

# BMJ Open Communicating risk in active surveillance of localised prostate cancer: a protocol for a qualitative study

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**To cite:** Rapport F, Hogden A, Gurney H, *et al.* Communicating risk in active surveillance of localised prostate cancer: a protocol for a qualitative study. *BMJ Open* 2017;**7**:e017372. doi:10.1136/bmjopen-2017-017372

► Prepublication history for this paper is available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2017-017372>).

Received 19 April 2017

Revised 2 August 2017

Accepted 13 September 2017



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## ABSTRACT

**Introduction** One in five men is likely to receive a diagnosis of prostate cancer (PCa) by the age of 85 years. Men diagnosed with low-risk PCa may be eligible for active surveillance (AS) to monitor their cancer to ensure that any changes are discovered and responded to in a timely way. Communication of risk in this context is more complicated than determining a numerical probability of risk, as patients wish to understand the implications of risk on their lives in concrete terms. Our study will examine how risk for PCa is perceived, experienced and communicated by patients using AS with their health professionals, and the implications for treatment and care.

**Methods and analysis** This is a proof of concept study, testing out a multimethod, qualitative approach to data collection in the context of PCa for the first time in Australia. It is being conducted from November 2016 to December 2017 in an Australian university hospital urology clinic. Participants are 10 men with a diagnosis of localised PCa, who are using an AS protocol, and 5 health professionals who work with this patient group (eg, urologists and Pca nurses). Data will be collected using observations of patient consultations with health professionals, patient questionnaires and interviews, and interviews with healthcare professionals. Analysis will be conducted in two stages. First, observational data from consultations will be analysed thematically to encapsulate various dimensions of risk classification and consultation dialogue. Second, interview data will be coded to derive meaning in text and analysed thematically. Overarching themes will represent patient and health professional perspectives of risk communication.

**Ethics and dissemination** Ethical approval for the study has been granted by Macquarie University Human Research Ethics Committee, approval 5201600638. Knowledge translation will be achieved through publications, reports and conference presentations to patients, families, clinicians and researchers.

## INTRODUCTION

Prostate cancer (PCa) is the fourth leading cause of death among Australian men<sup>1</sup> and is the most commonly diagnosed cancer for men in North America and Europe. Age-adjusted incidence rates are 85.6 per 100 000 for North America and 59.3 per 100 000 for Europe,<sup>2</sup> while in Australia, an estimated

## Strengths and limitations of this study

- As a proof of concept study, the small sample size and single setting limit the scope of the findings. Even so, this allows richer data and more detailed accounts than would be possible were this a larger, more widespread study.
- Information gathered from this study could closely inform the eventual development of patient-centric risk assessment procedures, for national and international application.

18138 new cases were diagnosed in 2016.<sup>3</sup> Risk of developing PCa is strongly associated with age, with one in five men likely to receive a diagnosis by the age of 85 years.<sup>1,4</sup>

Some localised cancers have a very low risk of metastasising, especially those of low histological grade and of low volume, and are unlikely to cause death.<sup>5</sup> The more aggressive form of PCa, if untreated, can metastasise to bone, lymph nodes and other organs, causing substantial morbidity and eventual death.<sup>6</sup> Low-risk cancers are thought to be genetically distinct from the more aggressive forms and, if diagnosed accurately, do not require treatment, and these men are typically eligible for active surveillance (AS).<sup>7</sup> AS fundamentally involves patients and clinicians making judgements about the balance of risks of PCa against the risks of definitive treatment, in addition to the disadvantages and risks implicated in the surveillance process, which can involve invasive and discomforting biopsies, ultrasounds and multiparametric MRI scans.<sup>8,9</sup>

