . . . They are just so fixed that they can’t accept a lot of challenge around that. And I remember one particular patient . . . went for a predictive test solely because she wanted to have risk reducing surgery, no other reason. She wouldn’t really engage too much in the pre-test counselling, she just wanted the test to show she was positive so she could have the risk reducing surgery. And she was always a worry.’(GC3).

### 3.4. How practitioners reconciled empathy for patients’ distress with distrust for ‘emotional’ decision-making: ‘warranting’ the patient

Despite their explicit concerns that the ‘emotional’ nature of patients’ decisions to seek RRM was a reason for not acquiescing, no practitioner identified any study patient as having made an ‘emotional’ decision. Instead they uniformly described their patients as ‘well informed’ and ‘sensible’. Practitioners’ interviews suggested how they moved from general mistrust of patients’ ‘emotional’ decision-making to endorsing specific patients as ‘well informed’ and ‘sensible’. Crucially, they did not examine how patients actually made decisions. Although they routinely asked why patients wanted RRM and checked that patients were aware of the implications for surgical risk and living with a mastectomy, there was no evidence that practitioners probed whether patients had considered the ‘pros’ and ‘cons’ of RRM or whether and how they had weighed these different considerations. S1, indeed, was

explicit that getting involved in P2’s decision-making was not his role: *‘She had already made a decision to have surgery. My role was . . . not to help her make a decision . . . she has come to wanting surgery so I, I don’t think I had any role in initiating or . . . helping her make a decision. But what I think I helped with was a clear understanding of what’s to be expected from the surgery.’*

Instead, practitioners ‘warranted’ patients as capable of making good decisions. Warranting had four elements, the first used by all practitioners, the others used only by surgeons who were responsible for the RRM decision (see Table 2). First, all practitioners ensured that patients had received information about RRM, including associated risks and available alternatives including chemoprevention and monitoring. Second, adopting a term used to describe medical contraindications, surgeons assured themselves that patients did not present ‘red flags’ – mental health or other problems that might compromise their ability to make sensible decisions. Third, surgeons challenged patients to consider ‘what if’ scenarios in which RRM led to adverse outcomes or failed to prevent cancer. Finally, surgeons ‘tested’ patients’ resolve by delaying the RRM decision to ensure that their motivation was not transient.

Patients’ reactions to clinicians’ warranting varied. Some described these strategies appreciatively, as helping them make a ‘more balanced’ (P11, CRRM) decision; *‘It was the right decision for S3 to make me wait, because I think had I have done it first, at the same time, I might have regrets’* (P9, CRRM). Others experienced them as obstructions to be overcome. When asked whether information had been helpful, P4 replied: *‘No, they’re just guessing. “Wait for this, wait for that”. So I put my foot down. “Well I’ve come off the medication now so you’ve got to do it.”’* (P4, CRRM). Similarly P12 (BRRM), having requested RRM immediately after BC diagnosis, described the surgeon’s delay as resistance: *‘[S4] said to me . . . which she then reiterated at my appointment after the surgery, which was that she’d like six months if at all possible between . . . It was like, “Oh shit, it goes on for another six months”. “No” I said, “This is what I want” . . . So I had made it very clear that this was, this was going to happen, and [S4] I think realised how serious that, that it was’.*

## 4. Discussion and conclusion

### 4.1. Discussion

Faced with patients who were distressed and wanted RRM, practitioners generally acceded. However, patients’ distress presented practitioners with a paradox. While regarding RRM as a clinically appropriate way to reduce distress, practitioners were cautious about acceding to decisions that patients had reached ‘emotionally’. In resolving this paradox practitioners were reluctant to evaluate, or intervene in, patients’ decision-making. Instead, they sought to ‘warrant’ the decision-maker as being

