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Questioning recommended treatment for prostate cancer: a qualitative analysis of the hidden voices of men resisting overdiagnosis and overtreatment

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Questioning recommended treatment for prostate cancer: a qualitative analysis of the hidden voices of men resisting overdiagnosis and overtreatment

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Abstract

Objective: To describe the lived experience of a possible overdiagnosis of prostate cancer among a group of men who resisted the conventional treatment recommended to them, often despite being told death was imminent without it.

Design: Qualitative interview study

Setting: Australia

Participants: 11 men aged 59-78 years who had been diagnosed with prostate cancer.

Outcomes: Experience of screening, diagnosis and treatment decision making and its impact on psychosocial wellbeing, life and personal circumstances.

Results: Men's accounts revealed profound consequences of both prostate cancer diagnosis and resisting medical advice for treatment, with effects on their psychological wellbeing, family, employment circumstances, identity, and life choices. Some of these men were tested for PSA without their knowledge or informed consent. The men felt uninformed about their management options and unsupported throughout treatment decision making. This often led them to develop a sense of disillusionment and distrust towards the medical profession and conventional medicine. The findings show how men who were told they would soon die without treatment (a prognosis which ultimately did not eventuate) reconciled issues of overdiagnosis and potential overtreatment with their own diagnosis and situation over the ensuing 1 to 20+ years.

Conclusions: Even among men who choose not to have recommended treatment for prostate cancer, and avoid associated harms like incontinence and impotence, our findings showed that the often hidden impact of the diagnosis itself is immense and far-reaching. A high priority for improving clinical practice is to ensure men are adequately informed of these potential consequences before screening is considered.

Article summary

Strengths and limitations of the study:

- This qualitative study used interviews to explore the stories of men, diagnosed with prostate cancer, who self-identified as resisting clinical recommendations for prostate cancer treatment.
- There are considerable challenges to identifying individuals with cancer who have not been treated and show some awareness of the issues of overdiagnosis; our study is the first to achieve this in prostate cancer.
- Our sample was small and the men were well educated and economically successful, which may have provided increased confidence, means and capacity to challenge medical advice.

The concept and reality of overdiagnosis and overtreatment of prostate cancer is now widely accepted. Autopsy studies in men who died of causes other than prostate cancer show that there is a substantial reservoir of non-progressive prostate cancer in the general male population that increases with age.[1] Screening for prostate cancer may therefore detect nonlethal cancers, leading to overdiagnosis and overtreatment. A precise estimate of the extent of overdiagnosis in any screening program is difficult, but estimates from the two largest prostate screening trials suggest that between 17-50% of prostate cancers are overdiagnosed.[2] Even a single PSA screening test is associated with substantial overdiagnosis and no reduction in prostate cancer mortality.[3] Overdiagnosed cancers are by definition cancers that are not destined to cause morbidity or mortality so men with these cancers can only be harmed by early detection and unnecessary treatment. Despite findings demonstrating that common, long-lasting harms triggered by the prostate-specific antigen (PSA) screening test counterbalance or even outweigh the benefits (which, if they occur, are delayed 10 to 15 years or more), and recommendations from most international medical bodies advising against PSA screening,[2 4 5] a significant number of men still undergo PSA testing.[6 7]

Once men receive an elevated PSA test result, a biopsy maybe performed. Biopsies have a high probability of finding prostate cancer that may never have caused clinical symptoms[8 9] and once diagnosed, many men with low-risk, localised cancer undergo active treatment immediately.[10] Mainstay active treatments for prostate cancer such as radical prostatectomy and radiotherapy can result in serious adverse consequences including impotence and incontinence.[11]

To reduce the harms of overtreatment, an active surveillance (AS) management approach is endorsed by a number of professional societies for men who present with low-risk (PSA <10, Gleason ≤6, clinical stage T1-2) prostate cancer.[12-15] AS involves closely monitoring the tumour (via clinical examinations, imaging, PSA tests, and prostate biopsies) and acting with curative intent if the disease progresses. Even prostate biopsies, which are often incorporated into AS, are associated with an increasing incidence of antibiotic-resistant sepsis.[16 17] A 10-year study of more than 1,500 men with screen-detected localised prostate cancer found no difference in death rates between men who received a radical prostatectomy or radiation and those who monitored their disease.[18] Numerous qualitative studies have explored men's views regarding the acceptability of an AS management approach, as well as men's experiences after opting for AS.[19-23] However, few studies discuss men's views on the impact of living with a cancer diagnosis in the long term after being recommended treatments that they feel may have been unnecessary. Moreover, no studies have explored men's choice *not* to follow any recommended management approach, and the consequences for them of so doing.

This study reports on the experiences of men diagnosed with prostate cancer between one and 20 years ago. They declined clinical recommendations for immediate treatment including radical prostatectomy and radiotherapy, and elected to devise and adopt their own management strategies for their prostate disease. Despite the medical advice they received at the time of diagnosis these men are still alive, and are coming to terms with a cancer diagnosis and medical advice that implied imminent death if the recommended (mostly surgical) treatment was not followed. Their narratives provide insight into the hidden experience of a potentially 'unnecessary' diagnosis of prostate cancer, including the psychological and social experiences of declining conventional cancer treatment, living with a slow growing or inconsequential cancer and maintaining physical and mental health.

Methods

Design

This study used qualitative interviews to explore the stories of men, diagnosed with prostate cancer, who self-identified as resisting clinical recommendations for prostate cancer treatment.

Patient and public involvement

The research question was triggered by two consumers' experience of overdiagnosis of prostate cancer. Consumers/patients provided advice on the study design and were involved in study recruitment. The results of the study will be disseminated to all study participants.

Participants and recruitment

11 men diagnosed with prostate cancer, located in three states in eastern Australia (New South Wales, Victoria and Queensland).

Men were eligible to participate in the study if they had received a biopsy-confirmed diagnosis of prostate cancer and initially declined clinical recommendations for treatment. Participants were included if they indicated the following characteristics : (1) reported awareness of the issues of overdiagnosis and/or overtreatment, (2) expressed doubt about the recommended treatment or their management decision, and (3) had drawn a connection between their personal situation and issues of overdiagnosis.

Most participants were recruited via an information and support group[1] for men with prostate cancer seeking non-surgical management. Two further eligible participants came into contact

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[1] This group was organised by one of the participants and is not connected to a charity group or any entity that is part of the medical establishment

with the research team independently. Researchers presented information about the study to potential participants at a support group meeting. Those men interested in participating returned an Expression of Interest form and were contacted to arrange an interview. Men who were interviewed were invited to share study information with other men (snowball sampling). All participants provided written consent.

Ethical approval was granted by the University of Sydney Human Research Ethics Committee (Project No.: 2015/736).

Data collection

An open-ended interview guide (Appendix 1) was developed by the research team, who have expertise in psychology, health communication, public health, and overdiagnosis. Interviews were conducted by three researchers (KM, BN, JH) trained in qualitative research methods between November 2015 and March 2016. Interviews were conducted at participants' homes, their offices, the University of Sydney, or Skype (4/11). Interviews lasted between 22 and 70 minutes, and were audio-recorded and transcribed verbatim. All clinical data was self-reported.

Analysis

Researchers conducted a thematic analysis, aiming to capture the diverse feelings and views expressed by the men. The interviewers (KM, BN, JH) met regularly to discuss salient observations from their interviews, which formed the basis of the initial coding framework. All interviewers read a subset of transcripts and discussed and revised the coding framework. Once the framework was finalised, BN coded all interviews using Framework Analysis in Excel.[24] KM iteratively checked the coding framework within and across themes and participants. Themes were summarised and checked by JH and KP who added further interpretation and insights.

Results

The 11 participants were 59 to 78 years old at the time of interview and 43 to 76 years when they were diagnosed with prostate cancer. One man received a PSA test after reporting urinary symptoms, the other 10 were asymptomatic when tested. Time since diagnosis: <2 years (n=3), 3-9 years (n=6), 10 years or more (n=2). The men's self-reported PSA level at the time of diagnosis was between 1.6 and 39.0 with Gleason scores between 6 and 9. Nine men held a bachelor's degree or above and none had any medical training or expertise in complementary medicine. All men initially elected not to follow the treatment pathway that was recommended to them.

Table 1 Participant characteristics and main reasons expressed for resisting recommended treatment

					Reasons expressed for resisting recommended treatment				
ID	Year of diagnosis	Age at diagnosis	PSA (ng/ml)	Gleason score	To avoid incontinence	To avoid impotence	Perceived pressure from urologist	Uncertain about outcomes/ best approach	Felt under-informed about options
Resisted prostatectomy throughout									
ID1	2015	76	5.4	7 (3+4)		✓	✓	✓	✓
ID2	2009	69	1.6	7 (3+4)		✓	✓	✓	✓
ID3	2011	60	3.0	9			✓		✓
ID4	1996	43	6.3	6		✓	✓		✓
ID5	2014	70	12.0	7 (3+4)	✓		✓		✓
ID6	2011	57	6.0	7 (3+4)	✓	✓	✓	✓	✓
ID7	2008	54	5.4	unknown					✓
ID8	2010	72	10.5	8 (4+4)	✓		✓	✓	✓
Initially resisted but then had prostatectomy (n=2) or radiotherapy (n=1)									
ID9	2015	64	39.0	7 (3+4)		✓	✓		✓
ID10	2001	56	2.0	6				✓	✓
ID11	2013	56	5.5	7				✓	✓

The men's accounts demonstrated broad and significant implications resulting from resisting professionally recommended treatment for prostate cancer. Here we report on the men's reasoning for resisting surgery, its impact on their personal lives, and their response to the experience, including distrusting conventional medicine. Four case studies are included which capture the individual stories of a selection of men.