AS is used instead of active treatments such as radiotherapy and prostatectomy and involves regular monitoring for possible progression.<sup>10</sup> The purpose of AS is multifarious, including to help mitigate the uncertainty arising from the imaging and prostate tissue biopsy absolutely classifying cancer as low risk,<sup>8</sup> while offering patients a choice of

avoiding radical treatments (and their side effects) and enabling timely curative treatments if cancer progression is indicated. Prostate biopsy is usually a random sampling of the gland, and high-grade cancers may be missed. Multiparametric MRI scans may not visualise up to 15% of high-grade cancers.<sup>11</sup> This means that a proportion of men with apparent low-risk cancer have undetected high-risk disease which may be identified on the AS protocol so that potentially curative therapy can be instigated. Curative therapy, which may include surgery, radiation therapy and hormonal therapy, can have serious side effects on patients' bladder and bowel continence, erectile function, fertility and hormone balance,<sup>12 13</sup> requiring a range of health services to manage these acquired complications. Life-saving measures present men and their families with the dilemma of how to manage the effects of treatment on their lifestyle and well-being.

Men undertaking AS generally have good quality of life<sup>14</sup> and comparable or lower levels of distress than those who undertake treatment.<sup>15</sup> However, many men decide against AS, even when medically appropriate.<sup>16</sup> In addition, between 13% and 50% of patients with AS go on to a curative treatment programme in the absence of an objective increased risk,<sup>17 18</sup> as a result of raised anxiety about cancer.<sup>18–20</sup>

The risk assessment procedures of AS include prostate-specific antigen (PSA) blood tests approximately every 3 months, digital rectal examinations (DREs) every 6 months, 12 monthly MRI scans and repeat biopsies every 2–3 years or earlier if indicated by an abnormally elevated PSA level.<sup>21 22</sup> There are still uncertainties regarding the scheduling of these tests and the extent to which each of the results predicts progression,<sup>21 23 24</sup> and this may affect the uptake of AS.<sup>10</sup> Research suggests that the probability of men on AS remaining progression-free at 2, 5 and 10 years is relatively high (91%, 76% and 70% respectively).<sup>25 26</sup> In addition, recent research indicates that patients classified with an intermediate risk of progression have similar levels of survival and progression as men at low risk, and thus AS is increasingly being offered to these men as well, as an alternative option to other action.<sup>27 28</sup>

### Risk communication in AS

Risk has been defined as the probability of a particular event happening,<sup>29</sup> such as risk of PCa metastasising. Risk is typically expressed numerically,<sup>30</sup> such as the percentage of patients who will get side effects from curative treatments, the probability of PCa progression or death at 10 years for those currently on AS. However, perceptions and understandings of certainties and uncertainties around such an event are highly individualised, influenced not only by controllability of clinical outcomes but also by gender issues and social factors.<sup>31</sup> Consequently, we aim to identify definitions of risk, from men's own experiences of AS, rather than from a predetermined or clinically driven assumption of what risk means for those being assessed for AS and those undertaking the treatment.

Monitoring procedures in AS, including DRE and PSA testing,<sup>12</sup> are invasive and potentially embarrassing for patients.<sup>32</sup> Despite this, test results that show no change in health status and that are given during AS consultations with healthcare professionals can be reassuring for men. In effect, as past research in oncology demonstrates, communication of risk is more complicated than just a numerical probability of risk, with patients wanting to know about what is a difficult issue to discuss: the implications of risk on their lives and mortality in concrete terms.<sup>33</sup> Interview studies exploring more general issues in AS suggest that communication is not always effective: patients report uncertainty regarding the meaning of their diagnosis, conflicting information about treatments and AS, and there is difficulty in understanding information provided by clinicians.<sup>34 35</sup>

Together these findings suggest that patients' individual perceptions of risk are also shaped by the conversations that takes place with clinicians during consultations and are influenced both by what people bring to the consultation and by what influences them during the consultation, which is highly dependent on the conversations that ensue, all of which affects psychosocial well-being and commitment to AS. Research is required to determine whether this is indeed the case. Given the intersubjective nature of risk communication, we need to explore both patients' and clinicians' perceptions of risk and priorities about risk communication in AS, as well as the form discussions of risk take during consultations (eg, formal risk assessment and informal conversation). Furthermore, given the potentially protracted nature of both AS and PCa, patients' needs for information about risks may change as their prioritisation of certain risks (such as infection through repeat biopsies and interruptions to everyday life) over other risks (for instance, death through PCa progression and side effects of other treatments) changes.

