Title: The impact of supportive nursing care on the needs of men with prostate cancer: a study across seven European countries

Running Title: The impact of supportive nursing care in prostate cancer

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Contributors:
JC-H and SF conceived the design of the study and acquisition of the data. JC-H, SF, DK, FCS, LD, HEF, BTJ were responsible for the design and analysis of the study. JC-H, KL, EvM, FC-S, BTJ, SK were responsible for undertaking data collection within their respective European countries. The initial draft of the paper was produced by JC-H and SF, and circulated between all authors for critical revision. All authors were involved in the descriptive data and read and approved the final manuscript.

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Conflicts of Interest:
None declared
ABSTRACT
Background: Prostate cancer is for many men a chronic disease with a long life expectancy after treatment. The impact on men of prostate cancer therapy has been well defined however; explanation of the consequences of cancer treatment has not been modelled against the wider variables of long term health care provision. The aim of this study was to explore the parameters of unmet supportive care needs in men with prostate cancer in relation to treatment and experience of health care.

Methods: A survey was conducted among a volunteer sample of 1001 men with prostate cancer living in seven European countries.

Results At the time of the survey 81% of the men had some unmet supportive care needs including psychological, sexual, health system and information needs. Logistic regression indicated that lack of post-treatment nursing care significantly predicted unmet need. Critically men’s contact with nurses and/or receipt of advice and support from nurses, for several different aspects of nursing care significantly impacted on men’s outcomes.

Conclusion: Unmet need is related not only to disease and treatment factors but is also associated with the supportive care men received. Imperative to improving men’s treatment outcomes is to also consider the access to nursing and the components of care they provide especially after therapy.

Key Words: Survivorship, Consequences of cancer treatment, Nursing, Supportive care, Prostate cancer
INTRODUCTION

Prostate cancer is a significant health burden within Europe with recent survival data suggesting that numbers of men with this disease will increase over the next 20 years (Berrino et al, 2007),(Siegel et al, 2012). Prostate cancer is being detected earlier and as a consequence more men receive treatment and subsequently face adverse effects of therapy (Resnick et al, 2013b). Despite improvements to cancer treatment some men will continue to experience long term consequences. Population based studies have highlighted that prostate cancer survivor’s report significant chronic illness compared to age matched controls; with poorer health status and reduced quality of life (Van Hemelrijck et al, 2010),(Higano, 2012),(Lustberg et al, 2012),(Elliott et al, 2011),(Khan et al, 2011). Increasingly there is recognition that lifestyle factors correlate with the risk of late pelvic symptoms after prostate cancer treatment (Thomas et al, 2013) and can impact on men’s overall survival (Kenfield et al, 2011). Such survivorship results in an enduring requirement for health care monitoring and challenges providers of cancer care, to effectively respond, to men’s long term supportive care needs (Harrison et al, 2009),(McCabe et al, 2011),(Simonelli et al, 2008). Critical to health service planning is recognising factors contributing to men’s poorer health and the ability to identify what supportive care packages, such as nursing, are needed at which time in the treatment and recovery pathway.

Although studies of prostate cancer often focus on functional outcomes of therapy the extent to which adverse effects bother men also needs careful evaluation (Luckett et al, 2009),(Pachman et al, 2012),(Seklehner et al, 2012). Understanding the importance of comprehensive patient outcomes is essential in delivering whole patient cancer care (Stanton, 2012),(Jacobsen et al, 2012). Studies exploring unmet needs of men with prostate cancer consistently show that these needs are highest in relation to psychological and sexuality
issues, as well as information about treatment and care in the health care setting (Boberg et al, 2003), (Stegina et al, 2001), (White et al, 2012). Several predictive analyses from unmet needs studies have found significant associations between unmet need and factors of age, education, marital status, treatment variables, disease characteristics and mental affect (Ream et al, 2008), (Smith et al, 2007). None of these studies have explored unmet need against the type or nature of supportive care these men received. Identifying the characteristics of unmet need and nursing outcomes over the cancer pathway can contribute to the evidence of impact of specialist nurses as well as clarify quality parameters in providing good aftercare. In this study we examine the relative predictive impact of prostate-specific dimensions of nursing care on the scope and extent of men’s unmet supportive care needs across seven countries within Europe.