Men's resistance to recommended treatment

The most common explanations for initially resisting prostatectomy were a desire for more information before deciding about surgery and, at the same time, feeling pressured by their urologist to undergo surgery immediately (Table 1 & 2). These factors together generated considerable uncertainty amongst the men. A number of men expressed fear of suffering impotence or incontinence following surgery, and generally felt more strongly about avoiding the risk of suffering one more than the other. Some were more familiar with the potential negative consequences of prostatectomy via a family member or friend who had undergone surgery and wanted to personally avoid similar outcomes.

Awareness and understanding of overdiagnosis and overtreatment was evident in the men's accounts and varied. Most were familiar with the general concepts at the time of the interview including the fact that a significant number of men live with untreated and undiagnosed prostate cancer, and that surgery might be unnecessary, costly, or result in undesirable outcomes. A few men reported that they initially resisted the recommended surgery specifically because of concerns about overdiagnosis and were aware of debates amongst the medical profession about these issues. All of the men sought second (or more) opinions because they were not willing to undergo invasive treatment, potentially unnecessarily, if there were other options available.

Men's resistance had a profound impact on their psychological wellbeing, life decisions and employment

The men resisted treatment even though for most of them, the delivery of their diagnosis was quite confronting (Table 2). Most felt considerable pressure to take urgent action. Several (n=4/11) were told that they would be dead in the next couple of years unless they had a prostatectomy, and felt immediately threatened and frightened by their impending death. The diagnosis, and how it was presented to them, had a significant impact on their personal circumstances. Some of the men, immediately after their diagnosis, began to prepare for their death by 'finalising their affairs', including extracting themselves from business partnerships leading to loss of income and change in financial circumstances. But the decision not to have the surgery had similarly profound effects on their lives as the actual cancer diagnosis. Two men were divorced following their diagnosis and attributed this as a major cause. One man directly stated that his marriage became untenable because his wife did not support his decision not to have a prostatectomy. Some men left work entirely, or modified their employment to make time to research and focus on their health and/or to pursue alternative treatments overseas.

> *'I had difficulty dealing with work and my other commitments…I gave it all up, walked out! I decided to walk out of my business… I decided to walk out of my partnership…'* (ID4)

Resisting intervention was also an intensely psychological experience. High anxiety and doubt, a sense of '*playing with fire*', commonly persisted for many years after their diagnosis and decision to resist, and continued to be experienced on a daily basis for some. The worst possible consequences of resisting, such as cancer spread and/or death, played heavily on the men's minds.

> *'I still doubt whether I've done the right thing, but so far so good'* (ID2)

Case study 1: BOB*

Bob had been living with a diagnosis of prostate cancer for 7 years at the time of interview, and was diagnosed aged 69 years. Bob's doctor began ordering annual PSA tests when he was 65, and he *went along with it* because the potential implications of having a PSA test were never explained to him. After a few years, his PSA was slightly raised (to 1.6), and the doctor recommended a biopsy, which he had. He described having blood in his urine and a loss of sensitivity following the biopsy, which was unexpected because he did not know anything about the possible side effects beforehand. Bob was diagnosed with prostate cancer, Gleason score 7. He reported that the urologist told him that he would be dead in three years if he did not have his prostate removed immediately, and said he could perform the surgery *a few days away*. Bob described feeling immobilised, not being able to think; *"dead in three years?" That's all I could think of.* He had just been told he might miss out on seeing his grandchildren grow up. He was already aware of the risks of prostate surgery and was very concerned about erectile dysfunction. When Bob asked for a second opinion, he was referred to his urologist's business partner, which prompted him to embark on a quest for alternative treatments himself. He did an enormous amount of independent research – reading *nothing else but medical books for 4 or 5 years*, sent his pathology to interstate and international specialists (at *enormous expense*), and then flew to New York for prostate scans. It was very consuming, in terms of time and emotionally. Bob withdrew from part of his business because he couldn't work as much, alongside studying medical texts. He experienced difficulty sleeping throughout, *waking up at 3am thinking of how little of your life you might have left*. He *felt very much alone because I didn't have a doctor who I believed in*. He returned to a radiologist in New York several more times to monitor any cancer progression. According to these scans, Bob's prostate cancer has not changed in any way in the 7 years since his diagnosis. Yet it has had a long-lasting impact. He continues to suffer sleeplessness, and wonders *every couple of days* whether he has done the right thing by not going ahead with the recommended treatment. He hopes he can help provide other men with more support to make their own decisions, because *this isn't riskless.*

Case study 2: JIM

Jim was diagnosed with prostate cancer at the age of 54. His story began when he went to his GP for a routine prostate check. The GP performed a digital rectal examination (DRE) but during the procedure, Jim reported that his GP *twisted his prostate*, which left him hospitalised, in agony, and with long-term side effects. Two years later, he had another DRE and a small nodule was felt by his GP. Jim was referred to a urologist for a biopsy and had his first ever PSA test; his PSA was elevated (5.4). Jim said he suffered terribly from the biopsy, it was very painful and there was *blood everywhere*, he said if he was more informed he would not have agreed to it. The biopsy showed that a small proportion of 1 of the 12 samples taken had evidence of prostate cancer. The diagnosis *was devastating, and it took me a while to get my head around that.* Jim was referred to an oncologist and another urologist: he had a good experience with the oncologist, but described his consultation with the urologist as *really off-putting,* especially when he was booked in for an immediate prostatectomy without any discussion about alternative management options. He began an extensive investigation of his options, *hours and hours of research* about prostate cancer and its treatment. He gathered information from men in a prostate cancer support group in a similar position, had ultrasounds and MRIs, and learnt about overdiagnosis and overtreatment. At the time of the interview, it had been 8 years since Jim had decided not to have a prostatectomy. He monitors his prostate cancer with annual ultrasounds and PSA tests and is very happy with his decision not to have active treatment. However, his decision has had a substantial impact on his life. Jim's wife could not accept his choice not to have the surgery, which ultimately contributed to a *debilitating* divorce. He defended his approach as considered, evidence-based, *not just going willy nilly down the holistic path*; yet described the psychological impact of resisting surgery as ongoing, *a mental thing that you have to deal with every day…it plays on your mind.* He advocated for men to have the opportunity to *stop and think about things and go, hang on a second, is this the right thing to do?*

*all names have been changed to preserve anonymity ** *italics* indicate verbatim quotes

Distrust of conventional medicine and embracing non-mainstream treatments

The men reported feeling disillusioned by conventional management options and medical opinion (Table 2). Most of those interviewed felt abandoned by their clinicians, specialists, and/or the Australian health care system when they resisted the recommended treatment. Some men expressed cynical views of the medical profession and speculated that the unequivocal advice for prostatectomy was driven by financial gain. They were concerned that they were not getting the full story, from any clinician, about the range of potential management options.

> *'I am profoundly dissatisfied with what I see as the blinkered view of possibilities offered … and the incapacity of these people to consider anything outside their carefully regulated areas of expertise.'* (ID5)

In response, they pursued extensive additional testing and imaging and dedicated enormous time and energy to researching other available options. Almost all of the men had actively sought out and embraced an alternative management strategy outside of the mainstream system. For some this involved herbal supplements, Chinese medicine, or major dietary and lifestyle changes. For several others it involved visiting international clinics and having ongoing tests and unproven treatments that were vastly expensive (e.g. hyperthermia). Several suffered pain and discomfort from their procedures, but still perceived them as a far better alternative than prostatectomy.

> (Hyperthermia) *'not an entirely pleasant experience but not nearly as debilitating as the radical (prostatectomy)'* (ID5)

Table 2: Summary of key findings with illustrative quotes

Main finding	Selected quotes
Men resisted the recommended treatment for a range of reasons	*'Erectile dysfunction would really upset me a great deal'* (ID2) *'I was very worried about the possibility of long term incontinence…the idea of having to wear pads in my underpants for possibly the rest of my life was not attractive'* (ID5)
Feeling rushed and pressured to make decisions	*'[urologist said] based on your history and my examination I think if you don't have surgery you'll be dead in 5 years'* (ID9); *'(urologist said) you shouldn't let this go too long, 3 months max, you should be on the table and get rid of it'* (ID1)
Some men's resistance had a profound impact on their quality of life and life decisions	*'So when someone tells you you're going to die in three years and you make a decision not to have an operation – you've got to make some life changes…I decided to make massive life changes'* (ID4) *'Immediately after the diagnosis I was thinking, ok, so how do I finalise my affairs?'* (ID3). *'It's a mental thing that you have to deal with every day… it plays on your mind'* (ID7) *'3am in the morning when you wake up and you start thinking of how little of your life you might have left'* (ID2)
Some men distrusted conventional medicine and embraced non-	*'It just looked like a money making experience for me'* (ID7) *'[I] found out a hell of a lot more about the limited choices that*

mainstream treatments	*conventional medicine offers…slash, burn or poison, surgery, radiation or chemo'* (ID6)
Some men reported lack of supportive environments to make decisions about testing or treatment	*'He [urologist] said "you don't want to be mucking around with this, you know, it is cancer"…he really scared the hell out of me… I thought, I better do this, whatever it is'* (ID6) *'I felt very much alone because I didn't have a doctor who I believed in'* (ID2)
Some men, over time, reframed the diagnosis and decisions made	*'I played that game for about three years, running around the world [seeking alternative ways of healing, treatment]…then I realised nothing was happening, I was fine'* (ID4) *'As time went on that level of anxiety, with knowledge… and additional information, and knowing how rigged the medical profession operates in this, in this particular sphere, it has sort of gone down'* (ID6)

Lack of supportive environment to make informed decisions about testing or treatment

It was clear across the interviews that the men were offered limited, if any, time or resources to encourage or enable them to make an informed decision about either PSA testing or treatment. The majority of men were not familiar with what a PSA screening test was and received no information prior to being screened; some did not even know they had been screened until they were told their PSA was abnormal.

