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Development of a conceptual framework to improve sexual wellbeing communication in routine prostate cancer care

Eilís McCaughan^{*1.}, Kader Parahoo^{1.}, Carrie Flannagan^{1.}, Roma Maguire^{2.}, John Connaghan^{2.}, Mary Steele^{3.}, Samantha Thompson^{4.}, Suneil Jain^{5,6.}, Mike Kirby^{7.}, Nuala Brady^{8.}, Seán R O'Connor^{1,9.}

* Corresponding author

^{1.} Institute of Nursing and Health Research, Ulster University, Jordanstown, Northern Ireland, UK.

^{2.} Department of Computer and Information Sciences, University of Strathclyde, Glasgow, UK.

^{3.} Centre for Clinical and Community Applications of Health Psychology, Psychology, Faculty of Social and Human Sciences, University of Southampton, Southampton, UK.

^{4.} Urology Department, Belfast City Hospital, Belfast, Northern Ireland, UK.

^{5.} Centre for Cancer Research and Cell Biology, Queen's University Belfast, Belfast, Northern Ireland, UK.

^{6.} Clinical Oncology, Northern Ireland Cancer Centre, Belfast City Hospital, Belfast, Northern Ireland, UK.

^{7.} Faculty of Health and Human Sciences, University of Hertfordshire and The Prostate Centre, London, UK.

^{8.} Northern Health and Social Care Trust, Northern Ireland, UK.

^{9.} Centre for Public Health, Queen's University Belfast, Belfast, Northern Ireland, UK.

Corresponding author at:

Eilís McCaughan

Professor in Cancer Care

Institute of Nursing and Health Research

Ulster University

Coleraine, Co Derry

N Ireland

BT52 1SA

Telephone: 028 70124091

Email: em.mccaughan@ulster.ac.uk

Abstract

Objective:

To systematically develop a framework to improve sexual wellbeing communication in routine prostate cancer care.

Methods:

The Theoretical Domains Framework was used to guide a multi-phase process used to identify components of the framework based on evidence reviews, semi-structured interviews and stakeholder workshops. 'Think-aloud' testing was used to explore usability, potential barriers and other factors relevant to implementation.

Results:

A conceptual communication framework consisting of 'Engagement' (E), 'Assessment' (A), information and 'Support' (S) and 'Sign-posting' (Si) sections was developed. The framework emphasises routine engagement to normalise sexual concerns, brief, non-sensitive assessment, personalised advice based on treatment and relationship status, and a mechanism for referral to additional support or self-management resources in the form of a patient and partner handout. Usability testing identified strategies to promote implementation.

Conclusions:

The proposed framework is appropriate for use in routine practice and appears to be acceptable to patients, partners and healthcare professionals. Its use may help address gaps in sexual wellbeing support for men and partners living with prostate cancer. Further work will be conducted evaluating an online engagement tool, modelled on the framework.

Practice Implications:

The EASSi framework can facilitate and structure sexual wellbeing conversations and ensure fundamental but individualised support is provided routinely in prostate cancer care.

Keywords: Communication; Sexual Wellbeing; Quality of life; Prostate cancer

1. Introduction

Prostate cancer is the most common cancer among men [1,2]. As a result of increasing survival rates, long-term side-effects associated with different treatment approaches are common [3]. In a recent, large scale survey, proximately 80% of men reported poor sexual function post-treatment [4]. Changes to sexual function are a major issue in the post-treatment phase and can result in high levels of anxiety, depression, relational dis-satisfaction and reduced overall quality of life [5-7].

Treatment guidelines [8,9] endorse delivery of psychosexual care for prostate cancer patients with recommendations made for the minimal level of support that should be provided. This includes provision of individualised information tailored to need, clear advice about potential long-term side-effects of treatment, and ensuring ongoing access to specialist care including erectile dysfunction clinics. Despite these recommendations, information varies greatly and is not provided routinely across services [4], with patients and partners frequently reporting that they do not receive adequate support to manage these concerns [10-12].

Initiating discussions around sexual concerns in clinical practice can be challenging. A number of potential barriers have been identified including structural factors such as limited contact time [13] or non-availability of onward referral services. Process factors influenced by inter-personal communication may also limit discussions further. For example, healthcare professionals often regard patients' sexual lives as being too personal to ask about and they may actively avoid the issue [14-16]. They also report that management of sexual issues is not within their professional role, and that they feel unequipped to deal with sexual issues, highlighting a lack of resources to offer patients if they do identify a problem [17]. Men themselves can feel uncertain about discussing concerns with healthcare professionals and may not be fully aware of the potential side-effects of treatment. Broader social influences and attitudes to sex and sexuality, including embarrassment, not being comfortable with the topic or not wishing to cause offence can also be barriers. However, given their frequency and substantial impact [4], sexual concerns should be discussed routinely with patients, and healthcare professionals are ideally placed to provide this support.

For healthcare professionals to address sexual health and wellbeing needs of men living with prostate cancer, they require knowledge and skills to effectively engage with patients and assess needs to provide appropriate evidence-based management [18]. One approach which could support healthcare professional communication is use of written prompts or structured questions to guide conversations. For example, sexual dysfunction screening checklists could be used to identify needs [19]. Evidence-based frameworks or tools can also provide a mechanism to provide appropriate advice and information [20,21]. Such approaches may enhance patient-provider communication, particularly around complex or sensitive issues by ensuring a more standardised provision of information. For example, use of decision support tools in a variety of clinical settings have been found to increase knowledge and reduce decisional conflict [22]. However, there is currently limited evidence exploring how communication can be enhanced and how conversations around sexual wellbeing can be supported in routine practice. There is a clear need for approaches that are available at all phases of care and which provide all healthcare professionals with the skills and capacity to routinely deliver sexual care and support. It is important that any framework used to guide practice is clear, user-friendly and is able to be integrated into practice with limited training.