**Table 2**  
Practitioners' Strategies for 'Warranting' Patients as 'Informed' and 'Sensible' Decision-Makers.

| Strategy              | Description   | Illustrative quotation  |
|-----------------------|---|---|
| Information Provision | Practitioners gave patients necessary information, tailored to what they saw as common misconceptions about RRM.  | <i>'I emphasise, double-emphasise, and they understand the surgery is risk reduction, not risk elimination, because some people think "Oh, if I have this mastectomy that's the end of the story, I'll never have breast cancer". That is not true . . . I go over the concept of risk reduction in detail and make sure they understand that it's risk reduction and won't be disappointed in the future.'</i> (S1). |
| 'Red Flags'           | Alertness to patients wanting RRM for reasons other than risk reduction, such as breast enhancement, or problems including body dysmorphia or factitious disorders. | <i>'A patient who has come with lots of surgery for lumps and bumps, and all the histology that we reviewed was all benign but they were requesting bilateral prophylactic mastectomies. And no, I didn't think that sounded right either, because they had around eight [biopsy] surgeries and none of those were atypia, so you do wonder about something else going on in the background'</i> (S4).                |
| Adverse Scenarios     | Presenting 'worst-case' outcomes of RRM, such as where metastatic cancer may occur after RRM.   | <i>'Breast cancer is sneaky, it can come back ten/twenty years somewhere else, after your original surgery, and how would you feel, and I do put it quite specific, how would you feel if you have this surgery . . . I usually say if you are having a reconstruction it is three months recovery afterwards, how would they feel if, after all of that, they got a recurrence somewhere else?'</i> (S4).            |
| Slowing the Decision  | Surgeons postponed the decision to allow patients time to reconsider, particularly when patients asked surgeons for BRRM immediately after BC diagnosis             | <i>'We try and stall them. Not stop them, just stall them.'</i> (S4).<br><i>She was convinced of what she wanted to do. I delayed that for her. She would have . . . well her express wish was to do it, remove both breasts at the same time. So I delayed that and essentially stuck to our protocol.'</i> (S3 responding to P11's request for BRRM directly after diagnosis).                                      |

'well-informed' and 'sensible'. Studies in other clinical areas show that practitioners are concerned about whether patients can be trusted to undertake complex decisions [30], but this is the first to our knowledge that describes, and evaluates ethical and clinical implications of, strategies practitioners use to establish trust in patients' decisions.

The defining elements of the paradox that practitioners faced are grounded in broader ethical aspects of clinical practice. First, RRM can reduce patients' distress and fear of cancer [31], whereas there is little evidence that alternative risk-reduction procedures can. Practitioners therefore saw a case for using surgery for psychological benefits that probably could not be realized more conservatively. Ethical arguments in favour of surgery for psychological reasons have also been made in clinical areas including bariatric and cosmetic surgery [32,33]. Second, practitioners' mistrust of emotional decision-making reflects a broader cultural and clinical emphasis on patients making informed and well-thought out decisions about their care [5,8,12].

Guidance about practitioners' role in patients' decision-making offers little help in resolving the paradox they faced. Practitioners in this study satisfied guidance to ensure that patients had the information they needed, and considered options and their consequences [12]. However, SDM literature does not yet provide explicit guidance about how patients should consider and balance these options and consequences [8]. That is, SDM regards decision-making as a 'black box', to be managed and evaluated with reference to the inputs, such as practitioners' explanation of patients' options, and is less concerned with what happens inside the box.

In our study, practitioners also seemed to regard patients' decision-making as a black box inasmuch as they did not scrutinize patients' decision-making. Instead, they warranted patients as 'well-informed' and 'sensible' decision-makers. Whilst resolving the paradox for practitioners, warranting patients potentially introduces inequity. In particular, warranting favours patients who communicate distress most compellingly and consistently [17]. These might include the very patients that practitioners were concerned were making emotional decisions. Moreover, patients who are sufficiently determined to withstand practitioners' warranting strategies, and in whom fears or hopes overwhelm consideration of evidence might well be making decisions that disregard information they have received. Therefore, if practitioners rely solely on warranting patients, this would be hard to defend ethically.

