NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HEALTH AND SOCIAL CARE DIRECTORATE

QUALITY STANDARD CONSULTATION

SUMMARY REPORT

1 Quality standard title

Prostate cancer

Date of Quality Standards Advisory Committee post-consultation meeting:
27 February 2015

2 Introduction

The draft quality standard for prostate cancer was made available on the NICE website for a 4-week public consultation period between 2 January and 30 January 2015. Registered stakeholders were notified by email and invited to submit consultation comments on the draft quality standard. General feedback on the quality standard and comments on individual quality statements were accepted.

Comments were received from 27 organisations, which included service providers, national organisations, professional bodies and others.

This report provides the Quality Standards Advisory Committee with a high-level summary of the consultation comments, prepared by the NICE quality standards team. It provides a basis for discussion by the Committee as part of the final meeting where the Committee will consider consultation comments. Where appropriate the quality standard will be refined with input from the Committee.

Consultation comments that may result in changes to the quality standard have been highlighted within this report. Comments suggesting changes that are outside of the process have not been included in this summary. The types of comments typically not included are those relating to source guidance recommendations and suggestions for non-accredited source guidance, requests to broaden statements out of scope, requests to include thresholds, targets, large volumes of supporting information, general comments on the role and purpose of quality standards and requests to change NICE templates. However, the Committee should read this summary alongside the full set of consultation comments, which are provided in appendices 1 and 2.

3 Questions for consultation

Stakeholders were invited to respond to the following general questions:

1. Does this draft quality standard accurately reflect the key areas for quality improvement?

2. If the systems and structures were available, do you think it would be possible to collect the data for the proposed quality measures?

3. For each quality statement what do you think could be done to support improvement and help overcome barriers?

Stakeholders were also invited to respond to the following statement specific questions:

1. For draft quality statement 4: Which one specific adverse effect are men currently not being properly supported with that this statement should focus on?

4 General comments

The following is a summary of general (non-statement-specific) comments on the quality standard.

- Overall, stakeholders welcomed the quality standard and its quality improvement areas.
- Suggestion to offer supplements such as high strength fish oil and vitamin D to men with early stage prostate cancer and review their diet, physical activity and lifestyle as well as offer natural sleeping aids.
- Suggestion to exclude infection or contamination from the Quality Standard.
- Suggestion that a patient with family history of prostate cancer require referral.
- Concern raised about Clinical Commissioning Groups (CCGs) being able to financially supporting template biopsy for every patient.
- Suggestion that the Quality Standard needs to consider the diagnostic element of prostate cancer.
- Concern raised that the draft quality statements do not accurately reflect patient experience of sub-standard treatment and the limited number of 5 draft quality statements is inappropriate and unsafe.
- Suggestion to include measures on support to make informed choices, provision of evidenced based information, understandable and clearly communicated information, evidence from patient experience surveys that patients feel able to make decisions that are important to them.
- Concern raised that radiotherapy seems to be disproportionately supported as a treatment choice for prostate cancer for draft quality statements 2 and 3. This was felt to be an unbalanced view.
- Suggestion that sufficient nurse specialists are needed and lengthen the care pathway discussion at MDT.
- Suggestion to add the needs of gay, bisexual and other men who have sex with men, and of trans women, in relation to prostate cancer, in the equality and diversity considerations for all statements.

- Suggestion that the Quality Standard should go further by addressing shared decision-making, access to treatment of choice, self-management, shared care and non-curative care.
- Suggestion to include the reduction of national variation in treatment type and quality variability as an overarching outcome.
- Concern raised on the NICE Clinical guideline 175 such as the evidence for robotic surgery and the appropriateness of the two week wait.

Consultation comments on data collection

- Suggestion to include the need for a valid database to track patients managed in primary or secondary care or both.
- Data collection for the proposed quality measures can be adequately collected through the National Prostate Cancer Audit (NPCA) and the annual National Cancer Patient Experience Survey.
- NHS England would need to expand or maintain the structures put in place by these standards.
- The Quality Standard should be aware of the prostate cancer projects: True NTH PCUK and ProtecT.