> *'I had no idea what a PSA test was. The doctor said "it's time" and I went along with it'* (ID2); *'I wouldn't even have known what a prostate was about'* (ID10)

A number of the men shared stories of urologists who scheduled their prostatectomies in the same appointment that their diagnosis was given. Urologists were perceived to be treatment-focused and with little consideration of what the individual man might want or need from the consultation. This was despite it being clear that the men who resisted treatment personally valued things differently to the medical profession. The men perceived little support or reassurance, and described an environment that provided little encouragement for them to ask questions or express individual priorities. They had real concerns that they wanted to be heard –that biopsies and surgery might spread cancer, fear of the side effects of surgery, being treated unnecessarily – but reported that there was little possibility of discussing such matters with their urologist.

Reframing the diagnosis and decisions made

At the time of the interview, 8 of the 11 men had continued to resist the recommended prostatectomy, suffering no physical morbidity from prostate cancer. Several reflected on their personal situation and increasing awareness that their cancer had not progressed and may not ever do so, hence might not be the life-threatening scenario that had been presented to them. A number questioned whether seeking out alternative ways of healing and treatment had helped or whether they would have had the same outcome regardless.

> *'I played that game for about three years, running around the world* [*seeking alternative ways of healing, treatment*]*…then I realised nothing was happening, I was fine'* (ID4).

> *I've known for five and a half years that I've got cancer in me, and I'm still living, walking around, no side effects, no nothing… perhaps I will be ok* (ID8).

Some men explicitly considered the relevance of the overdiagnosis/overtreatment debate to their circumstances. One man, who did have a prostatectomy after resisting PSA screening for many years, wondered if he is one of the ones overdiagnosed or whether his diagnosis and surgery saved his life.

> *'There's a part of me that wonders did I fuck myself up because I waited three and a half years or did I fuck myself up because I had the cleanout…I'll never know. If I die in the next 5 years of metastasis then I'll know I waited too long… again, I'll never know. I mean, if I die of something else, I won't know if this never would've spread anyway, or they saved my life'* (ID9).

Case study 3: TED

Ted was 56 years old when he was diagnosed with prostate cancer (Gleason 6), 15 years before this interview. He had never had a PSA test until he was referred to a urologist for a urinary tract infection. He admitted that he didn't even know what the prostate was. A PSA of 2.0 prompted a biopsy. When the urologist told Ted that the biopsy had detected prostate cancer, he implied that it was bad, *he was pretty grim*, and wanted to arrange urgent treatment. Ted was very concerned. In hindsight he has realised that *he (urologist) told me things that were not true….that probably it'd spread.* He received anti-hormonal injections (from which he suffered *massive* hot flushes) in anticipation of delayed surgery, because he was in the process of moving back to Australia after living overseas for some years. When he returned, Ted consulted multiple urologists about his treatment options, all with vastly differing opinions. Despite being told by one urologist that he would be dead within 5 years, he decided not to go ahead with surgery, *I wasn't keen to have any intervention if it wasn't necessary…I didn't have a lot of problem living with cancer.* Instead, at the advice of a non-interventionist urologist, he monitored the tumour via biopsies and PSA, which made his first urologist angry. Ted did eventually have treatment: first, brachytherapy, because it did not seem to be very invasive. It was painless and without side effects. Four years later, he had external beam radiation, again with minimal side effects. After 14 years of living with prostate cancer, Ted finally had a prostatectomy at the advice of his urologist after his PSA doubled (PSA increased from 2 to 4), despite originally being firmly against intervention. He describes the flow on effects that can eventuate from a positive PSA test: *you're damned if you do and it's a damned if you don't. You know, because you're on a dilemma and you really don't know how serious this dilemma is. '…I stayed with it—well I hadn't stayed with it I had it for 14 years and I eventually did have the treatment…I did have to have it in the end'.* He said over the 14 years he had plenty of time to find out about the possible side effects of surgery, most of which he didn't want. Following the prostatectomy, he had a lot of anal pain, lacks fecal control, and is impotent. He doesn't regret postponing the surgery. *But if you come to me in 5 years' time and I'm almost dead because I didn't have the surgery earlier I might have a different idea, mightn't I? … 'I hope I have nothing to regret, we'll see in 3 or 4 years' time but I'm getting past the 5 years that [the urologist] reckoned I would have' (to live).*

Another man strongly resisted the recommended management for a number of years following an elevated PSA result due to awareness of the harms of overdiagnosis but then reported having developed secondary cancer. He subsequently had mixed views on overdiagnosis because he is living with a progressed cancer that may have benefited from earlier detection. He questioned whether he should have agreed to further testing and treatment sooner.

> *''All that overdiagnosis is to try and save the one, turns out I'm the one so, I have mixed views on it'* (ID11).

Both men showed signs of self-blame for their decision-making. The uncertainty about whether the decisions they had made were the right ones seemed to play heavily on their minds and was ultimately unresolvable.

Case study 4: PETER

Peter was diagnosed with prostate cancer (Gleason 7) in 2013 at 56 years. He had for many years resisted having a biopsy, which was recommended to him following an elevated PSA (but normal DRE). He described a urologist *trying to force me to have a biopsy against my better judgment.* He felt that the information about *the wisdom of having a biopsy done simply on the basis of a rising PSA* was *conflicting,* and had heard concerns about overtesting and overdiagnosis on the radio. He recalled *at the time thinking I probably didn't have a serious problem…I thought the odds were still in my favour.* Instead, Peter chose to undergo ultrasounds of his prostate and had a new procedure (laser ablation) in New York: a *radical new treatment having great success.* He considered it his *best shot at having the treatment done and dusted*. It cost $30,000 (which *seemed like a good bet at the time…In hindsight I'd love to get my money back if I could*) and was *extremely uncomfortable* and *undignified, intrusive.* Initially, the specialists *pretty well declared the whole process a success*, and he was told to *go home and you shouldn't have any more worries.* However 12 months later his PSA had risen to 24, *so I clearly had a bit of a problem.* A full body CAT scan revealed a suspicious area in his hip, which was potentially a secondary cancer. The specialist's recommendation was for Peter to have hormone treatment – which he *really struggled with* - and then *fairly aggressive* radiation treatment. A radical prostatectomy was not an option after he had had the laser treatment. His thought process *at the time was, I'd pursued the sort of alternative treatment path thinking at the time that it was unlikely I had a severe problem anyway…I was sort of just being a little cautious.* But, *it turns out I was in that small percentage that had a serious growth. The alternative treatment hadn't worked.* By this stage he had realised that he *couldn't afford to screw around with this anymore,* his efforts *trying to manage my own prognosis* had been unsuccessful and he resorted to finding the best specialist he could. Peter described the whole process as *a rollercoaster.* At the time of interview, it had been two years since his radiation therapy. He continues to have side effects including some impotence and rectal bleeding. Peter had to reduce his working hours, *it has a real impact, a big impact.* He suffers from anxiety attacks and described sometimes being *almost petrified with fear.* The prostate cancer causes significant worry, *I'm still concerned that it's probably going to get me…I suspect that it's a matter of time.* Peter admitted that with hindsight he would have *changed my course of action… clearly I should have had a biopsy done.* He believes that it was a good decision to leave the first urologist and not to have had a biopsy straight away, but would have sought better specialist advice sooner, and had a prostatectomy if it was recommended. Peter continues to believe that there is *some truth* in the overdiagnosis and overtreatment argument, *but turns out I'm in that very small percentage…all that overdiagnosis is to try and save the one, turns out I'm the one, so I have mixed views on it…I'd be in much more serious trouble* had I not had the treatment.

Discussion

This study provides important, relevant insight into the lived experience of overdiagnosis. It reveals the substantial and sustained burden on men's lives as they continue to live with a potentially inconsequential cancer diagnosis alongside their decision to decline recommended treatment. Such accounts are rarely reported in the literature, hidden in part because we are mostly unable to identify individuals who have been overdiagnosed, given that it is rare to leave cancer untreated. Importantly these men's views contrast with many cancer patients' beliefs that their diagnosis was life-saving or life affirming and reveal the profound negative psychosocial impact of diagnosis.

Clinicians have traditionally under-appreciated the adverse impact of prostate cancer diagnosis and treatments thus resulting in limited visibility of these effects in the medical literature until recent years.[11 25 26] Previous work with clinicians shows that a strong driver of the continued use of PSA testing is the fear of missing a patient's cancer [27-29]. However, this fails to recognise the potential downstream consequences on men of unnecessary testing and overdiagnosis.