MATERIALS AND METHODS

We surveyed men with a diagnosis of prostate cancer living in Denmark, France, Ireland, Netherlands, Spain, Turkey and the UK via on-line and paper questionnaire. Survey information was posted on support group, charity and nursing organisation websites and leaflets were distributed through support networks and clinic settings. The questionnaire was translated and response was anonymous.

The Supportive Care Needs Survey (SCNS) is a valid and reliable 34-item tool for assessing cancer patients’ unmet needs. It assesses five domains: psychological; sexuality; health system and information; physical and daily activity and patient care and support (Boyes et al, 2009). Need for help is rated on a five-point scale: 1 = not applicable, 2 = satisfied, 3 = low need, 4 = moderate need and 5 = severe need. Five items from the SCNS prostate-specific module related to urinary function, bowel function and hormonal effects were also used.
The EuroQol EQ-5D-3L is a standardised, valid and reliable measure of health status for clinical and economic use (Pickard et al, 2007). It measures five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each is scored on a three-point scale representing no problem, some problem and extreme problem. A self-rating scale of Health State is scored from 0-100 on a visual scale, 0 representing the ‘worst imaginable health state’ and 100 representing the ‘best imaginable health state’.

Experience of supportive nursing care was measured using a scale developed by the authors. It contained nine dimensions of supportive care commonly provided by hospital nurses. The items were developed based on research literature utilising evidence from specialist nursing domains (Eicher et al, 2012) and clinician and patient consultation in each of the seven countries. Response was measured on a four point scale by participants indicating for each dimension if they strongly agreed, agreed, disagreed or strongly disagreed that they had received advice and support. If they had not seen a nurse at all for that dimension of care they were asked to check a fifth column. These questions aimed to provide patient-reported data for nursing provision and covered supportive care across the disease journey.

We also collected demographic characteristics (age, education, living status, ethnicity and country of residence), and disease and treatment characteristics (time since diagnosis, treatment modality, time since treatment, time last assessed by a clinician and stage of disease).

We hypothesised that demographic and treatment characteristics, patient reported outcomes of quality-of-life (mental-affect and health state) and patient experience would be associated
with unmet needs of men with prostate cancer. Descriptive analysis examined sample characteristics and patient-reported outcome measures. Analysis for SCNS domains was conducted on an overall response of no need (all item responses of not applicable or satisfied) vs. some need (at least one item response of low, moderate or high unmet need). Within each domain, missing item responses were imputed using multiple imputations (Markov Chain Monte Carlo method) in SPSS version 19.0.

Predictive modelling for some need was developed using the backwards elimination selection procedure to identify suitable logistic regression models for each of the five domains based on the pooled model results. Where possible, interactions were included in the models but none were found to be significant. All testing was conducted at the 5% significance level. Covariates incorporated into the models included known predictors of need from other published studies: age, country of residence, education, living status, stage of disease, time since diagnosis, time since last assessed, treatment modality, treatment status nested within treatment degree, mental affect (measured by the EuroQol item on depression and anxiety) and health state (Figure 1). Nine variables relating to supportive nursing care across the disease journey were introduced to the final analysis to assess whether men’s experience of nursing care could explain any variation over and above that explained by the initial models. Backwards elimination was used to remove non-significant terms. The resulting final models were all statistically significant $p<0.001$ for all domains. The Youden indices ranged from 0.316 to 0.564. Sensitivity and specificity were higher comparing the models with nursing care variables to the initial models for the psychological, health system and information and the patient care and support domains.
RESULTS