5 Summary of consultation feedback by draft statement

5.1 Draft statement 1

Men with prostate cancer have a named nurse specialist who can provide information and support on treatment options and their adverse effects.

Consultation comments

Stakeholders made the following comments in relation to draft statement 1:

- In general, stakeholders welcomed this statement with the role of the named nurse specialist being a key clinical contact to the patient and carers as supported in the National Cancer Patient Experience Survey (NCPES) results.
- The provision of a personalised care plan for men with prostate cancer was also welcomed to enable discussion about treatment expectations and consequences plus access to care and wider social care support as part of the plan.
- Concern raised about the current lack of prostate cancer clinical nurse specialists and their actual access.
- Suggestion to include process measures about the provision of a personalised care plan and supported decision making.
- Suggestion that the named professional doesn’t have to be a specialist nurse but could be a non-medical practitioner with core skills related to prostate cancer.
- Suggestion to replace statement wording ‘who can provide information’ to ‘and have sufficient information’.
- Suggestion to specify ‘nurse specialist’ as a ‘cancer nurse specialist’ to aid data collection.
- Suggestion to add clarification on how the man, should contact the nurse specialist, when and for what reason.
- Concern raised that the proportion of men receiving information is not consistent with their satisfaction with information provided.
- Suggestion to include the benefits of ‘wait and see’ approach for elderly men as opposed to invasive investigations.

- Concern raised that urology specialist nurses are not trained in the use of chemotherapy or radiotherapy. The definition on this therefore needs to be tightened.
- Suggestion that the process measure needs to be measurable with evidence of a service provided by an appropriately trained cancer nurse specialist who follows the patient pathway from diagnosis onwards.
- Concern raised on the need for access to specialist nurses and specialist services as help could be provided locally in community settings rather than hospitals.
- A suggested additional area was a discussion of all management options with the man irrespective of local service arrangements.

Consultation question 3

Stakeholders made the following comments in relation to consultation question 3:

- There should be a named and contactable urology or oncology clinical nurse specialist for every patient.
- Concern raised on the resource implications of ensuring there are enough nurse specialists for all men with prostate cancer.

5.2 Draft statement 2

Men with low-risk localised prostate cancer for whom radical prostatectomy or radical radiotherapy is suitable are offered the option of active surveillance.

Consultation comments

Stakeholders made the following comments in relation to draft statement 2:

- A number of stakeholders welcomed this statement as a key area for quality improvement with possible data collection.
- Suggestion to re-word statement to focus on discussion with the man and informed decision-making.

- Suggestion to include offering surgery to men with low-risk localised prostate cancer.
- Suggestion to emphasise patient choice and involvement in shared decision-making such as patient decision aids and staff counselling training in the rationale section.
- Suggestion to expand the scope of the process measures on informed decision making and patient experience.
- Suggestion that the statement wording is unclear as active surveillance should be offered as one treatment option alongside others. The statement should emphasise patient choice.
- Suggestion to add focal therapies to the statement as a less invasive option in addition to active surveillance.
- Concern raised on the safety of widespread implementation of active surveillance as it was felt not yet to be justified by the guidance evidence.
- Suggestion to change this statement’s focus to address all treatment modalities for low-risk localised prostate cancer.
- Query raised on what optimal method is being used to inform patients of the staging of their condition.
- Comment raised that the active surveillance protocol (in table 2 in NICE guideline CG175)recommends mpMRI if not previously performed but does not state what action is to be taken on the results.
- Suggestion that brachytherapy may be used in combination with external beam radiotherapy.

Consultation question 3

- Active surveillance should be viewed as equal to radical treatment options.

5.3 Draft statement 3

Men with intermediate- or high-risk localised prostate cancer are offered a combination of radical radiotherapy and androgen deprivation therapy.