1.2. Overview of existing sexual care models

A number of sexual care models have previously been proposed and tested in clinical settings. These include the PLISSET [23], EX-PLISSIT [24], and BETTER [25] approaches. The EX-PLISSIT model [24], and its precedent, the PLISSIT model [23], have been the most widely examined. The PLISSIT model involves: asking for or giving patients 'Permission' to discuss sexual wellbeing, giving 'Limited Information', about sexual side-effects of treatment, making 'Specific Suggestions' based a full evaluation of current problems, and providing or referring to more 'Intensive Therapy' including psychosexual therapy. It is aimed at providing increasing levels of engagement or intensity. The BETTER model [25] is aimed at supporting health professionals to incorporate sexual wellbeing assessment in cancer care settings. The model includes: 'Bringing-up' the topic of sexual concerns, 'Explaining', or normalising the topic by framing it as an important quality-of-life issue, 'Telling' the patient about resources for addressing any sexual concerns, consideration of 'Timing', by ensuring any discussion accounts for the patient's readiness to talk about sexual issues,

providing 'Education' including information on side-effects of treatment and lastly, 'Recording' or documenting the assessment, treatment and outcome, including follow-up plans, in patients' medical records. The above models provide differing approaches to sexual care and support. The PLISSIT model involves a counselling-based, stepped approach. For example, using a non-judgemental listening approach to determine patient's information needs [26]. The BETTER model uses behavioural and person-based methods including use of reminders or prompts, problem solving techniques and planning notes recorded in patients' clinical records [25].

1.3. Rationale for a conceptual framework to guide brief sexual wellbeing conversations

The need for a brief approach to ensure sexual wellbeing is routinely discussed was identified based on previous work by members of the project team [26-29], and through discussions with cancer care professionals and patient support groups. This process identified that the proposed framework should promote active engagement with all patients, include an assessment to provide essential information on potential side-effects, and refer to appropriate ongoing support, including self-management approaches. Following a rapid evidence review and initial qualitative work with patients and healthcare professionals, a co-development approach was used to devise an initial outline for an engagement and support framework intended to facilitate routine, sexual wellbeing discussions in the clinical setting.

While existing care models such as PLISSIT and BETTER provide well developed and structured approaches, they have limited active behaviour change components to support effective implementation into practice. In addition, both models include aspects which may present limitations to ensuring brief sexual care discussions take place routinely. This includes that healthcare professionals are asked to seek explicit permission or approval to talk about sexual concerns at any point where it might be discussed and also consider timing by ensuring patients are ready to discuss sexual concerns.

A further concern is that these approaches may provide an 'opt-out' leading to healthcare professionals not initiating discussions based on a perception that the patient is not ready or does not wish to discuss sexual issues. Previous evidence

indicates that men with prostate cancer and their partners do want healthcare professionals to discuss sexual issues and side-effects of treatment [30]. Despite this, sexual wellbeing discussions are often infrequent and limited in scope, with partners often not involved in any conversations that do take place [31]. Furthermore, healthcare professionals using judgement to determine when it is appropriate to discuss sexual concerns with patients can be problematic. The sensitivity of the topic and structural factors in current care systems, including that patients may not see the same healthcare professional at each appointment can mean that even essential advice and support on the impact of treatment is not discussed with a patient at any stage in their care. This highlights a need for a framework which supports healthcare professionals to routinely initiate sexual wellbeing discussion and, addresses barriers to such discussions taking place. In addition, the framework should normalise sexual issues in prostate cancer care, include partners and address expectations around recovery by introducing the concept of a 'new sexual health normal'. A framework that specifies and acknowledges the impact of treatment on sexual wellbeing of both men and their partners as well as providing appropriate support has potential to improve healthcare professional communication and patient-important outcomes.

1.4. Aim

The aim of this paper is to describe the systematic development of a conceptual framework designed to facilitate routine conversations about sexual wellbeing in prostate cancer care. Detail is provided on the rationale, evidence-base and theoretical underpinning of the framework. Iterative development, based on the views of patients, partners and healthcare professionals explored using qualitative methods is also described.

2. Methods

The Theoretical Domains Framework (TDF) [32] was used as a guide to identify key components of the proposed conceptual framework and explore barriers and factors relevant to implementation. The TDF includes 14 domains influencing clinical behaviour including knowledge, skills, professional role and identity, beliefs about capabilities, decision processes, environmental context and social influences.

2.1. Ethics

Ethical approval for the study was provided via the Office for Research Ethics Committees Northern Ireland (ORECNI) (Reference number: 17/NI/014). All participants gave written, informed consent before participation.

2.2. Procedures

Systematic evidence reviews, qualitative interview methods and stakeholder workshops were used to inform development of the proposed framework (see table 1 for a summary of qualitative methods used). The process consisted of four distinct phases. [i] Identifying changes needed to reduce the evidence-practice gap. [ii] Identifying barriers, facilitators and theories likely to explain necessary behaviour changes. [iii] Identifying appropriate, feasible and acceptable framework components, including modes of delivery, as well as behaviour change components likely to overcome barriers and assist facilitators. [iv] Identifying proposed mechanisms of change and selection of appropriate outcomes to measure change and evaluate the framework.

2.3. Phase i. Identifying changes needed to reduce the evidence-practice gap

The initial step in development involved a scoping review to explore requirements and expected components for each section of the framework. This was carried out to identify existing interventions and patient and healthcare professional perceived needs around sexual wellbeing communication in cancer care. Qualitative evidence was also gathered from individual, semi-structured interviews with key stakeholders, and findings from an interactive stakeholder workshop including men, partners, policy makers and healthcare professionals were used to identify requirements and expected components of the proposed framework (See table 2). As well as identifying the requirements of the framework, interviews with healthcare professionals and patients were used to assess views on current practice. All interviews were audio recorded, transcribed and analysed using deductive content analysis methods.