#### 4.2. Practice implications

Recent introduction of argumentation theory into SDM offers an alternative solution to practitioners' dilemmas [34]. Argumentation theory describes the ethical responsibility for practitioners and patients to provide clear arguments for their preferences, and to elicit and take account of the reasons for the other party's views. In other words, practitioners are expected to respect but also critically evaluate patients' decisions. Importantly, evidence from trials recruitment shows that practitioners' skilful exploration of patients' preferences can elicit, and help patients to clarify, their arguments and expose the logic of their positions [35]. Conversely, evidence from primary care shows that patients are more likely to consider the views of practitioners who provide evidence-based and logical arguments for their own positions [36]. Use of argumentation is consistent with recent bioethics literature that argues that practitioners sometimes need to be active in helping patients make better decisions [5,8]. In RRM, an argumentation approach could start with practitioners asking patients to explain how they developed their preferences, allowing practitioners to judge the evidence-base and logic of patients' reasoning, and to challenge this with counter-arguments if necessary.

Whether an argumentation approach could lead some patients to change their minds, particularly those whose decisions were based on emotion or misapprehensions or were poorly reasoned is for future work to discover. Practitioners might, however, change their own decisions. They might, for example, reverse an initial decision to accede to RRM where they expose patients' unrealistic arguments. Even where decisions are unchanged, they would arguably be more defensible ethically inasmuch as patients would have understood and reviewed available options, and patients and practitioners would have each made their arguments explicit.

Although practitioners' reliance on warranting patients seems generally to deliver patients the surgery that they seek, it is questionable to regard this as protecting patients' autonomy. The corollary of practitioners' reliance on warranting is that patients obtain surgery by presenting emotional distress and by withstanding practitioners' 'tests', yet they might not have seriously considered the consequences or alternatives. Recent ideas of relational autonomy recognize that patients' choices are inherently constrained by context and that autonomy lies, not in the frequently unrealistic ethic of self-determination, but in interpersonal relationships, particularly with practitioners, which support patients and help them develop capacity to participate in decisions

[21]. From this perspective, an argumentation approach is a practicable way to protect and enhance patient autonomy in decisions, such as those about RRM, where patients seek interventions that have uncertain benefits or serious risks.

#### 4.3. Limitations

Although there were no institutional constraints on practitioners' decision-making, the study surgical and clinical genetics units shared a practice culture, and the ways in which practitioners approached RRM might not apply elsewhere. As we were unable to predict patients' requests for RRM, we could not obtain transcripts of consultations in which RRM was discussed, and therefore do not definitively know what was said. Our findings are thus reliant on retrospective accounts. It is possible, for example, that clinicians might have discussed patients' preferences in greater depth than interview responses indicated. Some patients who request RRM might change their minds. However, we could not identify such patients during the study period and thus could not study how views about RRM might change.

#### 4.4. Conclusion

Although from the UK health-care system, our findings are potentially relevant to any system where practitioners have responsibility for decisions about invasive treatments, such as RRM, that patients request. Indeed, they may be particularly relevant for more consumer-focussed health-care systems. Current conceptualisations of SDM do not describe how practitioners and patients should come to shared decisions that balance patients' wishes for such procedures with ensuring that their preferences are evidence-based and well-reasoned. By obliging both patients and practitioners to describe reasoning underlying their preferences, an argumentation approach to SDM would open the 'black box' of individuals' preference formation and allow practitioners and patients to 'share' clinical decisions in ways that protect and extend patient autonomy whilst ensuring that decisions are well-made.

#### Competing interests

The authors have no competing interests to declare.