Consultation comments

Stakeholders made the following comments in relation to draft statement 3:

- Concern raised that the draft quality statement needs to be re-worded to reflect that optimally these therapies should be combined. Patients should also be offered radical prostatectomy and have the discussion about the risks and benefits of both options.
- Concern also raised that the use of the word 'offered' in this context is misleading. The statement wording does not make it clear that a combination of radical radiotherapy and androgen deprivation therapy is not the only option. This combination should be offered alongside other treatment options.
- Suggestion that surgery should also be offered in the management of intermediate and high-risk localised prostate cancer.
- Query raised on the importance of this statement with a suggestion to re-focus this on equality of access to treatment regardless to the disease stage and geographical location.
- Suggestion to include appropriate access to experimental treatments in the rationale.
- Concern raised on the generic lay audience descriptor. This needs more specific detail in line with the statement.
- Suggestion that radical prostatectomy and cryotherapy are also treatment options for men with intermediate- or high-risk localised prostate cancer.
- Suggestion to add radiotherapy in the denominator as some men will also have surgery.
- Suggestion to list all luteinising hormone-releasing hormone agonists.
- Suggestion that the outcome should reflect patient informed decisions rather than targets for surgical or non-surgical options.
- Suggestion to reword the statement to state that these men 'should be offered surgery or a combination of radiotherapy and hormones'.
- Suggestion to include a discussion with the nurse specialist about the potential impact of bone active therapy in reducing the risk of osteoporosis.

Consultation question 3

- Suggestion to ensure patients are involved in an informed discussion in relation to treatment options.

5.4 Draft statement 4

Men with prostate cancer have access to specialist services and interventions to manage the adverse effects of treatment.

Consultation comments

Stakeholders made the following comments in relation to draft statement 4:

- In general, stakeholders welcomed this statement as an important area of quality improvement raising the potential issues and associated treatment side-effects. However in relation to the consultation question, a number of stakeholders reported difficulty in focusing on one specific adverse treatment effect as it is based on patient experience with marked variation.
- Suggestion to focus at the minimum on erectile dysfunction and urinary and bowel incontinence as adverse treatment effects and to specify the services and interventions needed for the management of these and their psychosocial impact of prostate cancer and its treatment.
- Suggestion to include access to multi-disciplinary teams (MDTs) at diagnosis and their important role in managing treatment side effects was emphasised.
- Suggestion to include measures on the role of MDTs managing side effects, the main treatment complications and the inclusion of patient experience surveys.
- Suggestion to add psychological distress, depression and anxiety to the list of common side effects.
- Suggestion to focus on erectile dysfunction as one specific adverse effect as it is poorly managed and would be a good measure.
- Suggestion to include the importance of physiotherapy prior to treatments to prevent incontinence and sexual dysfunction in the rationale.
- Suggestion to include physiotherapy under specialist services and interventions.

- Suggestion to focus on access to the appropriate specialist services for prevention and management of osteoporosis for men on androgen deprivation therapy.

Consultation question 3

- Integration within and between MDTs was raised as essential for the treatment strategy with ongoing support from wider specialists to manage pain and the adverse effects of treatment.

- Local patient support groups such as meetings with other men with prostate cancer was encouraged to offer a sense of support.

Consultation comments on question 4

- Difficulty raised to highlight one specific adverse effect.
- Variable management of adverse effects between centres and patients was reported.
- Three stakeholders suggested to focus on gastro-intenstinal problems or radiation induced enteropathy as one specific adverse effect.
- A stakeholder suggested that this statement should address the psychosexual needs of gay, bisexual and other men who have sex with men with prostate cancer.

5.5 Draft statement 5

Men with biochemical evidence of hormone-relapsed metastatic prostate cancer have their treatment options discussed by the urological cancer multidisciplinary team (MDT).

Consultation comments

Stakeholders made the following comments in relation to draft statement 5:

- Stakeholders welcomed the multidisciplinary approach in this statement with possible data collection.
- Suggestion to broaden the statement so that specialist services are made available for prostate cancer as well as treatment related problems.

