**Title: Evaluating the utility of written information in treatment choice of active surveillance in men with low risk prostate cancer.**

**Abstract**

Active surveillance (AS) is a treatment option offered to men with low risk prostate cancer, as an alternative to other radical curative interventions. AS involves regular consultations, digital rectal examinations and repeat biopsies, and men need to be given relevant and accessible information to help them make an informed choice about their treatment plan. In a local NHS Trust, AS has been offered for several years, yet it is not known whether the written patient information which is given to men at diagnosis is useful to them. In the context of patients being active participants in their own care, it is important to review the ways in which we disseminate information to help people make treatment choices. This small evaluative study was designed to explore men’s views of the utility of written information in their decision making about treatment options for low risk prostate cancer. Data were collected through semi structured interviews, and interview transcripts were thematically coded. Findings suggest that written information is less useful to men than clinical consultations, which may have implications for the ways in which we involve and support men with prostate cancer in making their treatment decisions.

**Key Words**

Prostate cancer; active surveillance; patient information; decision making; treatment decisions; informed choice.

**Introduction**

Prostate cancer accounts for around 26% of all the male cancers diagnosed in the UK and it is predominantly a disease of older men (65-79 years old). Around 25% of prostate cancers occur in men younger than 65 (NICE, 2014), and it is estimated that 84% of patients diagnosed will survive 10 years or more (Cancer Research, 2015). The use of the prostatic specific antigen (PSA) blood test is widespread, and whilst it is an effective diagnostic tool it has also has raised concerns about the over-detection of prostate cancer. The sensitivity of the PSA test means that low risk conditions that would otherwise have remained dormant (Dall’Era et al, 2008), are being increasingly identified. These low risk cases are defined by National Institute for Health and Care Excellence (NICE 2014) and European Urology Guidelines (2013) as prostate cancer where a man has a PSA below 10 and a clinical stage of T1-T2a, and where histological findings are equal to or below Gleason 6. Routine prostate screening is not currently practiced in the UK (NHS, 2015a) but with an increased demand for PSA testing from the public, more men are being diagnosed with low risk, confined, prostate cancer (Dall’Era et al, 2008).

In the UK there are currently several treatment options available to manage prostate cancer, including radical radiotherapy, radical prostatectomy and surveillance programmes such as ‘watch and wait’ and active surveillance (NICE 2014). Active surveillance (AS) can offer an alternative to immediate radical intervention and follows a protocol of repeated PSA blood tests, digital rectal examination (DRE) and in some cases, biopsies and magnetic resonance imaging (MRI).The primary goals of AS monitoring are to avoid unnecessary treatment of an indolent disease, but also to promptly identify evidence of higher risk disease that merits immediate intervention (Kates et al, 2015).

Early studies evaluating AS suggest that this treatment approach has clinical merit. A prospective phase 2 trial of 299 men with intermediate risk prostate cancer showed an 8 year disease specific survival rate of 99% (Klotz, 2006) and in a later study Klotz et al (2010) estimated the risk of dying from other causes during AS as 18.5 times greater than prostate specific mortality. Large scale randomised controlled trials (RCTs) of the effectiveness of AS are limited, and the ‘Protec T’ trial is currently investigating the relative effectiveness and cost of the different treatment options in 1643 men with clinically localised prostate cancer (Lane et al, 2014). Findings are due to be reported in 2016, and it is expected that they will be able to clarify the crucial trade off between survival gains and potential harm associated with over detection and the different treatment options available for prostate cancer (Lane et al, 2014).

**Patient information and decision making**

Within the UK the need for patient involvement in treatment and decision making is central to the philosophy of patient centred healthcare, and emphasised in a range of national policies and guidelines. These include The Cancer Plan (DOH, 2001), Prostate Cancer Guidance (NICE 2014), Quality Standards for Prostate Cancer (NICE 2015), Living with and beyond Cancer (DOH, 2013) and Patient Experience in Adult NHS services (NICE 2012). Central to all these policies is recognition of the need for appropriate patient information and support about choice and treatment options. UK policy advocates that patient information should be evidence based, unbiased, high quality, and individualised.