2.4. Phase ii. Identifying barriers and facilitators, and theories likely to explain necessary behaviour changes

To provide an overview of the theoretical assumptions underpinning the proposed framework, a mixed-method systematic review was conducted to identify the barriers to communication around sexual wellbeing in clinical practice [33]. Barriers and

facilitators to sexual wellbeing discussions were explored further by conducting an additional series of interviews with men and partners, and group discussions with healthcare professionals.

2.5. Phase iii. Identifying framework components likely to overcome barriers and assist facilitators

Outline structure and content for the framework was reviewed by members of an expert group who were asked to comment on appropriateness of language, tone, quality and accuracy of information, as well as necessity of the content and mode of delivery. In addition, written content, including language and tone, were explored through individual semi-structured interviews with men, partners and healthcare professionals (see supplementary file 1 for interview topic guide). The framework was then tested by healthcare professionals, as part of a 'think- aloud' process facilitated by the lead author (EMcC). This preliminary framework was also tested with patients who were undergoing treatment (using a simulated conversation conducted outside of their routine care appointments). These discussions were observed, and perspectives were sought on framework content, and utility. Selection of behaviour change components was based on relevance, and perceived feasibility of implementing the framework in practice.

2.6. Phase iv. Identifying proposed mechanisms of change and selection of appropriate outcome measures

Proposed mechanisms by which use of the framework could lead to changes in practice were identified and used to select key outcome measures for evaluating the effectiveness of the framework. These outcomes included the extent to which use of the framework would improve healthcare professional beliefs and self-efficacy as well as patient satisfaction with use of the framework, and with the level of sexual wellbeing support provided (See figure 2).

3. Results

3.1. Findings from evidence reviews

The scoping review identified 21 studies reporting primarily on patient perceived needs and experiences of sexual wellbeing communication. Seven studies explored

interventions designed to improve communication and support. Analysis of these interventions provided a summary of the different components and strategies used. The majority were not based on any underpinning theory or model and most were relatively long or intensive, including a number of separate sessions delivered over time. Most were also focused primarily on physical consequences and side-effects of treatment and did not account for different information needs. Patient perceived information and support needs included written information on different side-effects of treatment, as well as information for partners.

Data from the additional mixed-methods review which explored barriers to communication around sexual wellbeing in clinical practice were synthesised using a meta-ethnographic approach [33]. Fifty-seven, second-order concepts were extracted from 30 included studies. These were used to develop a conceptual framework based on five third order themes covering attitudes to sex and sexual wellbeing, patient factors, organizational factors, strategies to overcome barriers, and training needs. The review found healthcare professionals acknowledged the importance of discussing and providing support for sexual wellbeing needs, but recognised it is not routinely provided. Patient specific factors and organizational issues such as lack of time were frequently identified as barriers, however, intra-personal and social perceptions around sexual issues, including fear of embarrassment and assumptions made about age and sexuality appeared to have the strongest influence on healthcare professional perspectives. The review highlighted a need for brief educational and support tools to promote effective conversations with patients.

3.2. Findings from qualitative interviews

Data from the 76 participants including patients, partners and healthcare professionals involved in the qualitative evaluation (see table 1) identified that healthcare professionals and patients felt discussions around sexual wellbeing were limited and variable in content. Furthermore, it was acknowledged that discussions that did occur tended to have a biomedical focus centred on medication for erectile dysfunction and included limited support or onward referrals to address any other issues that did emerge. The experiences of patients and healthcare professionals also tended to differ, with healthcare professional typically being more satisfied with the content of sexual wellbeing discussions and the support offered. However, they did report a lack

of resources to offer and did not use any framework or model to help guide sexual wellbeing conversations. Patients often reported not being aware of sex being discussed, particularly early after diagnosis. Discomfort with the topic of sexual wellbeing was perceived by some healthcare professionals to be a significant factor limiting the ability to assess and address the needs of men with prostate cancer, and their partners.

3.3. Underpinning theories and behaviour components of the conceptual framework

Appropriate theories and models have a critical role in identifying factors contributing to behavioural interventions. Social cognition theory is focused on an individual's motivation and actions based on situational outcomes, action outcomes and perceived self-efficacy [34-36]. The theory of reasoned action [37-39] was also seen as critical to the framework. In this context, this theory integrates both behavioural and normative beliefs and suggests that the most significant influencing factor is intention, which is determined by attitudes towards discussing sexual concerns in practice. This factor is strongly affected by personal beliefs around sex, as evidenced in the mixed-methods review conducted as part of the exploratory phase in this development process [33]. Intention is determined by favourable or unfavourable attitudes towards discussing sexual issues, as well as normative pressures, or a perception, which can be both positive or negative, around what others, including patients and other healthcare professionals might think. Perceived control in relation to the individual healthcare professional's ability to perform the action or behaviour of using the framework in practice is also an important determinant.

3.4. Description of the final conceptual framework

Findings from initial development and testing of the preliminary framework were summarised and key components were selected using an iterative approach. This process was led by the research team, with input from members of the expert panel. The panel included patients, healthcare professionals with expertise in prostate cancer care, health communication, patient education and behaviour change techniques and principles. During this phase, multiple versions were drafted, and iteratively reviewed with changes to the content and structure being made at each step. The confirmed sections and components of each section were then combined to generate the final

version of the EASSi (Engagement, Assessment, Support and Sign-posting) framework (See figure 1).

The overall development process indicated a requirement for a framework to promote engagement and ensure sexual wellbeing support is routinely provided in prostate cancer care. The final conceptual framework intends to achieve this aim by providing a mechanism to ensure sexual wellbeing is consistently raised as a topic for discussion at all stages of care, including at pre-treatment and early post-treatment phases. The EASSi framework also ensures the impact of common treatment-associated sexual concerns is widely acknowledged. In addition, it includes fundamental but individualised support that can be delivered feasibly by all healthcare professionals during brief appointments. The framework can therefore be regarded as a foundation level component of overall sexual wellbeing support and management and a pathway to more intensive ongoing support services where needed. The framework complements existing models as it is designed to assist all clinicians, working in any setting (including those with limited experience or exposure to managing sexual wellbeing issues in practice) to engage with men and partners, discuss sexual issues and provide an 'essential' level of sexual wellbeing support as part of routine practice.