In this sample, feeling uninformed and perceived pressured from specialists were considered more important reasons to resist surgery than avoidance of potential side effects of treatment. The findings demonstrate the real-life consequences of violations of the ethical principle of autonomy, with men reporting being tested for PSA without their knowledge. This is consistent with existing literature suggesting that many Australian men are not having treatment options for early prostate cancer adequately explained to them, and urgent surgical treatment is still frequently encouraged.[30] Research from the US suggests a similar picture with informed decision-making rare, [31] even when decision support is provided. [32 33 34] Recent findings from the US and Australia similarly suggest shared decision-making around PSA testing and prostate cancer treatment is limited. [30 33 35]

Men in this study felt inadequately prepared and unsupported from the point of the initial PSA screening test, to biopsy and treatment decision-making. A qualitative study of individuals who self-identified as having an overdiagnosed thyroid cancer and decided not to intervene with surgical treatment revealed similar findings to this study.[36] Their experience was characterised by feelings of isolation and ongoing anxiety resulting from lack of social and health care system acceptance and support for their decision to resist treatment. The view that treatment is needed and life-saving is normalised such that attitudes contrary to that norm may be dismissed and rejected.

This study identifies, for perhaps the first time that distrust in conventional medicine may ensue from feeling inadequately informed. It is noteworthy that many of the men pursued expensive alternative tests and treatments that have little current supporting evidence of efficacy, with a strong desire to 'do something'. This revelation is not surprising given that a recent Australian study documented increased distress and anxiety in men who opted to monitor their low-risk prostate cancer rather than actively treat it,[37] and a 5-year follow-up study found that 23% of men discontinued active surveillance despite no evidence of cancer progression.[38]

Active surveillance was not a common option when some men in our sample were first diagnosed and changing technologies and new knowledge have advanced the field. Uptake of AS is increasing in Australia with current estimates indicating around 36% of men with low risk prostate cancer accept AS [39] but uptake remains relatively low in the US (<15% of men with low risk disease). [40] Importantly, several men in our sample diagnosed within the last 1-5 years felt they were offered little choice beyond surgery, suggesting that despite the evolving evidence clinical practice is slow to change.

Strengths and limitations

To our knowledge, this is the first study to document how men diagnosed with prostate cancer reconcile issues of overdiagnosis and overtreatment and make sense of these issues in relation to their own situation. There are considerable challenges to identifying individuals with cancer who have not been treated and show some awareness of the issues of overdiagnosis. Our study is the first to achieve this in prostate cancer.

Our sample was small and the men were well educated and economically successful, which may have provided increased confidence, means and capacity to challenge medical advice. Recent evidence suggests that men with higher education and income in Australia and US are more likely to have PSA testing and therefore be diagnosed with prostate cancer.[41 42] Our participants were initially recruited through a support group founded by men who had resisted surgical management of prostate cancer, so may not be representative of all men diagnosed with prostate cancer who decide against conventional treatment. However, the aim of qualitative research is not to be representative, rather to demonstrate the range and depth of experiences that may arise in a given situation. Many of the cancer-related fears and uncertainties expressed by the men in our sample are similar to those reported in studies from North America[43 44] and are likely to transcend international borders. They therefore provide important leads for further research internationally.

Conclusion

Overdiagnosis of prostate cancer remains a problem. The immense psychosocial consequences of a potentially unnecessary diagnosis must be taken into account in any discussions and decisions about PSA screening. These findings underscore the need to respect the ethical principle of autonomy by supporting men to make informed decisions about both screening and treatment in a clinical situation laden with so many uncertainties.

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Appendix I

Interview Guide

The goal for this interview is for you to take us through how you were diagnosed with prostate cancer and describe your experiences and thoughts about your diagnosis. This is important so that we can gain an understanding of the range of men's views and experiences with the disease.

Also, this interview will be audio-recorded to ensure that we have an accurate record of your responses, and everything you say will be kept strictly confidential. If it is alright with you I will start the audio-recording now.

Do you have any questions before we begin?

So firstly if I (we) could just ask you a few demographic questions:

1. **What is your age?**
2. **What is your current work status (working full-time, working part-time, retired)?**
   - Can you please describe your current or previous occupation?
3. **What is your highest level of education?**

Now can you please take me (us) through from the start how you came to be diagnosed with prostate cancer and how it has affected your life?

Prompts:

- GP / PSA test experience (screening or symptom led, informed about screening in any way or not)
- Specialist experience (tests offered, diagnosis given, prognosis given, treatments offered, communication)
- Language doctor used to describe your condition and impact of the term 'cancer'
- Second opinions
- Kinds of information given by the doctors about the diagnosis
- Feelings about initial diagnosis
- Experience and attitudes towards biopsy
- Impact on self, family, friends, life, work, feelings during everyday life, spirituality (refer to Brodersen et al. questionnaire items as potential list of additional prompts if issues not raised)
- Influence of family and friends in the process of treatment decision making and coping
- Trust in the medical profession
- Overdiagnosis – some people feel that there shouldn't be PSA testing in the first place – What's your view about that?
- Treatment decision making – What treatment was chosen? How do you feel about your treatment decision?
- How was information found?
- Impact of being part of a support group? (Prostate-Cancer Organisation)

If haven't mentioned: How long ago was it that you started on your prostate cancer journey?
[If appropriate] It sounds like you had a difficult experience with XYZ… To help us try and improve things for other men who may find themselves in your situation in the future:

Ask men to read out and discuss

Items from Brodersen quality of life questionnaire (Brodersen J, Thorsen H. Consequences of Screening in Breast Cancer (COS-BC): development of a questionnaire. *Scand J Prim Health Care* 2008;26:251-6.

I have felt scared.
I have felt terrified.
I have been worried about my future.
I have been upset.
I have felt restless.
I have been nervous.
I have been irritable.
I have been quieter than normal.
I have found it hard to concentrate.
My appetite has changed.
I have withdrawn into myself.
I have had difficulty dealing with my work or other commitments.
I have had difficulty doing everyday things around the house.
I have felt sad.
I have been worried.
I have felt time passed slowly.
I have been uneasy.
I have felt unable to cope.
I have been depressed.
I have felt less interest in sex.
I have kept busy to take my mind off things.
I have felt less attractive.
I have slept badly.
It has taken me a long time to fall asleep.
I have woken up far too early in the morning.
I have been awake most of the night.

What do you think is the most important thing that could be changed to improve the experience you had?

Well ___________ I think we're just about ready to wrap up the interview. Thank you very much for your time, it is really appreciated. Do you have anything further to add or have questions for me before we wrap up?

Okay, thanks again and should you have any additional questions all of our contact details are provided on the Participant Information Sheet we handed out to you.

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Manuscripts

Resisting recommended treatment for prostate cancer: a qualitative analysis of the lived experience of possible overdiagnosis

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Abstract

Objective: To describe the lived experience of a possible prostate cancer overdiagnosis in men who resisted recommended treatment.

Design: Qualitative interview study

Setting: Australia

Participants: 11 men (aged 59-78 years) who resisted recommended prostate cancer treatment because of concerns about overdiagnosis and overtreatment.

Outcomes: Reported experience of screening, diagnosis and treatment decision making and its impact on psychosocial wellbeing, life and personal circumstances.

Results: Men's accounts revealed profound consequences of both prostate cancer diagnosis and resisting medical advice for treatment, with effects on their psychological wellbeing, family, employment circumstances, identity, and life choices. Some of these men were tested for PSA without their knowledge or informed consent. The men felt uninformed about their management options and unsupported through treatment decision making. This often led them to develop a sense of disillusionment and distrust towards the medical profession and conventional medicine. The findings show how men who were told they would soon die without treatment (a prognosis which ultimately did not eventuate) reconciled issues of overdiagnosis and potential overtreatment with their own diagnosis and situation over the ensuing 1 to 20+ years.

Conclusions: Men who choose not to have recommended treatment for prostate cancer may avoid treatment-associated harms like incontinence and impotence, however our findings showed that the impact of the diagnosis itself is immense and far-reaching. A high priority for improving clinical practice is to ensure men are adequately informed of these potential consequences before screening is considered.

Article summary

Strengths and limitations of the study:

- This qualitative study used interviews to explore the stories of men, diagnosed with prostate cancer, who self-identified as resisting clinical recommendations for prostate cancer treatment.
- There are considerable challenges to identifying individuals with cancer who have not been treated and show some awareness of the issues of overdiagnosis; our study is the first to achieve this in prostate cancer.
- Our sample was small and the men were well educated, economically successful, and had high health literacy, which may have provided increased confidence, means and capacity to challenge medical advice.

The concept and reality of overdiagnosis and overtreatment of prostate cancer is now widely accepted. Autopsy studies in men who died of causes other than prostate cancer show that there is a substantial reservoir of non-progressive prostate cancer in the general male population that increases with age.[1] Screening for prostate cancer may therefore detect nonlethal cancers, leading to overdiagnosis and overtreatment. A precise estimate of the extent of overdiagnosis in any screening program is difficult, but estimates from the two largest prostate screening trials suggest that between 17-50% of prostate cancers are overdiagnosed.[2] Overdiagnosed cancers are by definition cancers that are not destined to cause morbidity or mortality so men with these cancers can only be harmed by early detection and unnecessary treatment.[3] Extensive evidence suggests that common, long-lasting harms triggered by the prostate-specific antigen (PSA) screening test counterbalance or even outweigh the benefits (which, if they occur, are delayed 10 to 15 years or more), and most international medical bodies advise against PSA screening.[2 4 5] Yet a significant number of men still undergo PSA testing, [6 7] many of whom are poorly informed.