### Study objectives

The primary objective of the study is to examine how risk for PCa is perceived, experienced and communicated in the context of AS, and what implications this has for treatment and care. From this, our secondary objectives are as follows:

1. to clarify how patients and their healthcare professionals define risk, experience risk and prioritise the risks involved in AS for PCa;
2. to reveal the form that discussions take and the differences between patients' and clinicians' views;
3. to disclose the impact of discussions of risk assessment results and their effect on the consultative process;
4. to assess patients' needs for further information, further discussions of risk and ongoing clinical support;
5. to identify optimal strategies for clinicians to communicate risk more clearly in line with patients' needs and expectations.

## METHODS AND ANALYSIS

### Study design

This is a multiperspectival, multimethod, qualitative proof of concept study undertaken at a single site in Australia to test out the use and value of mixed qualitative data collection and analysis methods in this context. Data will be collected using observations, patient questionnaires and interviews, and interviews with healthcare professionals will also be undertaken.<sup>36</sup> Principles of applied thematic analysis<sup>37</sup> will form the theoretical underpinnings of the analysis work. An applied thematic analysis of interview transcripts, informed and enriched by notes taken during observed consultations, lends itself to the proposition that in order to understand the world, one must answer research problems practically, from the ground up, and from a 'real world' perspective.<sup>37</sup> With these principles in mind, data will be gathered in situ, and knowledge will be built over time, as textual data are thematically analysed. In this study, observational note taking will complement in-depth, semistructured interviews, with clinicians and patients, and both data sets will be considered corroboratively so that notes from observations add detail and nuance to understandings of how consultations are conducted. This will be embellished by clinicians' and patients' interview question responses. As a clearer picture of the topic area is revealed, through textual evidence, theory development will be enabled. As in the Grounded Theory approach, in applied thematic analysis, theory is inductively derived as data are gathered, and it is only realised once a full data set is complete, when categories and concepts within texts can be identified and examined. Once complete, these can then be linked in to formal theoretical models.<sup>38</sup>

### Sample and setting

#### Setting

The university hospital urology clinic where this study will take place is one of only 26 in Australia with a dedicated Prostate Cancer Specialist Nurse, who is the single point of contact for patients and their families throughout their PCa management and treatment. Consultations for localised PCa at the university hospital urology clinic with a urologist or specialist nurse involve clinician–patient discussions about initial tests (eg, confirmatory biopsies), cancer diagnosis and prognosis, test results and AS and other treatment options. Hence, the clinic has been chosen as the study setting in view of its identification as an important consultation environment in which risk and AS may be communicated with a range of healthcare professionals and treatments negotiated through multiple consultations between patients and health professionals. This creates a useful setting to study experiences of, and communications about, risk in AS for PCa.

#### Participants

A minimum of 10 patients, recently diagnosed with PCa and/or undertaking an AS protocol through a university hospital urology clinic, will be recruited. We anticipate

that the sample size in this proof of concept study will result in saturation, based on our previous work in breast cancer.<sup>29</sup> Patients will be sampled based on their meeting the study inclusion criteria: (a) men over the age of 18 years, (b) diagnosed with localised PCa (c) considered a candidate for AS or (d) already on an AS protocol. Medical criteria for inclusion are based on the D'Amico and Smith<sup>39</sup> classification system: Gleason sum six or less (Gleason 3+3=6, or Gleason 3+4=7 if low volume on biopsies (one positive biopsy)); PSA 10mg/mL or less; and T1c-T2a disease (T1c (impalpable) or T2a (unilateral palpable)). In addition, inclusion may also be defined by volume of cancer on biopsy.

Exclusion criteria include (a) men under the age of 18 years, (b) men who the dedicated clinician or members of the clinical team deem unsuitable for participation due to physical, cognitive or emotional risk, or as a result of communication barriers, and (c) non-English speakers. Additionally, a sample of five healthcare professionals from the multidisciplinary PCa team, including urologists, surgeons and the Pca Specialist Nurse, will be recruited.