The 'Engagement' section was intended to include an acknowledgement: that sexual wellbeing is not easy to discuss; that sexual side-effects of treatment can have a substantial effect on how men see themselves as individuals; that relationships (both established and casual) can be affected and that sexual issues can lead to reduced or stopped sexual activity. However, a key facet of this section and the overall framework was that the facilitated discussion should also engender a sense of hope and introduce wider sexual thinking beyond focusing on erectile dysfunction. The 'Assessment' section was included primarily to ensure information and support provided during the discussion could be personalised by including information on different side-effects based on treatment type. For example, providing information on bowel sensitivity for patients undergoing radiotherapy. The assessment was also intended to be brief and exploratory only, thereby avoiding issues perceived to more 'sensitive', such as current or previous sexual activity. The 'Support' section was aimed at providing tailored information on common sexual challenges and at normalising sexual concerns. In addition, it was intended to provide an

acknowledgement of the sense of loss or indeed grief that may be experienced by men and their partners, while also providing information on strategies to cope with this potential loss. A key aim of the support section was to promote resilience and persistence. An important tenant of the section was inclusion of information relevant to the need for those in any current or future relationship to work together and adopt a willingness to try new approaches to manage sexual side-effects of treatment. The final 'Sign-posting' section was aimed at providing more in-depth support, including sources of additional information, online self-management, and erectile dysfunction clinic information. It was intended to provide a mechanism by which the healthcare professional, the patient and the partner could discuss and select appropriate resources based on the content of the sexual wellbeing discussion.

Key changes between the preliminary and final framework and the rationale for the modifications made are detailed below.

3.5. Modifications to the final framework based on feedback from testing

Testing provided additional insight into the experiences of using the EASSi framework and sign-posting sheet in practice, with healthcare professionals finding the approach to be valuable in time-constrained clinical settings. Content reviews and 'think-aloud' tests using the framework were carried out including healthcare professionals and patients (see table 1). A key finding from this testing was that patients were more engaged with the frameworks content than healthcare professionals had thought they would be and that use of the framework facilitated improved face-to-face communication. A further observation was that the printed sheet given during the 'Sign-posting' section of the framework was not used routinely.

Key changes based on feedback and testing included reducing the length of the engagement section. The assessment questions were also reduced to include only questions asking about treatment, relationship status and phase of care. Additional questions around ethnicity and sexual orientation were omitted since they were not needed for the type of information and support that the final framework provided. However, to ensure relevant information and support is still provided, online resources were included on the printed sheet given during the 'Sign-posting' section of the framework. Due to the uncertainty around the purpose of the sheet, it was also

modified by reducing the overall number of resources included on the sheet from nine to seven, and by highlighting a key online self-management programme so that it is provided to all patients, with other resources selected based on patient need and choice. A couple's communication activity was also included on the reverse of the sign-posting sheet. Detailed information on erectile dysfunction clinics, including their staffing and procedures, was also removed from the 'Support' section due to a lack of routine availability of these services. The overall approach was also amended by using more reflective language. For example, replacing the suggested wording where providing information on side-effects in the support section with 'some men tell us that....' rather than 'what you should know'. Information on the number of side-effects in the support section were also reduced, primarily to reduce potential overloading of information while ensuring discussions are still meaningful.

To support use of the framework, a practical face-to-face training approach was developed based on why each component part of the tool is needed, and on how each part can be used. This training was aimed at supporting healthcare professionals to use the framework and sign-posting sheet. This training also included relevant background information and suggested methods for integration into everyday practice. In addition, a simplified single page version of the framework was developed to provide a brief prompt or reminder that could be used as a poster in clinical areas to remind healthcare professionals to include all four components in sexual wellbeing discussions. The training and healthcare professional perspectives on feasibility and acceptability were evaluated at a 2-hour facilitated workshop attended by 21 clinical nurse specialists which included small group discussions and demonstrations. In addition, attendees completed a modified sexual attitudes and beliefs survey [40] prior to and immediately after the workshop. Analysis of this data using paired sample t-tests indicated that the brief training in use of the EASSi framework led to a significant positive change in overall sexual attitude scores, as well as significant improvement in participant's confidence that they would not have any difficulty talking to patients about sexual wellbeing ($t = -2.35$; $P=0.02$), and an increase in agreement with the statement that discussing sexual concerns with patients is part of their job ($t=-2.16$; $P= 0.04$). Participants reported that the framework had potential to be valuable to their own practice and highlighted the importance of providing greater depth to conversations about sexual concerns. They also indicated how the framework could widen the scope

of such discussions beyond erectile function. Another common issue raised was that the structured format was useful for providing 'prompts' at each stage of the conversation, facilitating discussions which were seen as sometimes being difficult to initiate and sustain.

3.6. Linking theoretical domains to the conceptual framework

The main health professional behaviours which the framework seeks to modify were firstly; to ensure they engage with all men, regardless of phase of care, treatment type, or assumptions about the need to discuss sexual wellbeing with the individual patient. A second behaviour was to ensure all men are provided with some support and advice on potential side-effects. A third behaviour targeted was to ensure that all men are provided with some ongoing support through provision of a sign-posting sheet, pointing towards useful resources including self-management. Finally, a fourth behaviour targeted was to ensure there is a pathway to more in-depth, specialist support services where appropriate. These behaviours were derived from clinical practice recommendations [8,9] and were selected as there is supporting evidence that they could be potentially modifiable and targeted at healthcare professionals working in different prostate cancer care settings. Barriers and enablers impacting on implementation of the target behaviours were identified through analysis of the individual semi-structured interviews and group discussions. These factors were explored based on their underpinning theories and any relevant behaviour change techniques. Details on possible barriers to use of the framework and potential methods to overcome these barriers are shown in table 3. Behaviour change technique selection was determined by feedback and consensus decisions among the research team on likely effectiveness. Potential mechanisms supporting use of the framework included use of a delivery mode able to support use in practice (See figure 2). Key principles and characteristics of the final framework are summarised in Table 4.