Once men receive an elevated PSA test result, a biopsy may be performed. Biopsies have a high probability of finding prostate cancer that may never have caused clinical symptoms[8 9] and once diagnosed, many men with low-risk, localised cancer undergo active treatment immediately.[10] Surgery (radical prostatectomy) is the most frequent treatment method used among men with clinically localised prostate cancer in Australia.[11] Mainstay active treatments for prostate cancer such as surgery, radiation therapy, and hormone therapy can result in serious adverse consequences including impotence and incontinence (with surgery) and bowel problems (with radiation therapy).[12]

To reduce the harms of overtreatment, an active surveillance (AS) management approach is endorsed by a number of professional societies for men who present with low-risk (PSA <10, Gleason ≤6, clinical stage T1-2) prostate cancer.[13-16] AS involves closely monitoring the tumour (via clinical examinations, imaging, PSA tests, and prostate biopsies) and acting with curative intent if the disease progresses. A 10-year study of more than 1,500 men with screen-detected localised prostate cancer found no difference in death rates between men who received a radical prostatectomy or radiation and those who monitored their disease.[17] Numerous qualitative studies have explored men's views regarding the acceptability of an AS management approach, as well as men's experiences after opting for AS.[18-22] However, we know of no studies that have explored men's choice *not* to follow any recommended management approach, and the consequences for them of so doing.

This study reports on the experiences of men diagnosed with prostate cancer between one and 20 years ago. They declined clinical recommendations for immediate treatment including radical prostatectomy and radiotherapy and elected to devise and adopt their own management strategies for their prostate disease. Despite the medical advice they received at the time of diagnosis these men are still alive and are coming to terms with a cancer diagnosis and medical advice that implied imminent death if the recommended (mostly surgical) treatment was not followed. Their narratives provide insight into the hidden experience of a potentially ‘unnecessary’ diagnosis of prostate cancer, including the psychological and social experiences of declining treatment advice, living with a slow growing or inconsequential cancer and maintaining physical and mental health.

Methods

Design

This study used qualitative interviews to explore the stories of men, diagnosed with prostate cancer, who self-identified as resisting clinical recommendations for prostate cancer treatment.

Patient and public involvement

The research question was informed by two consumers’ personal experience of being diagnosed with prostate cancer. The consumers/patients provided advice on the study design and results and were involved in study recruitment. The findings of the study will be disseminated to all study participants.

Participants and recruitment

11 men initially diagnosed with localised prostate cancer, located in three states in eastern Australia (New South Wales, Victoria and Queensland).

Men were eligible to participate in the study if they had received a biopsy-confirmed diagnosis of prostate cancer and initially declined clinical recommendations for treatment. Participants were included if they indicated the following to the interviewer: (1) awareness of the issues of overdiagnosis and/or overtreatment, (2) expressed doubt about their recommended treatment or their management decision, and (3) had drawn a connection between their personal situation and issues of overdiagnosis/overtreatment.

Most participants were recruited via an information and support group[1] for men with prostate cancer seeking non-surgical management. Two further eligible participants independent of the support group were identified after they emailed members of the research team or their academic networks to seek advice about prostate cancer. Researchers presented information about the study to potential participants. All potentially eligible men were sent/given an Expression of Interest form. Those who returned the form were contacted to arrange an interview. They were invited to share study information with other men (snowball sampling). All participants provided written informed consent prior to the interview. All men who expressed interest in the study and met the inclusion criteria agreed to be interviewed and were included in the study.

Ethical approval was granted by the University of Sydney Human Research Ethics Committee (Project No.: 2015/736).

Data collection

An interview guide (Appendix 1) was developed by the research team who have expertise in psychology, health communication, public health, and overdiagnosis. Interviews were conducted by three academic researchers (KM, BN, JH) trained in qualitative research methods between November 2015 and March 2016. The interviewers had no immediate personal or professional experience with prostate cancer or PSA screening, and do not work with men who have prostate cancer. Interviews were conducted at participants' homes, their offices, the University of Sydney, or Skype (4/11). We interviewed as many men as possible who met the inclusion criteria. Since this is a difficult sample to identify we cannot state that we reached thematic saturation.[23] . Interviews lasted between 22 and 70 minutes and were audio-recorded and transcribed verbatim. All clinical data was self-reported.

Analysis

The analysis was an iterative process and commenced during data collection. Researchers conducted a thematic analysis, aiming to capture the diverse feelings and views expressed by the men. The interviewers (KM, BN, JH) met regularly to discuss salient observations from their interviews, which formed the basis of the initial coding framework. All interviewers read a subset of transcripts and discussed and revised the coding framework. Once the framework was finalised, BN coded all interviews using Framework Analysis in Excel.[24] KM iteratively checked the coding framework within and across themes and participants. Themes were summarised

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[1] This group was organised by one of the participants and is not connected to a charity group or any entity that is part of the medical establishment

and checked by JH and KP who added further interpretation and insights. Four case studies are presented in the results which were selected to represent a range of experiences of diagnosis and decision making among the sample. Written consent was obtained from the relevant parties for the publication of the case studies.

Results

The 11 participants were 59 to 78 years old at the time of interview and 43 to 76 years (average age 62 years) when they were diagnosed with prostate cancer (Table 1). In Australia the mean age of prostate cancer diagnosis is 69 years. One man received a PSA test after reporting urinary symptoms, the other 10 were asymptomatic when tested. Time since diagnosis: <2 years (n=3), 3-9 years (n=6), 10 years or more (n=2). The men's self-reported PSA level at the time of diagnosis was between 1.6 and 39.0 with Gleason scores between 6 and 9. Nine men held a bachelor's degree or above and one was a medical specialist; none had expertise in complementary medicine. All men initially declined the treatment recommended to them. Surgery (prostatectomy) was the first/only treatment recommended to 10/11 men.

Table 1 Participant characteristics and main reasons expressed for resisting recommended treatment

					Reasons expressed for resisting recommended treatment				
ID	Year of diagnosis	Age at diagnosis*	PSA (ng/ml)	Gleason score	To avoid incontinence	To avoid impotence	Perceived pressure from urologist	Uncertain about outcomes/ best approach	Felt under-informed about options
Resisted prostatectomy throughout									
ID1	2015	76	5.4	7 (3+4)		✓	✓	✓	✓
ID2	2009	69	1.6	7 (3+4)		✓	✓	✓	✓
ID3	2011	60	3.0	9			✓		✓
ID4	1996	43	6.3	6		✓	✓		✓
ID5	2014	70	12.0	7 (3+4)	✓		✓		✓
ID6	2011	57	6.0	7 (3+4)	✓	✓	✓	✓	✓
ID7	2008	54	5.4	unknown					✓
ID8	2010	72	10.5	8 (4+4)	✓		✓	✓	✓
Initially resisted but then had prostatectomy (n=2) or radiotherapy (n=1)									
ID9	2015	64	39.0	7 (3+4)		✓	✓		✓
ID10	2001	56	2.0	6				✓	✓
ID11	2013	56	5.5	7				✓	✓

The men's accounts demonstrated broad and significant implications resulting from resisting professionally recommended treatment for prostate cancer. Here we report on the men's reasoning for resisting, its impact on their personal lives, feeling unsupported, and their response to the experience, including distrusting conventional medicine and questioning decisions made (Table 2). Four case studies are included which capture the individual stories of a selection of men.

Men's resistance to recommended treatment

The most common explanations that the men gave for initially resisting prostatectomy were feeling under-informed about their options and, at the same time, feeling pressured by their urologist to undergo surgery immediately (Table 1 & 2). These factors together generated considerable uncertainty amongst the men. Several men diagnosed within the last 1-5 years said they were offered little choice beyond surgery, despite being eligible for active surveillance. A number of men expressed fear of suffering impotence or incontinence following surgery, and generally felt more strongly about avoiding the risk of suffering one more than the other. Some were more familiar with the potential negative consequences of prostatectomy via a family member or friend who had undergone surgery and wanted to personally avoid similar outcomes.

The men's accounts indicated varied awareness and understanding of overdiagnosis and overtreatment. Most were familiar with the general concepts including the fact that a significant number of men live with untreated and undiagnosed prostate cancer, and that surgery might be unnecessary, costly, and result in undesirable outcomes. Some men had very sophisticated knowledge. A few men explicitly stated that they resisted the recommended surgery specifically because of concerns about overdiagnosis and were aware of debates amongst the medical profession about these issues. Some only encountered the concept of overdiagnosis following their own extensive researching after their diagnosis; one participant said that he read ten books on the subject.

Men's resistance had a profound impact on their psychological wellbeing, life decisions and employment

The men resisted treatment even though most of them described experiencing considerable pressure to take urgent action. Several (n=4/11) were told that they would be dead in the next couple of years unless they had a prostatectomy and felt threatened and frightened by their impending death. Some of the men, immediately after their diagnosis, began to prepare for their death by 'finalising their affairs', including extracting themselves from business partnerships leading to loss of income and change in financial circumstances. But the decision not to have the surgery had similarly profound effects on their lives as the actual cancer diagnosis. Two men were divorced following their diagnosis and attributed this as a major cause. One man directly stated that his marriage became untenable because his wife did not support his decision not to have a prostatectomy. Some men left work entirely or modified their employment to make time to research and focus on their health and/or to pursue alternative treatments overseas.