#### Recruitment procedure

The study is being conducted from November 2016 to December 2017. During the recruitment period, patients who are due to come in for a consultation at the clinic, and who meet the study inclusion criteria, will be contacted. Eligible participants will be identified by the urologists and the Prostate Cancer Specialist Nurse during urology clinic sessions. A researcher attending the clinic will then approach the patient to ascertain their interest in participation. Those willing to be involved will sign a consent form agreeing to have their next consultation observed and to take part in an interview with a researcher from the study team. The first 10 patients who meet the study inclusion criteria and who consent to participate during the agreed time frame will form the patient cohort.

Health professional recruitment will be achieved using purposive sampling. Five members of the multidisciplinary team will be approached to take part in interviews, with emphasis on gathering a diverse range of professional opinions and a cross section of professional views from those most likely to work with patients with AS.

#### Data collection

Data will be collected using four methods: observations of consultations for localised PCa, between male patients eligible for, or currently on, an AS protocol; a patient survey; patient interviews; and healthcare professional interviews (table 1).

#### Observations of consultations

The first stage of data collection will involve observations of 10 PCa consultation sessions. Observational method is a qualitative research technique that allows an independent observer to document an event in its natural setting.<sup>40</sup> They are useful methods to employ in health services research because they allow in-depth examinations to

**Table 1** Study objectives and associated data collection methods

Study objective	Data collection methods
1 Clarify how patients and their multidisciplinary teams define risk, experience risk and prioritise the risks involved in AS for PCa	Observation of consultation Patient questionnaire Patient interview Healthcare professional interview
2 Reveal the form that discussions take and differences between patients' and clinicians' views.	Observation of consultation Patient interview Healthcare professional interview
3 Disclose the impact of discussions of risk assessment results and their effect on the consultative process	Observation of consultation Patient interview
4 Assess patients' needs for further information, further discussions of risk and ongoing clinical support	Patient questionnaire Patient interview
5 Identify optimal strategies for urologists to communicate risk more clearly in line with patients' needs and expectations.	Observation of consultation Patient interview Healthcare professional interview

AS, active surveillance; PCa, prostate cancer.

take place of what people (eg, patients and clinicians) actually do, rather than just what they say they do. Observation will enable the study team to explore communication in PCa consultations in detail, as they take place, and in the natural practice setting. We will base our observations on the premise that one must examine both the depicted context and the content of an encounter at one and the same time—what van Manen<sup>13</sup> describes as a mixture of the semantic and mantic stimuli.<sup>41</sup> Thus, we will consider the setting within which the consultations take place (including the rooms used, how clinicians and patients face one another, what events unfold and how frequently), the spoken word (such as the emphasis given to certain phrases, the topics discussed and authorial presence) and the non-verbal cues (such as gestures and body language, and emotions as expressed).<sup>42</sup>

Audio recordings will provide a detailed record of the consultation, and field notes will be used to document the visual elements. Observed consultations will be undertaken with a named study researcher present. With consent, the researcher will audio-record the consultation. An observation checklist will be used to document discussions of treatment options, risk classification and assessment procedures and plans for future treatment and care. The timing of discussion topics, in the context of the patient's journey through the system, will be noted, alongside the language used to convey risk (eg, probabilities and jargon) and who (patient or healthcare professional) brings up issues related to risk. Interactions that reflect or contradict the notion of shared decision-making procedures and negotiated care<sup>43</sup> will also be identified. Finally, the researcher will note body language and non-verbal exchanges between the patient and the healthcare professional.

Patient questionnaire

Before commencing patient interviews, patient participants will complete a short, written questionnaire to

provide the team with demographic details and a background of their clinical history. These details will assist with contextualising their interview accounts.

Patient interviews

Following observed consultations, interviews with patients will be conducted. Interview questions will be semistructured to provide further information on what risk means to patients, and perceptions of risk communication, from the perspectives of the study participants (table 2). Risk may include risk of cancer with and without active treatment as well as the risk of different kinds of side effects (physical and emotional) from different types of treatments, including AS. Moreover, there are at least two different components of each of these risks: likelihood perceptions and severity perceptions. Interview questions will allow for expansion on any themes that arise. To explore the topics, in-depth interviews are expected to take between 30 and 40 min. Interview data will help to contextualise the observation findings, clarify any inconsistencies or misunderstandings that were identified and further develop our understanding of patients' and health professionals' perceptions and experiences of risk in PCa.