- Concern raised on MDT capacity which was reported as already compromised in current practice so this statement is too challenging with many departments unable to achieve. Alternatively it was suggested that this statement should state that men with advanced disease are being offered all the available treatment options and have the opportunity to see the appropriate expert to have the treatment discussion.
- Clarification requested in the rationale on which patients will be referred to oncology and to palliative care.
- Concern raised that palliative care is based on patients according to symptoms and not diagnosis.
- Clarification requested that the man needs to be involved in the discussion about the treatment options.
- Concern raised that there may not be a role for the full MDT in the management of biochemical relapse.
- Suggestion that salvage treatments are available for hormone relapsed organ confined prostate cancer.
- Concern raised that the statement wording may suggest that only those with hormone-relapsed prostate cancer should be covered by MDT which is not the statement's intent.
- Suggestion to re-word statement wording by adding "In addition to newly diagnosed cases…" at the start of the statement.
- Suggestion for greater emphasis on referral to palliative care team.
- Concern raised that local MDTs are not appropriately equipped to make decisions on modern treatment combinations.
- Suggestion to include more on skeletal preservation and metabolic or cardiovascular issues.
- Suggestion to include the involvement of both GPs and palliative care specialists for decision-making in these discussions.

Consultation question 3

- Concern raised about the resource capacity required to access to an uro-oncologist let alone a complete MDT.

Appendix 1: Quality standard consultation comments table

ID	Type	Stakeholder	Statement No	Comments
1	SH	The British Pain Society	General	The British Pain Society welcomes the quality standard and would like to endorse it.
2	SH	HQT Diagnostics	General	Suggest test and supplement with Vitamin D so that 25(OH)D is between 100-150 nmol/LOverview at:www.vitamindwiki.com/Cancer+-+Prostate Trials have been done that showed improvement in Gleason Score when 100micrograms/day (4,000IU) of oral Vitamin D were given to men with early-stage Prostate cancer where the recommendation was “Watch & Wait”More at: B.W. Hollis, et al., Vitamin D3 supplementation, low-risk Prostate cancer, and health disparities,J. Steroid Biochem. Mol. Biol. (2012),http://dx.doi.org/10.1016/j.jsbmb.2012.11.012 Trials have been done with different oral doses of Vitamin D to evaluate vitamin D metabolite levels and Ki67 labelling in surgical prostate tissue. Safety measures, PTH, and prostate-specific antigen (PSA) were also assessed More at:http://press.endocrine.org/doi/pdf/10.1210/jc.2012-4019
3	SH	HQT Diagnostics	General	Suggest test and supplement with high strength Fish Oil so that:Omega-3 Index: >8%Omega-6/3 Ratio: <3:1 More at: www.expertomega3.com/omega-3-study.asp?id=46 www.hqt-diagnostics.com
4	SH	HQT Diagnostics	General	Suggest refer patient to Dietitian or Nutritional Therapist to review diet and lifestyle(www.bda.org.uk or www.bant.org.uk) More at: http://www.ncbi.nlm.nih.gov/pubmed/16425098 http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3631124/pdf/10552_2013_Article_179.pdf http://www.lef.org/Protocols/Cancer/Prostate-Cancer/Page-01
5	SH	HQT Diagnostics	General	Suggest provide advice about diet and physical activity More at:http://prostatecanceruk.org/media/11576/diet_physical_activity_and_prostate_cancer_final.pdf
6	SH	HQT Diagnostics	General	Ensure that the patient has 8-10 hours of sleep a night Offer natural sleeping aids such as Natrasleep or prescribe equivalents to Melatonin such as Circadin Adjust dose by trial so that sleep is adequate without the patient being drowsy the next day More at: http://www.cancer.gov/cancertopics/pdq/supportivecare/sleepdisorders/Patient/page2