> *'I had difficulty dealing with work and my other commitments…I gave it all up, walked out! I decided to walk out of my business… I decided to walk out of my partnership…'* (ID4)

Resisting intervention was an intensely psychological experience. High anxiety and doubt, a sense of '*playing with fire*', commonly persisted for many years after their diagnosis and decision to resist and continued to be experienced on a daily basis for some. The worst possible consequences of resisting, such as cancer spread and/or death, played heavily on the men's minds.

> *'I still doubt whether I've done the right thing, but so far so good'* (ID2)

Case study 1: BOB*

Bob had been living with a diagnosis of prostate cancer for 7 years at the time of interview, and was diagnosed aged 69 years. Bob's doctor began ordering annual PSA tests when he was 65, and he *went along with it* because the potential implications of having a PSA test were never explained to him. After a few years, his PSA was slightly raised (to 1.6), and the doctor recommended a biopsy, which he had. He described having blood in his urine and a loss of sensitivity following the biopsy, which was unexpected because he did not know anything about the possible side effects beforehand. Bob was diagnosed with prostate cancer, Gleason score 7. He reported that the urologist told him that he would be dead in three years if he did not have his prostate removed immediately, and said he could perform the surgery *a few days away*. Bob described feeling immobilised, not being able to think; *"dead in three years?" That's all I could think of.* He had just been told he might miss out on seeing his grandchildren grow up. He was already aware of the risks of prostate surgery and was very concerned about erectile dysfunction. When Bob asked for a second opinion, he was referred to his urologist's business partner, which prompted him to embark on a quest for alternative treatments himself. He did an enormous amount of independent research – reading *nothing else but medical books for 4 or 5 years*, sent his pathology to interstate and international specialists (at *enormous expense*), and then flew to New York for prostate scans. It was very consuming, in terms of time and emotionally. Bob withdrew from part of his business because he couldn't work as much, alongside studying medical texts. He experienced difficulty sleeping throughout, *waking up at 3am thinking of how little of your life you might have left*. He *felt very much alone because I didn't have a doctor who I believed in*. He returned to a radiologist in New York several more times to monitor any cancer progression. According to these scans, Bob's prostate cancer has not changed in any way in the 7 years since his diagnosis. Yet it has had a long-lasting impact. He continues to suffer sleeplessness, and wonders *every couple of days* whether he has done the right thing by not going ahead with the recommended treatment. He hopes he can help provide other men with more support to make their own decisions, because *this isn't riskless.*

Case study 2: JIM

Jim was diagnosed with prostate cancer at the age of 54. His story began when he went to his GP for a routine prostate check. The GP performed a digital rectal examination (DRE) but during the procedure, Jim reported that his GP *twisted his prostate*, which left him hospitalised, in agony, and with long-term side effects. Two years later, he had another DRE and a small nodule was felt by his GP. Jim was referred to a urologist for a biopsy and had his first ever PSA test; his PSA was elevated (5.4). Jim said he suffered terribly from the biopsy, it was very painful and there was *blood everywhere*, he said if he was more informed he would not have agreed to it. The biopsy showed that a small proportion of 1 of the 12 samples taken had evidence of prostate cancer. The diagnosis *was devastating, and it took me a while to get my head around that.* Jim was referred to an oncologist and another urologist: he had a good experience with the oncologist, but described his consultation with the urologist as *really off-putting,* especially when he was booked in for an immediate prostatectomy without any discussion about alternative management options. He began an extensive investigation of his options, *hours and hours of research* about prostate cancer and its treatment. He gathered information from men in a prostate cancer support group in a similar position, had ultrasounds and MRIs, and learnt about overdiagnosis and overtreatment. At the time of the interview, it had been 8 years since Jim had decided not to have a prostatectomy. He monitors his prostate cancer with annual ultrasounds and PSA tests and is very happy with his decision not to have active treatment. However, his decision has had a substantial impact on his life. Jim's wife could not accept his choice not to have the surgery, which ultimately contributed to a *debilitating* divorce. He defended his approach as considered, evidence-based, *not just going willy nilly down the holistic path*; yet described the psychological impact of resisting surgery as ongoing, *a mental thing that you have to deal with every day…it plays on your mind.* He advocated for men to have the opportunity to *stop and think about things and go, hang on a second, is this the right thing to do?*

*all names have been changed to preserve anonymity ** *italics* indicate verbatim quotes

Distrust of conventional medicine and embracing non-mainstream treatments

The men reported feeling disillusioned by conventional management options and medical opinion (Table 2). Many of those interviewed felt abandoned by their clinicians, specialists, and/or the Australian health care system when they resisted the recommended treatment. Some men expressed cynical views of the medical profession and speculated that the unequivocal advice for prostatectomy was driven by financial gain. They felt concerned that they were not getting the full story, from any clinician, about the range of potential management options.

> *'I am profoundly dissatisfied with what I see as the blinkered view of possibilities offered … and the incapacity of these people to consider anything outside their carefully regulated areas of expertise.'* (ID5)

In response, they pursued extensive additional testing and imaging and dedicated enormous time and energy to researching other available options. Almost all of the men had actively sought out and embraced an alternative management strategy outside of the mainstream system. For some this involved herbal supplements, Chinese medicine, or major dietary and lifestyle changes. For several others it involved visiting international clinics and having ongoing tests and unproven treatments that were vastly expensive (e.g. hyperthermia: targeted heat therapy applied to the area of the prostate). Men reported hearing about alternative treatments such as hyperthermia from other men in the support group. Several suffered pain and discomfort from their procedures, but still perceived them as a far better alternative than prostatectomy.

> (Hyperthermia) *'not an entirely pleasant experience but not nearly as debilitating as the radical (prostatectomy)'* (ID5)

Table 2: Summary of key findings with illustrative quotes

Main finding	Selected quotes
Men resisted the recommended treatment for a range of reasons	*'Erectile dysfunction would really upset me a great deal'* (ID2) (to avoid impotence) *'I was very worried about the possibility of long term incontinence…the idea of having to wear pads in my underpants for possibly the rest of my life was not attractive'* (ID5) (to avoid incontinence) *'[urologist said] based on your history and my examination I think if you don't have surgery you'll be dead in 5 years'* (ID9); *'(urologist said) you shouldn't let this go too long, 3 months max, you should be on the table and get rid of it'* (ID1) (perceived pressure)
Some men's resistance had a profound impact on their psychological wellbeing, life decisions and employment	*'So when someone tells you you're going to die in three years and you make a decision not to have an operation – you've got to make some life changes…I decided to make massive life changes'* (ID4) *'Immediately after the diagnosis I was thinking, ok, so how do I finalise my affairs?'* (ID3). *'It's a mental thing that you have to deal with every day… it plays on your mind'* (ID7)

	'3am in the morning when you wake up and you start thinking of how little of your life you might have left' (ID2)
Some men distrusted conventional medicine and embraced non-mainstream treatments	*'It just looked like a money making experience for me'* (ID7) *'[I] found out a hell of a lot more about the limited choices that conventional medicine offers…slash, burn or poison, surgery, radiation or chemo'* (ID6)
Some men reported lack of supportive environments to make informed decisions about testing or treatment	*'He [urologist] said "you don't want to be mucking around with this, you know, it is cancer"…he really scared the hell out of me… I thought, I better do this, whatever it is'* (ID6) *'I felt very much alone because I didn't have a doctor who I believed in'* (ID2)
Some men, over time, reframed the diagnosis and decisions made	*'I played that game for about three years, running around the world [seeking alternative ways of healing, treatment]…then I realised nothing was happening, I was fine'* (ID4) *'As time went on that level of anxiety, with knowledge… and additional information, and knowing how rigged the medical profession operates in this, in this particular sphere, it has sort of gone down'* (ID6)

Lack of supportive environment to make informed decisions about testing or treatment

It became evident across the interviews that the men felt they were offered limited, if any, time or resources to encourage or enable them to make an informed decision about either PSA testing or treatment. The majority of men were not familiar with what a PSA screening test was and received no information prior to being screened; some did not even know they had been screened until they were told their PSA was abnormal.

> *'I had no idea what a PSA test was. The doctor said "it's time" and I went along with it'* (ID2); *'I wouldn't even have known what a prostate was about'* (ID10)

A number of the men shared stories of urologists who scheduled their prostatectomies in the same appointment that their diagnosis was given. Only one participant was advised, after seeking a second opinion, to take his time in making a decision about surgery, which he said was very helpful at the time. Urologists were often perceived to be surgery-focused and with little consideration of what the individual man might want or need from the consultation. The men perceived little support or reassurance and noted an environment that provided little encouragement for them to ask questions or express individual priorities. They described real concerns that they wanted to be heard –that biopsies and surgery might spread cancer, fear of the side effects of surgery, being treated unnecessarily – but reported feeling that there was little possibility of discussing such matters with their urologist.

Men reported discussing their decision to resist the recommended treatment with family (mostly wives/partners and adult children) and friends. Some stated that their decision to refuse treatment led to some conflict in their relationships while others described their partners as being very supportive. Three of the men reported feeling reassured of their decision not to have surgery after making contact with other men who had made similar decisions (but implied their decision had been made before discussing with others). *'I'm grateful that I came across - that I did the research and came across the people who are in the same boat'* (ID7).

Reframing the diagnosis and decisions made

At the time of the interview, 8 of the 11 men had continued to resist the recommended prostatectomy, suffering no physical morbidity from prostate cancer. Several reflected on their personal situation and increasing awareness that their cancer had not progressed and may not ever do so, hence might not be the life-threatening scenario that had been presented to them. A number questioned whether seeking out alternative ways of healing and treatment had helped or whether they would have had the same outcome regardless.