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#### References

- [1] R.M. Veatch, Models for ethical medicine in a revolutionary age. What physician-patient roles foster the most ethical relationship? *Hastings Cent. Rep.* 2 (1972) 5–7.
- [2] G. Elwyn, A. Lloyd, C. May, T. van der Weijen, A. Stiggelbout, A. Edwards, et al., Collaborative deliberation: a model for patient care, *Patient Educ. Couns.* 97 (2014) 158–164, doi:<http://dx.doi.org/10.1016/j.pec.2014.07.027>.
- [3] G. Makoul, M.L. Clayman, An integrative model of shared decision making in medical encounters, *Pat. Educ. Couns.* 60 (2006) 301–312.
- [4] L. Sandman, C. Munthe, Shared decision-making and patient autonomy, *Theor. Med. Bioeth.* 30 (2009) 289–310.
- [5] A. Cribb, V.A. Entwistle, Shared decision-making: trade-offs between narrower and broader conceptions, *Health Expect.* 14 (2011) 210–219.
- [6] P. Gulbrandsen, M.L. Clayman, M.C. Beach, P.K. Han, E.F. Boss, E.H. Ofstad, G. Elwyn, Shared decision-making as an existential journey: aiming for restored autonomous capacity, *Pat. Educ. Couns.* 99 (2016) 1505–1510.
- [7] V.A. Entwistle, A. Cribb, I.S. Watt, Shared decision-making: Enhancing the clinical relevance, *J. Res. Soc. Med.* 105 (2012) 416–421.
- [8] S.L. Brown, P. Salmon, Bridging ethical theory with clinical reality: a matched intervention approach to shared decision-making in cancer, *Health Expect.* (2018), doi:<http://dx.doi.org/10.1111/hex.12853> (in press).
- [9] K. Rowe, K. Moodley, Patients as consumers of health care in South Africa: the ethical and legal implications, *BMC Med. Ethics* 14 (14:15) (2013).
- [10] Tan SS-L, N. Goonawardene, Internet health information seeking and the patient-physician relationship: a systematic review, *J. Med. Internet Res.* 19 (2017) e1.
- [11] J. Cardasis, D. Brush, Responding to patient requests for nonindicated care, *Virt. Ment.: Am. Med. Assoc. J. Ethics* 13 (2011) 16–20.
- [12] G. Elwyn, T. Miron-Schatz, Deliberation before determination: the definition of good decision-making, *Health Expect.* 13 (2009) 139–147.
- [13] L.C. Hartmann, D. Schaid, J.E. Woods, T.P. Crotty, J.L. Myers, et al., Efficacy of bilateral prophylactic mastectomy in women with a family history of breast cancer, *New Engl. J. Med.* 340 (2013) 77–84.
- [14] S.K. McDonnell, D. Schaid, J.L. Myers, C.S. Grant, J.H. Donohue, et al., Efficacy of contralateral prophylactic mastectomy in women with a family history of breast cancer, *J. Clin. Oncol.* 19 (2001) 3938–3943.
- [15] L. Lostumbo, N.E. Carbine, J. Wallace, J. Ezzo, K. Dickersin, Prophylactic mastectomy for the prevention of breast cancer, *Cochrane Database Syst. Rev.* 4 (2004), doi:<http://dx.doi.org/10.1002/14651858.CD002748.pub2> Art.No.: CD002748.
- [16] M.H. Frost, J.M. Slezak, N.V. Tran, et al., Satisfaction after prophylactic mastectomy: the significance of mastectomy type, reconstructive complications, and body appearance, *J. Clin. Oncol.* 23 (2005) 7849–7856, doi:<http://dx.doi.org/10.1200/JCO.2005.09.233>.
- [17] H. Beesley, C. Holcombe, S.L. Brown, P. Salmon, Risk, worry and cosmesis in decision-making for contralateral risk-reducing mastectomy: analysis of 60 consecutive cases in a specialist breast unit, *Breast* 22 (2013) 179–184.
- [18] H.G. Fielden, S.L. Brown, P. Saini, H. Beesley, P. Salmon, How do women at increased risk of breast cancer perceive risks of cancer and of risk-reducing treatments and decide between them? A narrative synthesis of qualitative research, *Psycho-Oncol.* (2017), doi:<http://dx.doi.org/10.1002/pon.4349>.