Proposed outcomes for assessing pathways mediating change in practice, and for evaluating use of the conceptual framework at the individual level include healthcare professional and patient sexual attitudes and beliefs, self-efficacy for discussing sexual concerns in clinical practice and satisfaction with framework content and structure. System level outcomes include number of patients where the EASSi framework is used and where sexual wellbeing is discussed, change in numbers of

patients using additional resources or being referred to other services and support, and assessment of the impact of framework use on clinical workload (See figure 2).

4. Discussion

This paper describes the systematic development process and the structure and content of a conceptual framework for facilitating sexual wellbeing discussions in routine prostate cancer care. The framework provides a mechanism to improve sexual wellbeing communication through provision of fundamental support delivered routinely, in a manner that still provides tailored advice based on treatment and relationship status. The EASSi conceptual framework, consisting of 'Engagement' [E], 'Assessment' [A], information and 'Support' [S], and 'Sign-posting' [Si] sections, further developed the earlier preliminary framework by refining its content to ensure only core content was included. The rationale for the EASSi framework was based on providing a mechanism to ensure sexual wellbeing is consistently raised as a topic for discussion at all stages of care. The framework can therefore be regarded as a foundation level component of overall, ongoing sexual wellbeing support and management. In this manner, it provides a flexible and responsive approach to deliver standardised but individualised levels of support that can be delivered feasibly by all healthcare professionals during routine appointments. Previous evidence highlights patient dissatisfaction associated with a perception that healthcare professionals are unwilling to discuss sexuality [41]. Use of the EASSi framework is intended to prompt important changes in clinical practice by ensuring essential sexual wellbeing support is provided to all men receiving prostate cancer care, and their partners.

Previous sexual care models [24,25] place an emphasis on healthcare professionals seeking explicit permission or approval to talk about sexual concerns at any point where it might be discussed and consider timing by ensuring patients are 'ready' to discuss sexual concerns. While the framework draws on some aspects of these existing models, it attempts to build upon them by ensuring wider access to routine sexual care and support in prostate cancer care. Its theoretical underpinning may actually be more directly related to brief behaviour change models such as the 5 A's model [42] which has been used as a framework to guide discussions in behavioural counselling interventions for smoking cessation and weight loss. The model stands for 'Ask', 'Advise', 'Assess', 'Assist', and 'Arrange' and is designed to be used briefly in

around three minutes [43]. Evidence indicates that the framework is most effective when all component parts are completed as part of a single, brief discussion [44].

Preliminary testing of the EASSi framework during development provides initial evidence supporting its use in prostate cancer care settings. The framework may be able to enhance communication around sexual wellbeing and improve support provided by ensuring more routine engagement and delivery of information on potential sexual side effects of treatment, and methods to address these concerns. Ensuring that discussions take place prior to or early during treatment can also be an important part of preparation for alterations to sexual function, managing expectations around recovery and providing a clear rationale for management approaches aimed at erectile dysfunction recovery [45-47]. A particular strength of the EASSi framework approach is the inclusion of a brief engagement and assessment section, alongside a level of support which can be provided based on need. Onward referral to other more specialist services is also included within the framework but other, readily accessible support options are also included, including online self-management resources designed for men and partners. Another strength of the EASSi approach is its flexibility, with scope to facilitate a brief conversation or used as part of a more involved discussion if time allows. The development process itself was also highly systematic and involved multiple user perspectives at all stage in the process, including those of patients and a range of professional groups. Another strength of the development process was use of the theoretical domains approach as a guide [32]. Development of the framework drew on theory, evidence, and exploration of key implementation issues to explore factors that might influence clinical behaviour. Testing of the framework in several stages provided valuable information about the feasibility of using the EASSi framework in practice. Unlike other sexual care models, the framework can be used across settings and without specific training or expertise in sexual care counselling. In addition, it includes evidence-based behavioural change elements. The brevity of the EASSi framework and the combination of a routine assessment alongside provision of appropriate support also means it can be used at any stage in care, from pre-treatment to longer-term follow-up.

One limitation that should be considered is that patients and healthcare professionals involved in development of the framework were predominantly individuals with a strong

clinical interest in the area of practice. Another potential limitation is that the development process involved patients and healthcare professionals primarily from the UK and the US, potentially limiting the relevance of the framework to other healthcare systems. Work is underway however, to explore the feasibility of using the framework in other contexts and settings. Additional work is also being carried out to test the feasibility of using a modified framework for delivery of other information and support types, including brief lifestyle advice.

To support healthcare professionals, the framework includes resources that can be giving to patients in an effort to reinforce key messages; as well as pointing to effective evidence based self-management resources. Development highlighted a number of important implementation factors, including that healthcare professionals may find it difficult to incorporate the framework, in its current format, into everyday practice. This implementation issue will be explored as part of formative evaluation of a tablet-based EASSi engagement tool tested across different clinical contexts, including in primary care and other cancer care settings. Other issues central to implementation included the individual attitudes and beliefs around sexual wellbeing that some healthcare professionals held. A brief training approach was therefore developed to promote implementation. As part of the framework development process, this training was initially developed and tested as a facilitated face-to-face workshop. However, this delivery mode is not feasible for wider implementation. This training will instead be developed as an e-learning module to ensure wider access for healthcare professionals supporting men with prostate cancer.