Data was based on 1001 complete questionnaires (Table 1). The majority of participants were aged between 61-80, of white ethnic origin and living with others, and there were similar numbers of men in each of the education categories (Table 2). Over one-quarter of the sample had been diagnosed within the last year, and one-quarter 1 and 2 years previously. 36.9% of men were receiving treatment at the time of the survey, 20.5% were <1 year out of treatment and 40.4% were ≥1 year out of treatment; few were considering treatment. Equal numbers of men had received radical prostatectomy, radiotherapy or hormone therapy (43.6%/44.6%/43.8%), fewer men had experience of active surveillance (16.2%) and watchful waiting (12.2%), 57.7% of men had received multiple treatments. Moderate or extreme anxiety or depression (mental affect) was reported by 33.7% of men and mean self-rating for health state was 74.3 (Standard Deviation 17.6 Median 80, 65/90) (Table 2).

More than 80% of men in the sample had some unmet need across the five domains measured; psychological, sexuality and health system and information needs had the greatest prevalence (Table 3). The prostate-specific symptoms were reported by over half the participants: incontinence or dysuria was the most prevalent, followed by hormonal symptoms and then bowel problems (Table 3). Over 45% of men indicated that they had not seen a nurse at all for one or more dimensions of care during their pathway (Table 4). When men had seen a nurse, support and advice was highest in pre-treatment and immediate treatment-related care: over 80% had received advice and support for, screening, diagnosis, side-effects and treatment after-care. However, fewer men reported advice and support for longer-term effects, home-care, choosing treatment options, referral and emotional support (Table 4).
Dimensions of post-treatment nursing care significantly and independently predicted unmet need. The most common aspect was for longer-term effects: men who had not seen a nurse about longer-term effects were twice as likely to have health system and information needs and patient care and support needs. Similarly, men who had not had advice and support from a nurse for longer-term effects were three times as likely to have health system and information needs and patient care and support needs. Additionally, men who had not received advice about longer-term effects were twice as likely to have psychological need (Table 5).

Three further areas were significantly associated with unmet need: not seeing a nurse for treatment side-effects was associated with psychological need, lack of advice and support for after-care was associated with patient care and support need and lack of advice and support for home care was associated with sexuality and health system and information need. Nursing care did not predict need in the physical and daily living domain (Table 5). A number of further factors impacted on unmet needs. The country a man lived in, the stage of his disease and the type of treatment he had experienced were the most common demographic and treatment predictors of unmet need (Table 5). Men in Spain were more likely to have psychological and health system and information needs, and together with men in France, they had a higher probability of sexuality-related needs than men in Denmark (reference category). Men with more extensive disease were more likely to have psychological and health system and information needs and to require help with patient care and support issues. Treatment modality was a significant predictor of unmet need in three respects. Having had chemotherapy was strongly predictive of need for help with physical and daily living issues, radical prostatectomy was predictive of unmet sexuality need, and men who had had radiotherapy were less likely to have psychological need than men who had not (Table 5).
Men who had finished treatment ≥1 years ago were significantly less likely to have physical and daily living needs compared to men on-treatment. The more recently a man had been assessed by a clinician the more likely he was to have health system and information needs. Conversely, men diagnosed 1-2 months ago were ten times more likely to need help with sexuality issues than men at diagnosis (within the last month). Neither age nor education or living status was found to be significant predictors of unmet need in any domain having included the nursing care predictors.

Patient reported parameters of mental affect and health state were each associated with unmet need for all domains (Table 5). Increasing health state by one unit produced an estimated decrease in odds of reporting need ranging between 1.7% and 4.2% across domains. Men with moderate or severe anxiety or depression were approximately twice as likely to have sexuality, health system and information, patient care and support or physical and daily living needs, but in line with previous studies, this association was greatly increased in relation to psychological need (Odds ratio = 7.604). Questionnaire format was significantly associated with unmet need: men who completed the survey in paper format were less likely than men who had completed it on-line to have unmet psychological physical and daily living needs (Table 6). The differences associated with this reporting may reflect that those more able to access paper format were often in the hospital setting whilst internet based questionnaires were more widely distributed.