ID	Type	Stakeholder	Statement No	Comments
7	SH	Royal College of Pathologists	General	The Royal College of Pathologists does not have any comments on the draft prostate cancer quality standard.
8	SH	Society and College of Radiographers	General	A high level document which makes very broad statements and aims
9	SH	Prostate Cancer UK	General	References 1. Quality Health for NHS England. Cancer Patient Experience Survey 2014 National Report [Internet]. 2014. Available from: http://www.quality-health.co.uk/resources/surveys/national-cancer-experience-survey/2014-national-cancer-patient-experience-survey/2014-national-cancer-patient-experience-survey-national-reports/688-2013-national-cancer-patient-experience-survey-national-report-pdf/file 2. Macmillan Cancer Support. Specialist adult cancer nurses in England - A census of the specialist adult cancer nursing workforce in the UK, 2014 [Internet]. 2014. Available from: http://www.macmillan.org.uk/Documents/AboutUs/Research/Researchandevaluationreports/Macmillan-Census-Report-England.pdf 3. Clark JA, Wray NP, Ashton CM. Living with treatment decisions: regrets and quality of life among men treated for metastatic prostate cancer. J Clin Oncol Off J Am Soc Clin Oncol. 2001 Jan 1;19(1):72–80. 4. Steer AN, Aherne NJ, Gorzynska K, Hoffman M, Last A, Hill J, et al. Decision regret in men undergoing dose-escalated radiation therapy for prostate cancer. Int J Radiat Oncol Biol Phys. 2013 Jul 15;86(4):716–20. 5. Department of Health. Quality of Life of Cancer Survivors in England - Report on a pilot survey using Patient Reported Outcome Measures (PROMS) [Internet]. Department of Health; 2012. Available from: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/267042/9284-TSO-2900701-PROMS-1.pdf6. Frisk J. Managing hot flushes in men after prostate cancer--a systematic review. Maturitas. 2010 Jan;65(1):15–22. 7. BritainThinks for Prostate Cancer UK. Research into the differential needs of men with prostate cancer at different life stages. Total sample size was 53 adults affected by prostate cancer across the UK (including 8 partners of

ID	Type	Stakeholder	Statement No	Comments
				men with prostate cancer). Fieldwork was undertaken between 5th February and 13th March 2014, comprising telephone interviews, focus groups and online qualitative research. 2014. 8. Macmillan Cancer Support and Prostate Cancer UK. Treating erectile dysfunction after surgery for pelvic cancers. A quick guide for health professionals: supporting men with erectile dysfunction [Internet]. 2015. Available from: http://prostatecanceruk.org/media/2491101/treating-ed-after-surgery-for-pelvic-cancers.pdf9. Macmillan Cancer Support and Prostate Cancer UK. Treating erectile dysfunction after radical radiotherapy and androgen deprivation therapy (ADT) for prostate cancer. A quick guide for health professionals: supporting men with erectile dysfunction [Internet]. 2015. Available from: http://prostatecanceruk.org/media/2491100/treating-ed-after-radiotherapy-and-adt-for-prostate-cancer.pdf10. Kirby MG, White ID, Butcher J, Challacombe B, Coe J, Grover L, et al. Development of UK recommendations on treatment for post-surgical erectile dysfunction. Int J Clin Pract. 2014 May;68(5):590–608. 11. White ID, Wilson J, Aslet P, Baxter AB, Birtle A, Challacombe B, et al. Development of UK guidance on the management of erectile dysfunction resulting from radical radiotherapy and androgen deprivation therapy for prostate cancer. Int J Clin Pract. 2015 Jan;69(1):106–23.
10	SH	Royal College of Nursing	General	The Royal College of Nursing invited members who work in this area of health to review the Prostate Cancer: draft quality standard. No comments were received. There are therefore no comments to submit on behalf of the RCN at this time.
11	SH	Department of Health	General	I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation.
12	SH	Tackle Prostate Cancer	General	It is disappointing that the authors of the Quality Standard do not see it as contributing to one of the greatest shortcomings in PCa services – variability in quality and type of treatment across the country. The patients' working group concluded that this was a key area.
13	SH	Tackle Prostate Cancer	General	The statement “The quality standard for prostate cancer specifies that services should be commissioned from and coordinated across all relevant agencies encompassing the whole prostate cancer care pathway” is very welcome, but nowhere is it repeated in the actual standard. It should be explicitly stated in or as one of the Quality Statements.