4.1. Conclusion

Existing sexual care models typically require more intensive intervention and are not ideally suited to use across clinical settings. Moreover, there is evidence that implementation of such models and frameworks in practice is limited. A series of evidence reviews and qualitative data exploring perspectives of key stakeholders highlighted a need for a conceptual framework to promote effective conversations with patients. It was identified that this should be brief, support healthcare professionals to initiate discussions around sexual concerns, address barriers to sexual wellbeing discussions and normalise sexual issues. The initial outline for the framework was based and an assumption that the first step is putting the topic 'on the table' for

discussion. An additional feature was that the framework should promote a 'shared conversation' between the health professional and patient, and that suitable language, appropriate content and some degree of support should be provided. A need was also identified for the framework to provide additional resources to which men, and partners, could be referred as part of routine sexual wellbeing discussions. Overall findings from the qualitative interviews and other feedback suggested that the final version of the EASSi framework was focused on creating the context to discuss sexual concerns and establish a degree of trust. Furthermore, the importance of active patient involvement in the discussion, as well as involvement of partners was also highlighted. Use of person-centred strategies to engage, assess, support and sign-post were also seen as critical.

4.2. Practice implications

The EASSi framework provides a brief, practical format to guide sexual wellbeing discussions in routine clinical practice. It includes four component parts, each designed to be used in sequence. The framework also includes tangible take home messages in the form of a printed handout or sign-posting sheet. The framework is at an appropriate level for use in routine practice and also appears to be acceptable to patients, partners and healthcare professionals. Its use may promote engagement around sexual wellbeing and ensure fundamental but individualised support is provided, potentially addressing current gaps in the routine provision of sexual wellbeing support for men with prostate cancer.

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Competing interests

The authors declare they have no competing interests.

Authors' contributions

EMcC, KP, RM, MS, ST, SJ and MK developed the original proposal for the study and the preliminary version of the framework. EMcC, CF, NB and SOC drafted and revised additional versions of the conceptual framework. EMcC, CF, RM, JC and SOC conducted usability tests and think-aloud interviews. SJ acted as chief investigator at the Northern Ireland Cancer Centre where testing and think-aloud interviews were held. SOC, KP and EMcC, drafted the initial manuscript. All authors revised the manuscript for important intellectual content and approved the final version.

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Table 1. Qualitative methods used during development of the conceptual framework

Qualitative method	Purpose	Participants (N)	Numbers
Interactive stakeholder workshop with group discussion*	To identify requirements and expected components of the proposed framework	Patients (5) Partners (3) Healthcare professionals** (16)	24
Individual semi-structured interviews	To assess views on current practice, and explore barriers and facilitators to sexual wellbeing discussions in practice	Patients (5) Partners (1) Healthcare professionals** (5)	11
Group discussion	To explore barriers and facilitators to sexual wellbeing discussions in practice	Healthcare professionals** (5)	5
Think-aloud interviews	To explore written content, including language, tone and structure of the preliminary framework To test usability of the preliminary framework during simulated conversations	Patients (4) Partners (2) Healthcare professionals** (9)	15
Training workshop with small group discussions	To explore barriers and facilitators to implementation of the framework in practice and assess impact of training on sexual attitudes and beliefs	Clinical nurse specialists (21)	21
			Total: 76

* Stakeholders included men with lived experience of prostate cancer, partners, Healthcare professionals and policy makers.

** Healthcare professionals included doctors, nurses, allied health professionals.

N: Number

Table 2. Aims and suggested components of the preliminary conceptual framework for improving routine sexual wellbeing communication in prostate cancer care

Key aims of the framework	Suggested components to achieve aim	Source of supporting evidence
To provide a professional, secure approach to initiating sexual wellbeing discussions	- Include language normalising sexual concerns as a symptom that needs addressing	Qualitative interviews
To prepare health professionals for the conversation	- Use language that quickly puts the topic 'on the table'	Qualitative interviews
To ensure (using a structured process) that all men (and partners) receive some sexual wellbeing support	- Inform the patient that sexual concerns are open for discussion	Qualitative interviews Evidence reviews
To ensure the patient is aware sexual wellbeing is going to be discussed		
To provide an early opportunity for issues to be raised by the patient or partner	- Include points where men can ask questions	Evidence reviews
	- Provide basic information on opening conversation at a future time or on 'how to have a conversation with a healthcare professional'	Evidence reviews Stakeholder workshop
	- Include acknowledgment of the importance of sexual wellbeing and the sensitivity of the topic	Qualitative interviews
	- Include recognition of partner role	Evidence reviews
	- Reassure on frequency of sexual concerns after diagnosis	Evidence reviews
An assessment should identify: Any treatment received Phase of care Sexual orientation Ethnic background Relationship status	- Provide a holistic assessment and approach by including questions on treatment type and psychosocial factors including sexual orientation, and relationship status	Stakeholder workshop Qualitative interviews

----- To provide a 'guideline' for giving sexual wellbeing support	- Provide a comprehensive assessment to guide personalized support and sign-posting	Evidence reviews
To provide reassurance that concerns are normal after diagnosis and treatment	- Normalise the assessment so it is treated like other side-effects of treatment	Qualitative interviews
	- Quickly provide standardised, essential information	Evidence reviews
	- Provide a mechanism to identify (limited, relevant) other concerns or current side effects of treatment	Qualitative interviews Stakeholder workshop
	- Identify any associated distress / depression / anxiety / unrealistic expectations	Stakeholder workshop
	- Identify importance of sexual concerns to patient	Qualitative interviews
	- Identify needs of patient and partner	Qualitative interviews Evidence reviews
	- Identify possible barriers to engagement	Evidence reviews Stakeholder workshop
----- To provide personalized support to men and partner	- Provide information on how sex life will be changed	Evidence reviews
To provide detail on what the long-term support options will be	- Include detail on sexual recovery as an ongoing journey	Qualitative interviews
To manage patient expectations about recovery	- Provide detail on expectations and potential side-effects of treatment	Evidence reviews Qualitative interviews
----- To emphasis the ongoing sexual recovery 'journey'	- Provide ongoing reminders or prompts	Evidence reviews
To introduce that possibly of a wider concept of sex and sexuality	- Provide resources that the partner can use if not present at appointment	Qualitative interviews
		Evidence reviews