**DISCUSSION**

This study makes an important contribution to the understanding of the role of supportive care in addressing survivorship needs for men with prostate cancer and the significance of
nursing on reducing men’s unmet needs. In addition to disease and treatment characteristics: lack of contact with a nurse, or advice was associated with men’s unmet needs. The areas of high need reflect other survey data (Boberg et al, 2003),(Feldman-Stewart et al, 2010), (Harrison et al, 2011) which suggests that current services may not be addressing on-going concerns that impact on men’s long term distress (Davies & Batehup, 2011),(Foster et al, 2009). This provides evidence that access to nurses has a significant influence on patient outcomes, and importantly indicates that there are areas of care, in particular after cancer treatment support, that nursing could improve.

Relatively few studies have hitherto researched how supportive nursing care can impact on men’s outcomes after prostate cancer treatment (Ream et al, 2009),(Cockle-Hearne & Faithfull, 2010; Faithfull et al, 2011), (Chambers et al, 2011; Sussman et al, 2011). Systematic reviews on efficacy of specialised oncology nursing interventions offer evidence that nurse provision leads to improvements in the management of chronic problems and increase patient knowledge, self-management, reduction in use of acute services and improve patients symptoms (Sussman et al, 2004),(Corner, 2003). Subsequently nurse-led care and co-ordination roles have been promoted as an important component of breast cancer services (Eicher et al, 2012) and have been embraced by cancer teams as part of quality care provision (Roselli Del Turco et al, 2010). Strong evidence that the provision of breast cancer specialist nurses have a psychological impact on women has come from randomised trials both during and after treatment. These studies indicate that nurse intervention reduces anxiety (Yates et al, 2005),(Wengstrom et al, 2001), distress and depression (Fors et al, 2011),(Strong et al, 2008) and increases satisfaction in women compared to usual care (Beaver et al, 2012),(Aranda et al, 2006). However, in a randomised trial of specialist nursing support for women compared with that provided by a psychologist there were no significant differences
in outcome (Arving et al, 2006). This would suggest that it is the intervention provided, targeted against the need, rather than necessarily the role that impacts on patient experience. Such a targeted model has been evaluated in Canada with specialist community nurses providing care co-ordination: this led to a marked improvement in patients unmet supportive care needs (Sussman et al, 2011). Defining the individual dimensions of supportive care required by men in this present study has provided potential targets for cancer nursing intervention within Europe. Fundamental to this is a comprehensive understanding of patient-specific need as an essential precursor to appropriate interventions and for facilitating access to relevant supportive care services (Chubak et al, 2012), (Stricker et al, 2011).

It is clear that treatment factors remain important predictors of patient outcome. Men in this study reported higher levels of unmet need in related to specific treatment modalities, including chemotherapy which was strongly predictive of need for help with physical and daily living issues and radical prostatectomy which was predictive of unmet sexuality needs. Men, who had had radiotherapy, were less likely to have psychological need than men who had not. These unmet needs are consistent with recent prospective clinical studies comparing radiotherapy and prostatectomy, men who underwent radical prostatectomy; were five times more likely to have urinary incontinence and twice as likely to have erectile dysfunction at 5 years than those men in the radiotherapy group (Resnick et al, 2013b). Late effects from prostate cancer treatment are often time dependent and men’s lifestyle and co-morbidity can impact on rectal, urinary and erectile dysfunction (Thomas et al, 2013). Sexual dysfunction is common in the older population and co-morbidities impact on the complexity of predicting erectile problems post treatment (Nelson et al, 2010). It is therefore important to have discussions with men about prevention and possible management of erectile dysfunction prior to and after therapy (Salonia et al, 2012).
The potential weakness of this study was that it was a ‘snap shot’ in time of symptoms and unmet needs it was therefore not possible to differentiate co-morbidities from those of prostate treatment effects. We did not find a relationship between age, education or living status and unmet need which has been found in other studies (Lintz et al, 2003);(Ream et al, 2008);(Smith et al, 2007);(Steginga et al, 2001). However, living in Spain was associated with a higher probability of unmet sexuality, psychological and health system and information need, and living in France was also associated with a higher probability of unmet sexuality need. This may be the result of differing cultural expectations in relation to sexual attitudes in these two countries. Men with cancer are less likely than women to recognise the need for help because of cultural and societal barriers especially in relation to sexual issues (Hautamaki-Lamminen et al, 2013),(Tamres et al, 2002),(Courtenay, 2000). It should also be emphasised that the association of unmet need with country of residence in this study was independent of the effect of supportive nursing care as measured.