- [19] L. Heiniger, P.N. Butow, M. Charles, k ConFab Psychosocial Group, M.A. Price, Intuition versus cognition: A qualitative explanation of how women understand and manage increased breast cancer risk, *J. Behav. Med.* 8 (2015) 727–739, doi:<http://dx.doi.org/10.1007/s10865-015-9632-7>.
- [20] A. Kleinman, Moral experience and ethical reflection: can ethnography reconcile them? A quandary for 'the new bioethics', *Daedalus* 128 (1999) 69–97.
- [21] N. Mendick, B. Young, C. Holcombe, P. Salmon, The ethics of responsibility and ownership in decision-making for treatment of breast cancer: triangulation of consultation with patient and surgeon perspectives, *Soc. Sci. Med.* 17 (2010) 1904–1911.
- [22] NICE, Classification and Care of People at Risk of Familial Breast Cancer and Management of Breast Cancer and Related Risks in People with a Family History of Breast Cancer (CG164), National Institute of Clinical Excellence, 2013.
- [23] S.L. Brown, D. Whiting, H.G. Fielden, P. Saini, H. Beesley, C. Holcombe, S. Holcombe, L. Greenhalgh, L. Fairburn, P. Salmon, Qualitative analysis of how patients decide that they want risk-reducing mastectomy, and the implications for surgeons in responding to emotionally-motivated patient requests, *PLoS One* (2017), doi:<http://dx.doi.org/10.1371/journal.pone.0178392> e0178392.
- [24] P. Salmon, B. Young, Qualitative methods can test and challenge what we think we know about clinical communication - if they are not too constrained by methodological 'brands', *Patient Educ. Couns.* 101 (2018) 1515–1517.
- [25] H.M. Levitt, S.L. Motulsky, F.J. Wertz, S.L. Morrow, J.G. Ponterotto, Recommendations for designing and reviewing qualitative research in psychology: promoting methodological integrity, *Qual. Psychol.* 4 (2017) 2–22, doi:<http://dx.doi.org/10.1037/qup0000082>.
- [26] S. Fram, The constant comparative analysis method outside of grounded theory, *Qual. Rep.* 18 (2013) 1–25.
- [27] N. Pelle, Simplifying qualitative data analysis using general purpose software tools, *Field methods* 16 (2004) 85–108.
- [28] W.B. Stiles, Evaluating qualitative research, *Evid. Ment. Health* 2 (1999) 99–101.
- [29] J. Kincheloe, P. McLaren, *Rethinking Critical Theory and Qualitative Research*, 2nd ed., Sage, London, 2000.
- [30] M. Arribas-Ayllon, S. Sarangi, Counselling uncertainty: genetics professionals' accounts of (non) directiveness and trust/mistrust, *Health Risk Soc.* 16 (2014) 171–184.
- [31] L. Heiniger, P.N. Butow, J. Coll, T. Bullen, J. Wilson, B. Baylock, B. Meisner, M.A. Price, Long-term outcomes of risk-reducing surgery in unaffected women at increased familial risk of breast and/or ovarian cancer, *Fam. Cancer* 14 (2015) 105–115.
- [32] J.A.M. de Roubaix, Benificence, non-maleficence, distributive justice and respect for patient autonomy - reconcilable ends in aesthetic surgery? *J. Plast. Reconstr. Aesthet. Surg.* 64 (2011) 11–16.
- [33] K. Persson, Why bariatric surgery should be given high priority: an argument from law and morality, *Health Care Anal.* 22 (2014) 305–324.
- [34] N. Labrie, P.J. Schulz, Does argumentation matter? A systematic literature review on the role of argumentation in doctor-patient communication, *Health Commun.* 29 (2014) 996–1008.
- [35] N. Mills, J.M. Blazeby, F.C. Hamdy, D.E. Neal, B. Campbell, C. Wilson, S. Paramasivan, J.L. Donovan, Exploring treatment preferences facilitated recruitment to randomized controlled trials, *Trials* 64 (2011) 1127–1136.
- [36] N. Labrie, P. Schulz, Exploring the relationships between participatory decision-making, visit duration, and general practitioners provision of argument to support their medical advice, *Pat. Educ. Couns.* 98 (2015) 572–577.