To provide access to further support-based on need

- Point to other to appropriate resources which may be useful at other phases of care
- Promote ongoing support available based on need

Qualitative interviews

Evidence reviews

Qualitative interviews

Table 3. Components of the conceptual framework included to address barriers and facilitators influencing implementation

Identified barrier or facilitator to use of the framework	Relevant Theoretical Domain [28]	Intervention components including behaviour change techniques*
Limited awareness of sexual wellbeing concerns and the impact on patients	1. Knowledge	Information about consequences (5.1) through use of framework and healthcare professional training
Beliefs about negative consequences of raising sexual wellbeing as a topic	6. Beliefs about Consequences	Information about consequences (5.1 and 5.3) through healthcare professional training and behavioural experiments (4.1) by observing patient responses during use of framework
Stage of care can be variable and patient information needs may differ (including patients in a pre-treatment phase)	11. Environmental context and resources	Instruction on how to perform the behaviour (4.1) and demonstration / modelling of behaviour (6.1) through use of framework which provides information based on patient phase of care
Limited time to address sexual concerns during appointments	11. Environmental context and resources	Information about consequences (5.1) and prompts and cues (7.1) using patient hand-out taken from appointment and use of framework
Perception that patients will not wish to discuss sexual wellbeing due to sensitivity of topic	6. Beliefs about Consequences 12. Social influences	Information about consequences (5.1) through use of framework and healthcare professional training
Perception that discussing sexual wellbeing with patients at early stage of treatment or soon after diagnosis is not a priority	11. Environmental context and resources	Information about consequences (5.1) through use of framework and healthcare professional training
Perception that providing sexual wellbeing support is a specialist role (or role of other healthcare profession)	3. Social/professional role and identity	Social comparison (6.1) through healthcare professional training
Perception that addressing sexual wellbeing will affect how colleagues view them professionally	3. Social/professional role and identity 6. Beliefs about Consequences	Social comparison (6.1) through healthcare professional training and restructuring environment (12.1) through use of framework in practice
Detailed assessment is needed to evaluate patient needs	6. Beliefs about Consequences 11. Environmental context and resources 1. Knowledge	Instruction on how to perform the behaviour (4.1) and demonstration / modelling of behaviour (6.1) through use of framework
Assessment can introduce concerns that health professionals do not have time or resources to address	6. Beliefs about Consequences 11. Environmental context and resources	Instruction on how to perform the behaviour (4.1) and demonstration / modelling of behaviour (6.1) through use of framework

Skills and beliefs about ability to provide appropriate or effective sexual care and support	4. Beliefs about capabilities 11. Environmental context and resources 2. Skills	Instruction on how to perform the behaviour (4.1) and demonstration / modelling of behaviour (6.1) through use of framework
Patients may only need additional resources at a later point in care	11. Environmental context and resources	Prompts and cues (7.1) using patient hand-out taken from appointment
Patients not remembering information, or which additional support resources are recommended	1. Knowledge 10. Memory, attention and decision processes 11. Environmental context and resources	Prompts and cues (7.1) using patient hand-out taken from appointment

* Michie S et al. The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: building an international consensus for the reporting of behavior change interventions. Ann Behav Med. 2013 Aug;46(1):81-95.

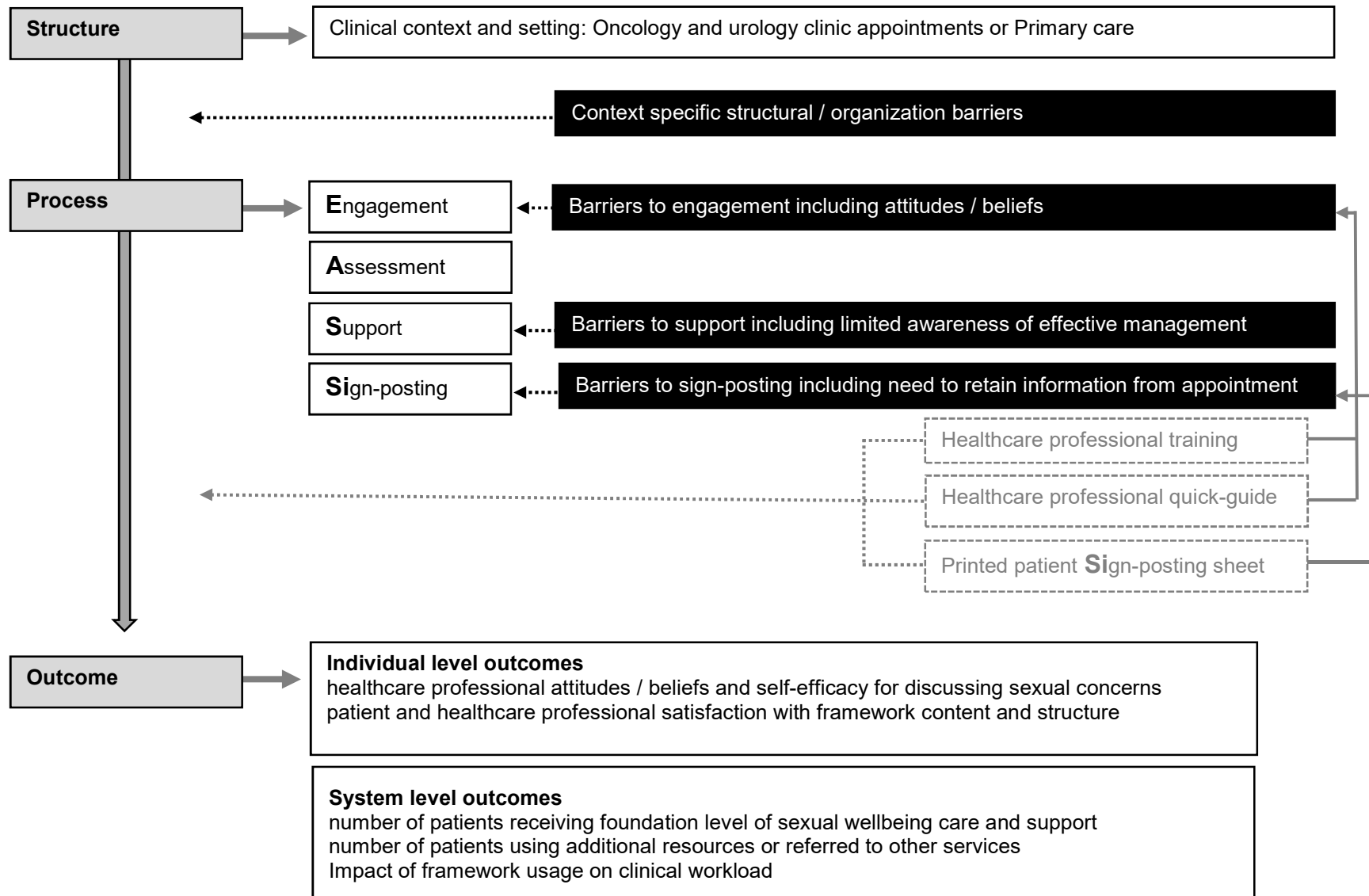
Table 4. Key principles and characteristics of the final version of the EASSi conceptual framework