> *'I played that game for about three years, running around the world* [*seeking alternative ways of healing, treatment*]*...then I realised nothing was happening, I was fine'* (ID4).

> *I've known for five and a half years that I've got cancer in me, and I'm still living, walking around, no side effects, no nothing… perhaps I will be ok* (ID8).

Some men explicitly considered the relevance of the overdiagnosis/overtreatment debate to their circumstances. One medically trained participant was highly informed about issues of overdiagnosis and overtreatment. He had reluctantly agreed to having a PSA test – a 'flawed screening test' – as an insurance requirement, after resisting screening for many years. This man, who had a prostatectomy after a very high PSA reading, wondered if he is one of the ones overdiagnosed or whether his diagnosis and surgery saved his life.

> *'There's a part of me that wonders did I fuck myself up because I waited three and a half years or did I fuck myself up because I had the cleanout...I'll never know. If I die in the next 5 years of metastasis then I'll know I waited too long… again, I'll never know. I mean, if I die of something else, I won't know if this never would've spread anyway, or they saved my life'* (ID9).

He indicated that he had spent considerable time questioning and reviewing the decisions he had made.

> *'I had lost a considerable amount of weight...I went to see the urologist and he said...you know, because of your PSA, he didn't say because you waited but it was implied, that maybe if I had addressed this three and a half years ago…'* (ID9)

Case study 3: TED

Ted was 56 years old when he was diagnosed with prostate cancer (Gleason 6), 15 years before this interview. He had never had a PSA test until he was referred to a urologist for a urinary tract infection. He admitted that he didn't even know what the prostate was. A PSA of 2.0 prompted a biopsy. When the urologist told Ted that the biopsy had detected prostate cancer, he implied that it was bad, *he was pretty grim*, and wanted to arrange urgent treatment. Ted was very concerned. In hindsight he has realised that *he (urologist) told me things that were not true….that probably it'd spread.* He received anti-hormonal injections (from which he suffered *massive* hot flushes) in anticipation of delayed surgery, because he was in the process of moving back to Australia after living overseas for some years. When he returned, Ted consulted multiple urologists about his treatment options, all with vastly differing opinions. Despite being told by one urologist that he would be dead within 5 years, he decided not to go ahead with surgery, *I wasn't keen to have any intervention if it wasn't necessary…I didn't have a lot of problem living with cancer.* Instead, at the advice of a non-interventionist urologist, he monitored the tumour via biopsies and PSA, which made his first urologist angry. Ted did eventually have treatment: first, brachytherapy, because it did not seem to be very invasive. It was painless and without side effects. Four years later, he had external beam radiation, again with minimal side effects. After 14 years of living with prostate cancer, Ted finally had a prostatectomy at the advice of his urologist after his PSA doubled (PSA increased from 2 to 4), despite originally being firmly against intervention. He describes the flow on effects that can eventuate from a positive PSA test: *you're damned if you do and it's a damned if you don't. You know, because you're on a dilemma and you really don't know how serious this dilemma is. '…I stayed with it—well I hadn't stayed with it I had it for 14 years and I eventually did have the treatment…I did have to have it in the end'.* He said over the 14 years he had plenty of time to find out about the possible side effects of surgery, most of which he didn't want. Following the prostatectomy, he had a lot of anal pain, lacks fecal control, and is impotent. He doesn't regret postponing the surgery. *But if you come to me in 5 years' time and I'm almost dead because I didn't have the surgery earlier I might have a different idea, mightn't I? … 'I hope I have nothing to regret, we'll see in 3 or 4 years' time but I'm getting past the 5 years that [the urologist] reckoned I would have' (to live).*

Another man strongly resisted the recommended management for a number of years following an elevated PSA result due to awareness of the harms of overdiagnosis but then reported having developed secondary cancer. He subsequently had mixed views on overdiagnosis because he is living with a progressed cancer that may have benefited from earlier detection. He questioned whether he should have agreed to further testing and treatment sooner.

> *'all that overdiagnosis is to try and save the one, turns out I'm the one so, I have mixed views on it'* (ID11).

Both men showed signs of self-blame for their decision-making. The uncertainty about whether the decisions they had made were the right ones seemed to play heavily on their minds and was ultimately unresolvable.

Case study 4: PETER

Peter was diagnosed with prostate cancer (Gleason 7) in 2013 at 56 years. He had for many years resisted having a biopsy, which was recommended to him following an elevated PSA (but normal DRE). He described a urologist *trying to force me to have a biopsy against my better judgment.* He felt that the information about *the wisdom of having a biopsy done simply on the basis of a rising PSA* was *conflicting,* and had heard concerns about overtesting and overdiagnosis on the radio. He recalled *at the time thinking I probably didn't have a serious problem…I thought the odds were still in my favour.* Instead, Peter chose to undergo ultrasounds of his prostate and had a new procedure (laser ablation) in New York: a *radical new treatment having great success.* He considered it his *best shot at having the treatment done and dusted*. It cost $30,000 (which *seemed like a good bet at the time…In hindsight I'd love to get my money back if I could*) and was *extremely uncomfortable* and *undignified, intrusive*. Initially, the specialists *pretty well declared the whole process a success*, and he was told to *go home and you shouldn't have any more worries.* However 12 months later his PSA had risen to 24, *so I clearly had a bit of a problem.* A full body CAT scan revealed a suspicious area in his hip, which was potentially a secondary cancer. The specialist's recommendation was for Peter to have hormone treatment – which he *really struggled with* - and then *fairly aggressive* radiation treatment. A radical prostatectomy was not an option after he had had the laser treatment. His thought process *at the time was, I'd pursued the sort of alternative treatment path thinking at the time that it was unlikely I had a severe problem anyway…I was sort of just being a little cautious.* But, *it turns out I was in that small percentage that had a serious growth. The alternative treatment hadn't worked.* By this stage he had realised that he *couldn't afford to screw around with this anymore,* his efforts *trying to manage my own prognosis* had been unsuccessful and he resorted to finding the best specialist he could. Peter described the whole process as *a rollercoaster*. At the time of interview, it had been two years since his radiation therapy. He continues to have side effects including some impotence and rectal bleeding. Peter had to reduce his working hours, *it has a real impact, a big impact.* He suffers from anxiety attacks and described sometimes being *almost petrified with fear.* The prostate cancer causes significant worry, *I'm still concerned that it's probably going to get me…I suspect that it's a matter of time.* Peter admitted that with hindsight he would have *changed my course of action… clearly I should have had a biopsy done.* He believes that it was a good decision to leave the first urologist and not to have had a biopsy straight away, but would have sought better specialist advice sooner, and had a prostatectomy if it was recommended. Peter continues to believe that there is *some truth* in the overdiagnosis and overtreatment argument, *but turns out I'm in that very small percentage…all that overdiagnosis is to try and save the one, turns out I'm the one, so I have mixed views on it…I'd be in much more serious trouble* had I not had the treatment.

Discussion

This study provides important, relevant insight into the lived experience of possible overdiagnosis. It reveals the substantial and sustained burden on men's lives as they continue to live with a potentially inconsequential cancer diagnosis alongside their decision to decline recommended treatment. Such accounts are rarely reported in the literature, hidden in part because we are mostly unable to identify individuals who have been overdiagnosed, given that it is rare to leave cancer untreated. Importantly these men's views contrast with many cancer patients' beliefs that their diagnosis was life-saving or life affirming and reveal the profound negative psychosocial impact of diagnosis.

Clinicians have traditionally under-appreciated the adverse impact of prostate cancer diagnosis and treatments thus resulting in limited visibility of these effects in the medical literature until recent years.[12 25 26] Previous work with clinicians shows that a strong driver of the continued use of PSA testing is the fear of missing a patient's cancer [27-29]. However, this fails to recognise the potential downstream consequences on men of unnecessary testing and overdiagnosis.

Particularly notable in this study were two men who had deliberately delayed testing and treatment because of concerns about overdiagnosis and overtreatment. They both eventually, reluctantly, received cancer treatment (one presented symptomatically with a secondary cancer, the other had a dramatic increase in PSA). At the time of interview they described significant uncertainty and angst about their decision to delay. Both had a very sophisticated understanding of overdiagnosis and recognised that they would never know if they had made the right decision. The guilt, questioning, and uncertainty that remains with that knowledge was significant and unresolvable.

In this sample, feeling uninformed and perceived pressured from specialists were considered more important reasons to resist surgery than avoidance of potential side effects of treatment. The findings demonstrate the real-life consequences of violations of the ethical principle of autonomy, with men reporting being tested for PSA without their knowledge. This is consistent with existing literature suggesting that many Australian men are not having treatment options for early prostate cancer adequately explained to them, and urgent surgical treatment is still frequently encouraged.[30] Research from the US suggests a similar picture with informed decision-making rare, [31] even when decision support is provided. [32 33 34] Recent findings from the US and Australia similarly suggest shared decision-making around PSA testing and prostate cancer treatment is limited. [30 33 35]

Poor public understanding of PSA screening and overdiagnosis is common (e.g. [36-38]) and likely exacerbated by lower levels of education and health literacy. [39] There is evidence that the harms of overdiagnosis and overtreatment are rarely explained to patients.[40 41] Overdiagnosis is a challenging concept to communicate [36 42] yet studies of prostate screening show that men want to be told about it.[43] Importantly, some research suggests that informing men about their options early, including the option of conservative treatment, might help mitigate long term decision regret.[44] Continued efforts to better communicate, inform, and empower men to avoid the implications described in this study are essential.