Interviews will be conducted face-to-face or by telephone at the participant's convenience. A patient interview schedule will cover perceptions of risk and risk status, experiences of formal and informal risk assessment and patients' priorities regarding the different risks involved in PCa. It will also ensure that patients' perceptions and expectations of AS and other PCa treatments, decision making around treatment and the trajectory of patient experience—from diagnosis through consultation for PCa—are aired. Finally, patients will be asked about the current sources of information they access for details about their risk in PCa, expectations and preferences for information in the future and their general aspirations for future health and well-being in the context of PCa.



**Table 2** Patient interview schedule

Topics		Exemplar questions
1	Experiences of information about risk in the oncology consultation	Can you tell me a bit about your experience of being diagnosed with prostate cancer? How did you come to understand what that meant?
2	Personal definitions of risk in the context of prostate cancer and active surveillance	What do you consider to be a risk in prostate cancer? Why?
3	Priorities regarding risks in prostate cancer and active surveillance	What are you most concerned about with your diagnosis of prostate cancer?
4	Whether priorities regarding risk in prostate cancer and active surveillance have changed.	Have your concerns changed since you were initially diagnosed?
5	The extent they consider these priorities as taken into account by health professionals	How have your doctor and other health professionals responded to your concerns?
6	Views and experiences on risk assessment and their risk classification	Have you undergone a formal risk assessment for your prostate cancer? If so, what was that like? What is your risk classification?  If not, has your doctor provided you details regarding your risk in prostate cancer? Have they talked about prognosis?  Can you tell me about your experience of prostate cancer testings? How have you found receiving the results of these tests?
7	Perceptions and expectations of active surveillance	What do you know about active surveillance?
8	How active surveillance has been discussed with health professionals	What has your doctor told you about active surveillance? How useful has this information been?
9	Treatment decisions, how they are made and by whom, how care is negotiated with healthcare professionals.	What about discussing other treatments with your doctor?
10	Their experiences of discussing risk in clinical consultations for prostate cancer	Can you tell me about your experience of talking to your doctors about your diagnosis and what it means?
11	Patients' aspirations for future health and well-being	What are your hopes for your treatment?

### Health professional interviews

An interview schedule for healthcare professionals will comprise views and expectations for risk communication and risk assessment, whether and how risk communication procedures change depending on the patient case, advice-giving style and approach to negotiated care. Healthcare professionals will be asked to reflect on perceived patient need and their personal preference regarding AS and other treatments for PCa.

### Data analysis

Analysis of observational and interview data will be conducted in two stages. In line with applied thematic analysis, we intend to use a 'bottom-up' approach to both the observational and interview data, with conclusions derived from these data sets, and new insights emerging as time progresses. Once no new insights are forthcoming, the applied thematic analysis framework is said to have reached a point of saturation, with no new categories emergent.<sup>44</sup>

### Stage 1: observational data

Observational data analysis will commence as data are collected and continue as additional data come on board in order to build a detailed understanding of each consultation. In documenting observations, the researcher will act as the 'research instrument', recording precisely what happens and also 'personal reactions to events, and changes in his or her views over time' (p184).<sup>40</sup> These will be considered researchers' field notes, forming the basis of a system for classifying clinical interactions. By using this staged data capture method, the classification system can be refined as additional data are collected, with attention focusing on any dissenting AS cases and perceived misunderstanding within the consultation. Such inconsistencies will be explored during interviews, and discussions will pay attention to differences in patient and professional understanding of events.

Audio recordings of observed consultations will be listened to in detail by a primary analyst, with a subsample of recordings also listened to by a secondary analyst to verify the analysis process. Notes from this work will be

used as part of feedback discussions between analysts and will assist in the development of the preliminary classification approach. These classifications are expected to include the type of consultation (eg, AS monitoring procedures, results given and treatments discussed); when and how risk is raised, and by whom, the terminology used to convey risk (eg, probabilities, jargon, personal or impersonal and clinical); emotional dimensions of risk; whether and how decisions about risk management are made; and if decisions are shared with patients.