Objectives of EASSi framework	Key features of EASSi framework included to meet objective
To promote routine engagement and ensure men with prostate cancer have a 'meaningful' conversation about sexual wellbeing after diagnosis (so all patients have access to essential information and support)	<ul style="list-style-type: none"> - Uses a simple format which can be used easily as part of routine appointments - Can be used to 'pre-plan' sexual wellbeing conversations
To provide a structure to sexual wellbeing conversations that includes a brief, standardised means of opening the conversation (putting the topic on the table)	<ul style="list-style-type: none"> - Can be used to 'restructure' the clinical setting or environment by providing a 'shared facility' which ensures the patient and healthcare professional take part in a joint discussion - Use of the framework ensures time is given to discussing sexual wellbeing during brief routine appointments - Provides appropriate terms relevant to opening sexual wellbeing conversations
To ensure a minimal level of psychosexual support is provided (which is relevant at all phases of care)	<ul style="list-style-type: none"> - Provides 'tailoring' of information and support based on need - Provides 'layering' of information based on need (ensuring framework can be brief but can facilitate a longer conversation if indicated)
To ensure routine sign-posting to appropriate resources (providing additional support, where needed and option to recap information discussed during the appointment)	<ul style="list-style-type: none"> - Provides referral to appropriate services based on need - Provides access to a more 'in-depth' online self-management programme to provide longer-term support - Includes printed handout for patients to take away from appointment as a reminder of key points

Figure 1. Purpose and outline content of the EASSi framework components

Section	Rationale for section and purpose	Outline of section content
Engagement	<p>Sexual dysfunction is a major problem and is often not addressed</p> <p>Section used to:</p> <p>Normalise sexual concerns</p> <p>Explain that a brief conversation about sex and prostate cancer will take place</p>	<p>Includes explanation that:</p> <p>There are many side-effects of prostate cancer treatment</p> <p>At the end a sheet will be provided with more detailed information and resources</p> <p>Sex can be a difficult subject which is not easy to talk about, but it is an important part of life</p>
Assessment	<p>Basic assessment is needed to provide tailored support</p> <p>Section used to:</p> <p>Ask about treatment type</p> <p>Stage of treatment</p> <p>Relationship status</p>	<p>Section asks three questions including following example:</p> <p>Have you had any of the following treatments?</p> <ol style="list-style-type: none"> 1. Radiotherapy 2. Hormone therapy 3. Surgery 4. Combined radio and hormone therapy
Support	<p>There are many sexual side-effects of treatment but also things that can help</p> <p>Section used to:</p> <p>Provide information on expected sexual challenges</p> <p>Acknowledge sex life will change</p> <p>Give brief advice on...</p> <p>What can be done</p> <p>Widening understanding of sex</p>	<p>Section provides advice (based on treatment) including:</p> <p>List of possible side-effects and some ideas to help.</p> <p>For example: Hormone side-effect 1: Less interest in having sex</p> <p>Advice:</p> <p>The treatment affects the level of testosterone in your body</p> <p>This has an effect on your sex drive</p> <p>Even if you have less sex drive, you can still feel pleasure</p> <p>And gives other advice on:</p> <p>need to think about sex in new ways, try new things and have patience and persistence</p>
Sign-posting	<p>After providing essential support need to signpost to other services</p> <p>Section used to:</p> <p>Point towards additional resources or services</p>	<p>Section includes provision of printed sign-posting sheet including:</p> <p>Online self-management</p> <p>Other information and support resources</p> <p>Useful tips and exercises</p> <p>Localised information on erectile dysfunction clinic</p>

Figure 2. Conceptual framework to improve sexual wellbeing communication in routine prostate cancer care using EASSi



Supplementary file 1: Topic guide for semi-structured interviews

Questions

1. Can you tell me about any experience you have of using a 'discussion tool' or conversation aid?
2. What would your expectations of such a tool be?
3. Are these expectations met by the proposed EASSi framework?
4. What parts of the EASSi framework did you like?
5. What would you want to change about the EASSi framework?
6. Is there anything else you would like the EASSi framework to include?
7. What do you think about the activities included in the EASSi framework?
8. What would help people to remember what was discussed after using the framework?
9. Who do you think is best placed to use the EASSi framework?
10. What do you think is the best setting for the EASSi framework to be used?
11. What do you think is the best format for the EASSi framework?
12. What do you think about how long the conversation guided by the framework should be?
13. Is there anything else you'd like to say about the EASSi framework?
14. Do you have any questions?