An important theme emerging from the analysis was the lack of support for on-going symptoms and concerns after treatment and their association with unmet need. Evidence from a recent patient reported outcome measure study within the UK (DoH, 2012) suggested information and preparation for cancer follow-up is limited. Patients described being “cut adrift” by the health system after active therapy (Corner et al, 2013). Patient satisfaction with health care provision is an important measure in assessing the structure and process of cancer care, and is associated with reduced quality-of-life including decline post-treatment in symptoms (Resnick et al, 2013a). In this present study recent assessment by a clinician and being a year or more out of treatment; were significant predictors of unmet need, indicating that clinician contact paradoxically did not always address men’s needs. This is also
confirmed in a longitudinal study of patients after cancer treatment, despite follow-up checks over 30% of patients, who had symptoms at end of therapy, continued to experience such symptoms 12 months later (Armes et al, 2009). Providing long-term care for prostate cancer patients has been reported as challenging especially in primary care (Zhou et al, 2010). In the USA studies have shown that only a minority of physicians feel able to manage the consequences of cancer treatment (Chubak et al, 2012),(McCabe et al, 2011),(Skolarus et al, 2011). Oncologists in the UK have also shown concern that primary care doctors have little experience of follow-up and longer-term effects of prostate cancer treatment (Watson et al, 2011). The predictive model in this study shows that unmet need can change over time in that men were much more likely to need help with sexuality issues when they had been recently diagnosed but as stage of disease progressed, unmet psychological, patient care and information needs remained.

Despite this being the first study in Europe to examine the relationship of supportive nursing care to patients’ unmet needs, and the comparatively successful response to the survey, there are strengths and weaknesses. In using the SCNS we have examined some need versus no need; in contrast some studies have categorised only moderate to severe need (Armes et al, 2009). We believe that it is important for defining supportive care packages to consider the range of unmet need since, if not supported; low need can become moderate or even high need at a later stage. A limitation with the SCNS is that it has been validated for paper and electronic administration via touch-screen computer (Boyes et al, 2002), but not currently for on-line use. There is evidence from this study that the tool could perform differently on psychological and physical and daily living domains when administered on-line: the statistical modelling indicated that men who completed the paper version were significantly less likely to have unmet need in these domains than men who completed the survey via the
internet. This difference in performance is unlikely to be the result of format selection bias as choice of format in this survey was not given at the point of completion. Further research would need to clarify this variation in the tool. A potential limitation of this study is that the outcomes are based on reported measures of nursing care, rather than on observed practice. However, the patient perspective is important in that it tells us what patient’s value in managing their care, and this is a crucial aspect to incorporate in evaluating cancer services within a patient-centred care framework (Luckett et al, 2009),(Velikova et al, 2002).

A fundamental shift is required to improve care for men with prostate cancer especially after treatment is completed. Furthermore the provision of nurses more consistently across the care pathway, with training to address sexual dysfunction and psychological care, should be a priority for enhancing supportive care. The provision of information, symptom management and long term side effects were areas in need of improvement. Recognition of specialist nurses within cancer multidisciplinary teams is not consistent across Europe and their inclusion should be essential in defining quality prostate cancer care. As the population of men increases so will the need for monitoring and management. Whether after care is received from oncology, urology or primary care, it is important that all health care professionals recognise the extent of long term consequences experienced by cancer patients. Health care services therefore need to provide effective and targeted supportive care for men after prostate cancer treatment to meet this growing population of survivors.

REFERENCES