### Stage 2: patient and healthcare professional interview data

Audio recordings of the patient and healthcare professional interviews will be transcribed by the study team. The preliminary classification developed through the collection of observation findings will be applied to the interview data. Further refinements of the classification will lead to the development of a final coding framework, agreed on by primary and secondary analysts through teamwork meetings, and discussed with wider study members through a study team workshop. The coding framework, once agreed through consensus, will be used to organise interview and observational data according to key themes arising in the data.

Thematic analysis will lead to the identification of the most frequently occurring themes and their concomitant categories to support disclosure of the meanings people bring to their health experiences. Thematic significance will be determined in line with literature on risk, PCa and AS, to focus on the implications of risk and risk consultation.<sup>45 46</sup> Triangulation will be conducted by method (observation, questionnaire and interview) and by source (patient and healthcare professional).<sup>47</sup> Verification of the subsample of field notes and transcripts by the secondary qualitative analyst will add to the veracity of the coding framework. Both researchers will use the workshop with the wider study team to discuss: the frequency and meaning of key themes, corroboration between interview and observational data, differences and similarities between patient and healthcare professional data, and the completeness of the interpretations made.

### ETHICS AND DISSEMINATION

Ethical approval for the study has been granted by Macquarie University Human Research Ethics Committee, approval number 5201600638. Data collection and analysis will be conducted in accordance with National Health and Medical Research Council ethical guidelines and those of the supporting human ethics research committee. All participants will give full, non-coercive consent and may withdraw from participation at any time. Procedures will be implemented to minimise the potential for harm or distress caused to patients, including ethics training for interviewers to manage any issues of concern (eg, stopping the interview if a participant becomes upset) and contact details to be supplied to patients for patient support groups. Participant privacy and confidentiality

will be respected by removing all identifying information from data, assigning pseudonyms to participant data and storing all study data safely and securely on password-protected computers or in locked cabinets at the university. Physical copies of transcription data will be stored separately to patient identifiers. All data will be destroyed after 7 years in accordance with ethical principles.

Study outputs will take several forms. First, a research report will be developed based on the study findings, including patients' needs regarding risk communication in PCa, support and information for AS. The report will make recommendations to healthcare professionals regarding optimal strategies for communicating about risk, in line with patient need and expectation. Second, an executive summary for wide-ranging dissemination through public and patient representative groups and through healthcare professional groups will be developed and distributed on request. Third, peer-reviewed papers will be produced for academic journals. Journals will be chosen strategically to maximise international appeal and extensive interest in study findings. In particular, publications will be targeted at those healthcare professionals working in PCa. Finally, presentations and workshops will be prepared for international conferences and to appeal to those working within the field who wish to develop methodological expertise in mixed-methods applications in PCa.

### Significance and impact of the study

This study acts as proof of concept study, testing out this qualitative, multimethod approach in the PCa context in Australia for the first time. In examining consultations and the experiences of patients who are considering, or undergoing an AS protocol, this study will ensure notions of risk, and the prioritisation of risk management is effective and well managed. The study will elucidate patients' and healthcare professionals' views of, and management strategies for, risk communication and risk assessment, as well as providing rich details regarding how reduction or containment of risk is managed effectively, different approaches taken and changes to people's views through the course of initial and subsequent risk assessment for PCa. As such, these findings will be essential for PCa risk communication development, helping not only to identify patients' changing needs for information, support and consultation but to know how clinical teams can better align service provision to patient need. Finally, these findings will underpin the development of future research in the field that focuses on an intervention-based approach to underpin risk assessment procedure for multisite, large-scale roll-out.

**Contributors** FR and HG designed the study. DG and KC contributed to the conceptual development of the study. The manuscript was prepared by KC and FR. AH revised this draft and all authors contributed to further revisions of the protocol manuscript.

**Competing interests** None declared.

**Ethics approval** Macquarie University Human Research Ethics Committee (HREC), approval number 5201600638.

**Provenance and peer review** Not commissioned; externally peer reviewed.

**Data sharing statement** Data will be available on request from the corresponding author.

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BMJ Open 2017 7:

doi: 10.1136/bmjopen-2017-017372

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