When a man is offered AS it is with the understanding that their prostate cancer is defined as low risk, and that radical curative treatments are also available as alternatives. With no single gold standard treatment being recommended for these men, appropriate information and support is essential to informed treatment choice (Zeliadt et al 2006). Quality standards for prostate cancer (NICE 2015) require that men are supported in their treatment decisions, and therefore the health professional’s role involves providing unbiased information and respecting the patient’s choice (NHS 2012).

In the local NHS Trust AS has long been offered as a treatment option for men with low risk prostate cancer, and has been delivered as part of the care pathway. Men are offered consultation with members of the medical team and with specialist nurse practitioners, and these consultations are supported by written information packs which men and their families may refer to whilst making their treatment decisions. This practice has been founded on an understanding that written information will complement the clinical consultation and help men to make an informed choice about their preferred treatment option (Gilbert et al 2014; Hurwitz et al 2015). Through local clinical governance mechanisms it has always been found that the local prostate cancer services are satisfactory to service users, but the value of the written information packs in supporting treatment choice has never been explored. In the context of the commitment to monitor the cancer patient experience, both nationally and locally (Carbello, 2008; Health Quality 2014), this evaluation study was therefore designed to explore the utility of the written information given to men who had opted for the active surveillance treatment option.

**Method**

In a recent National Cancer Experience questionnaire (Health Quality, 2014) very few local men with prostate cancer participated, so it was deduced that a more appropriate tool to capture the patients experience was individual interviews. The aim was to interview six current patient on the AS pathway, in order to provide a ‘snapshot view’ of the utility of the information packs. Semi-structured interviews are particularly useful for describing and defining an experience (Lazenbatt, 2002).

The questions used to frame the interviews were adapted from those used in Davison et al’s (2009) study, which explored factors influencing men’s choice of AS. In addition, areas that have guided national policy (NICE, 2012; DOH, 2013) and the current practice of the department also informed the interview topic guide. Taking into consideration the broader political and social context of the subject area allows the interviewer reflexivity, which can assist in unpacking assumptions they may have unwittingly brought to the evaluation (Green & Thorogood, 2011). A pilot interview was carried out with a man who was an activist member of the local prostate support group to establish that the questions were understandable, jargon free and relevant.

Permission to recruit and interview a sample of the patient population was secured from the Trust audit department and was authorised by the Clinical Governance, Information Governance, and Legal teams. Six patients consented to participate in the interviews and agreed to the discussion being audio recorded. All data were handled in accordance with the Data Protection Act 1998 (Carey, 1998).

The interviews were conducted by the prostate nurse specialist, guided by the interview topic guide and prompts. Interviews were transcribed verbatim to provide a reliable record (Green & Thorogood, 2011), and transcripts were then analysed using a thematic coding system (Robson, 2011).

**Findings & Discussion**

As in many qualitative evaluative studies the numbers participating in this study were small, but the similarities of the men’s experiences to the findings of other studies did provide some validation of the data and its analysis. However, it is acknowledged that the interviewer was also the specialist nurse, which may have led the participants to give a “public account” of their experiences (Green & Thorogood, 2011).

The participants’ age range was between 59 to 74 years, and they had been on the active surveillance pathway for between 6 months and 3 years. In one interview the patients’ wife was present, and dominated the discussion. Whilst this contribution provided valuable insights, indicative of her feelings, at this stage of the enquiry the study was only interested in the men’s perspectives, so the transcript was excluded from the analysis.

**The information packs**

The written information provided to our patients includes some web addresses for reliable information sources, and details of local support groups, so men were asked to describe the other sources of information they had accessed in reaching their decision to opt for AS. It was interesting to find that the internet and support groups were not widely used.

 *“I really didn’t go too deep into the internet .......in case we read too much”* (1004)

*“thankfully I haven’t got the internet” (1007)*

*”don’t use computers” (1002)*

*”I’m a techno phobe, I don’t use a computer. I’d rather build a wall “(1006)*

This finding contrasts with a number of other studies that have found the internet to be an invaluable resource for patients (Gilbert et al, 2014; Silk et al, 2013; Gorin et al, 2011; Davison et al, 2009). However, it may be typical of the local population and perhaps should be interpreted within the context of the socio-demographic profile of the area in which the NHS Trust is located. Although access to and use of Information and Communication Technology (ICT) was not explored in depth in this small study, it may be the case that the local population do not have easy access to ICT, or it could be indicative of the way people conceptualise trustworthy information when confronted with a cancer diagnosis.