Men in this study felt inadequately prepared and unsupported from the point of the initial PSA screening test, to biopsy and treatment decision-making. A qualitative study of individuals who self-identified as having an overdiagnosed thyroid cancer and decided not to intervene with surgical treatment revealed similar findings to this study.[45] Their experience was characterised by feelings of isolation and ongoing anxiety resulting from lack of social and health care system acceptance and support for their decision to resist treatment. The view that treatment is needed and life-saving is normalised such that attitudes contrary to that norm may be dismissed and rejected.

Although this study cannot discern causation, it could be that distrust in conventional medicine may ensue from feeling inadequately informed and unsupported. It is noteworthy that many of the men pursued expensive alternative tests and treatments that have little current supporting evidence of efficacy, with a strong desire to ‘do something’. This revelation is not surprising given that a recent Australian study documented increased distress and anxiety in men who opted to monitor their low-risk prostate cancer rather than actively treat it,[46] and a 5-year follow-up study found that 23% of men discontinued active surveillance despite no evidence of cancer progression.[47]

There was a wide range (1 to 20+ years) of time since diagnosis when the interviews took place. These findings should be considered in the context of changes over time and current management of localised prostate cancer. Prostate screening, diagnosis, and management strategies have changed rapidly over the years and we recognise that shifting policy, service provision, and information resources (e.g. internet) over that time might have impacted on men’s experiences and perceptions reported here. Changing technologies and new knowledge have advanced the field. Active surveillance, which is now recommended for men with low risk disease, was not a common option when some men in this study were first diagnosed. Uptake of AS as a management option for low risk prostate cancer is increasing in Australia with current estimates indicating around 36% of men with low risk prostate cancer accept AS [48]. Importantly, active surveillance was not offered as an option to several recently-diagnosed low-risk men in our sample, suggesting that despite the evolving evidence clinical practice is slow to change.

Strengths and limitations

To our knowledge, this is the first study to document how men diagnosed with prostate cancer reconcile issues of overdiagnosis and overtreatment and make sense of these issues in relation to their own situation. There are considerable challenges to identifying individuals with cancer who have chosen not to be treated and show some awareness of the issues of overdiagnosis. Our study is the first to achieve this in prostate cancer.

Our sample was small and the men were well educated, economically successful, and had high health literacy. This may have provided increased confidence and capacity to challenge medical advice, and to seek out and understand complex health information and concepts such as overdiagnosis and overtreatment. Recent evidence suggests that men with higher education and income in Australia and US are more likely to have PSA testing and therefore be diagnosed with prostate cancer.[49 50] Our participants were initially recruited through a support group founded by men who had resisted surgical management of prostate cancer. Although resisting treatment altogether may not be a common experience, the concerns and reactions of these men to their situation would likely be salient for the many men with localised prostate cancer who find themselves facing this unpleasant dilemma. Many of the cancer-related fears and uncertainties expressed by the men in our sample are similar to those reported in studies from North America[51 52] and are likely to transcend international borders. They therefore provide important leads for further research internationally.

We note that recall bias is possible given that it had been many years since diagnosis for some of the men in this sample, in addition to the impact of a cancer diagnosis on information retention.[53] However, men's past and current perceptions of how their diagnosis and decisions made still affects them is meaningful and relevant in this context.

Conclusion

Widespread overdiagnosis of prostate cancer remains an important health problem [2]. The immense psychosocial consequences of a potentially unnecessary diagnosis must be taken into account in any discussions and decisions about PSA screening. These findings underscore the need to respect the ethical principle of autonomy by supporting men to make informed decisions about both screening and treatment in a clinical situation laden with so many uncertainties. Ultimately, the way to address the psychosocial burden of overdiagnosis and overtreatment of localised prostate cancer (especially low risk prostate cancer) is to better inform men and move decision making upstream, prior to diagnosis and prior to screening. More efforts to support informed choice and shared decision making at the point of PSA testing are needed.

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Appendix I

Interview Guide

The goal for this interview is for you to take us through how you were diagnosed with prostate cancer and describe your experiences and thoughts about your diagnosis. This is important so that we can gain an understanding of the range of men's views and experiences with the disease.

Also, this interview will be audio-recorded to ensure that we have an accurate record of your responses, and everything you say will be kept strictly confidential. If it is alright with you I will start the audio-recording now.

Do you have any questions before we begin?

So firstly if I (we) could just ask you a few demographic questions:

1. **What is your age?**
2. **What is your current work status (working full-time, working part-time, retired)?**
    - Can you please describe your current or previous occupation?
3. **What is your highest level of education?**

Now can you please take me (us) through from the start how you came to be diagnosed with prostate cancer and how it has affected your life?

Prompts:

- GP / PSA test experience (screening or symptom led, informed about screening in any way or not)
- Specialist experience (tests offered, diagnosis given, prognosis given, treatments offered, communication)
- Language doctor used to describe your condition and impact of the term 'cancer'
- Second opinions
- Kinds of information given by the doctors about the diagnosis
- Feelings about initial diagnosis
- Experience and attitudes towards biopsy
- Impact on self, family, friends, life, work, feelings during everyday life, spirituality (refer to Brodersen et al. questionnaire items as potential list of additional prompts if issues not raised)
- Influence of family and friends in the process of treatment decision making and coping
- Trust in the medical profession
- Overdiagnosis – some people feel that there shouldn't be PSA testing in the first place – What's your view about that?
- Treatment decision making – What treatment was chosen? How do you feel about your treatment decision?
- How was information found?
- Impact of being part of a support group? (Prostate-Cancer Organisation)

If haven't mentioned: How long ago was it that you started on your prostate cancer journey?

[If appropriate] It sounds like you had a difficult experience with XYZ… To help us try and improve things for other men who may find themselves in your situation in the future:

Ask men to read out and discuss

Items from Brodersen quality of life questionnaire (Brodersen J, Thorsen H. Consequences of Screening in Breast Cancer (COS-BC): development of a questionnaire. *Scand J Prim Health Care* 2008;26:251-6.

I have felt scared.
I have felt terrified.
I have been worried about my future.
I have been upset.
I have felt restless.
I have been nervous.
I have been irritable.
I have been quieter than normal.
I have found it hard to concentrate.
My appetite has changed.
I have withdrawn into myself.
I have had difficulty dealing with my work or other commitments.
I have had difficulty doing everyday things around the house.
I have felt sad.
I have been worried.
I have felt time passed slowly.
I have been uneasy.
I have felt unable to cope.
I have been depressed.
I have felt less interest in sex.
I have kept busy to take my mind off things.
I have felt less attractive.
I have slept badly.
It has taken me a long time to fall asleep.
I have woken up far too early in the morning.
I have been awake most of the night.

What do you think is the most important thing that could be changed to improve the experience you had?

Well __________ I think we're just about ready to wrap up the interview. Thank you very much for your time, it is really appreciated. Do you have anything further to add or have questions for me before we wrap up?

Okay, thanks again and should you have any additional questions all of our contact details are provided on the Participant Information Sheet we handed out to you.

Standards for Reporting Qualitative Research (SRQR)*

http://www.equator-network.org/reporting-guidelines/srqr/

Page/line no(s).

Title and abstract

Title - Concise description of the nature and topic of the study Identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended	P1
Abstract - Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions	P2

Introduction

Problem formulation - Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement	P4-5
Purpose or research question - Purpose of the study and specific objectives or questions	P5

Methods

Qualitative approach and research paradigm - Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., postpositivist, constructivist/ interpretivist) is also recommended; rationale**	P5
Researcher characteristics and reflexivity - Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, and/or transferability	P6
Context - Setting/site and salient contextual factors; rationale**	P6
Sampling strategy - How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale**	P6
Ethical issues pertaining to human subjects - Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	P6
Data collection methods - Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings; rationale**	P6

Data collection instruments and technologies - Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study	P6
Units of study - Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	P6-7
Data processing - Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/de-identification of excerpts	P6-7
Data analysis - Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale**	P6-7
Techniques to enhance trustworthiness - Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale**	P6-7

Results/findings

Synthesis and interpretation - Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	P7-15
Links to empirical data - Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings	P7-15

Discussion

Integration with prior work, implications, transferability, and contribution(s) to the field - Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/generalizability; identification of unique contribution(s) to scholarship in a discipline or field	P16-18
Limitations - Trustworthiness and limitations of findings	

Other

Conflicts of interest - Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed	P20
Funding - Sources of funding and other support; role of funders in data collection, interpretation, and reporting	P20

*The authors created the SRQR by searching the literature to identify guidelines, reporting standards, and critical appraisal criteria for qualitative research; reviewing the reference lists of retrieved sources; and contacting experts to gain feedback. The SRQR aims to improve the transparency of all aspects of qualitative research by providing clear standards for reporting qualitative research.

**The rationale should briefly discuss the justification for choosing that theory, approach, method, or technique rather than other options available, the assumptions and limitations implicit in those choices, and how those choices influence study conclusions and transferability. As appropriate, the rationale for several items might be discussed together.

Reference:

O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. **Standards for reporting qualitative research: a synthesis of recommendations.** *Academic Medicine*, Vol. 89, No. 9 / Sept 2014
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