It was also interesting to find that local prostate cancer support groups were not accessed by any of the participants interviewed. The following are typical responses to questions about support groups and sharing information about the diagnosis,

 *” I told a few friends.......I didn’t go to any support group” (*1007)

*“my wife went to support groups [for her cancer] but I didn’t feel I needed to”* (1006)

The wider body of evidence regarding men’s participation in support groups is inconclusive, and Harrison et al (1995) suggested that men underutilise cancer support groups when compared to women. They also found that men were more likely to disclose their diagnosis to one confidante, while women used a large circle of friends and family. Thaxton et al (2005) reviewed the professional literature on prostate cancer support groups, and noted that a majority of prostate cancer patients will never attend a support group. Detailed explorations of reasons why this is the case have not been addressed, but again it may be related to men’s views of what they consider to be reliable and trustworthy sources of information when dealing with a potentially life changing diagnosis.

In addition to web and support group addresses, the written information packs given to men also includes the Prostate Cancer UKs Toolkit (Prostate Cancer UK, 2015). It was interesting to find that the content and quality of the information packs was not discussed by any interviewees, and it was not influential in their decision to chose the AS treatment option.

*” I probably glanced through it “(1002)*

*“it was telling me what I was told basically” (1003)*

*“just useful information” (1004)*

Given that the information packs are provided to reinforce and support men in their decision making these findings were particularly interesting. They once more raise questions about how men with low risk prostate cancer conceptualise their information needs and what, for them, constitutes a useful and reliable source of information.

**The clinical consultation**

Although the interviews were primarily seeking to explore the utility of the written information packs, the participants all spoke at length of the clinical consultation and its’ role in their decision making. Locally these significant consultations were with the physician and the clinical nurse specialist.

*” the doctors and everyone is um doing the best for me you know they’re looking out for me ...you’ve studied, you know what you’re talking about and he explained it to me “(*1004)

*“...with this clinic everything is explained to me and you know I understand it I mean I’m no expert but I’m not dim ...you’re looking after my interests .. you’re looking after my health ..” (*1004)

*“the specialist ...and I saw the specialist nurse and they were all really good*” (1006)

This finding is consistent with those of Silk et al (2013) and Gilbert et al (2014), who found the physician to be the most preferred and most helpful source of information for men with prostate cancer. Gilbert et al (2014) also suggested that the consultation was highly valued as it is specific to individual situations. It is perhaps not surprising that the participants in this study also preferred the individual consultation as their information source. A cancer diagnosis, even one that is ‘low risk’, may make men feel isolated, and possibly overwhelmed, by the potential impact on their future, so information which is specific to them and their circumstances is highly valued. However, this finding once again raises questions about the utility of written information packs for men when they are making treatment choices.

**Implications for practice**

Despite the recommendations that written information is paramount in the cancer patients’ journey (NICE, 2015a; DOH, 2013), this small study did raise some questions about the utility of written information packs for these men with low risk prostate cancer. The findings have indicated that written information and support may not be a priority for patients, and have also demonstrated that patients do not rely on written information to support their treatment decision making.

The consultations with the healthcare team appear to be the most valued source of information, and professionals’ recommendations were the leading influence in the treatment decision making of study participants. With additional pressure created by the emergence of vast amounts of information available on the internet, some of dubious provenance, it may be the case that the clinical consultation is now more important than ever as a point of access, communication, understanding and participation in care.

In the UK NHS all services are now subjected to severe austerity measures, and in the current climate it would be difficult to reconcile patients’ preferred information sources with the political requirement to make financial savings. Whilst written information packs may be inexpensive compared to expert staff costs, if they are not meeting patients information needs then they may themselves need to be reconsidered. An alternative approach (Azier et al 2013) suggests that all men with low risk prostate cancer are seen in combined specialist clinics with access to urology, surgery, and oncology services, supported by nursing services and information. Whilst these specialisms may not be available in all centres, a more practical option might be to ensure that clinical nurse specialists, or nurse led clinics, are always available to reinforce the consultation and support men’s information needs in making their treatment decisions for low risk prostate cancer.

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