ID	Type	Stakeholder	Statement No	Comments
14	SH	Tackle Prostate Cancer	General	Where is the evidence that the five statements listed are particular causes of concern, and that five statements are sufficient? Have the committee surveyed patient experience to establish this? It is our belief that these statements do not accurately reflect patient experiences of sub-standard treatment, and that the arbitrary limitation to a total of five statements is inappropriate and unsafe.
15	SH	National LGB&T Partnership	General	The National LGB&T Partnership has published an LGB&T Companion Document to the Public Health Outcomes Framework (available at www.lgf.org.uk/phof) and will publish an LGB&T Companion Document to the Adult Social Care Outcomes Framework in February, with the support of Public Health England and the Department of Health. These documents highlight the need for improved monitoring of patient sexual orientation and gender identity and provides evidence that LGB&T people are less likely to access screening services, which then delays diagnosis and has an impact on their outcomes.
16	SH	Royal College of General Practitioners	General	I agree with the proposals and have no changes to suggest.
17	SH	NHS Dorset CCG	General	The guidelines suggest that everyone with a raised PSA should be referred, therefore the two week wait would not be appropriate
18	SH	NHS Dorset CCG	General	Need to exclude infection/contamination.
19	SH	NHS Dorset CCG	General	If the patient had a family history of prostate cancer they would need referral.
20	SH	NHS Dorset CCG	General	Do not advocate template biopsy for everyone as the CCG would not be able to financially support it, unless it was part of the new guidance.
21	SH	Digital Assessment Service, NHS Choices	General	The Digital Assessment Service welcome the standard and have no comments as part of the consultation

ID	Type	Stakeholder	Statement No	Comments
22	SH	The Royal College of Radiologists / British Society for Urogenital Radiology	General	The RCR feels the Quality Standard is a good piece of work.
23	SH	Royal College of Physicians	General	We believe that the QS needs to be written taking account of the diagnostic element of prostate cancer standards. As stands, there is little reference to methodologies relating to biopsy and there is a need to consider MR. Whilst this is a difficult and largely unstandardised area, it is with us and there is the danger that without some sort of quality statement/standards document it will continue to develop in a very haphazard way.Surgery requires a much greater emphasis within sections on intermediate and high risk. There are clearly uncertainties about the true utility of lymph node dissection but it may be appropriate for some kind of commentary. This treatment approach is emphatically stated in the EAU guidelines (whether or not it is correct) and these are being followed in many countries. If the UK is to stand outside this guideline philosophy it may need to say why as some patients will read this literature.There needs to be greater attention to the need for research / documentation of specific outcome / participation in recognised audit etc. This should be a part of modern practice and it seems inappropriate to omit reference to it.
24	SH	NHS Dorset CCG	General	The Quality Standards apply to 'patients with prostate cancer WHO ARE REFERRED TO HOSPITAL' - this needs emphasis. (We have missed the boat regarding commenting on inappropriate referral of patients to hospital who are not going to benefit from interventional treatment or who did not have rising PSA - as this appeared in the early diagnosis draft guidelines)
25	SH	NHS Dorset CCG	General	The Quality Standards do not sufficiently emphasise the need for a valid database to track patients who are managed in either/both primary/secondary care.
26	SH	Wicket Minds	General	In light of our comments to expand the scope of this statement we would suggest the following

ID	Type	Stakeholder	Statement No	Comments
		LTD		measures are also included: a) Evidence of local arrangements to ensure that patients are supported to make informed choices using risk communication and decision support, such as patient decision aids. b) Evidence of local arrangements to ensure that information provided to facilitate shared decision-making is evidence-based, understandable and clearly communicated. c) Evidence from patient experience surveys and feedback that patients found that the information provided to facilitate shared decision-making was understandable and clearly communicated. d) Evidence from patient experience surveys and feedback that patients feel able to make decisions that reflect what is important to them.
27	SH	National LGB&T Partnership	Diversity, equality and language	The National LGB&T Partnership is very concerned to see that there is no mention of the specific needs of gay, bisexual or other men who have sex with men, and of trans women, in relation to prostate cancer. The issues raised in our response to the engagement exercise for this quality standard held in Aug-Sept 2014 are noted in the Equality Analysis but have not been included in the final Quality Standard. Without clear mention in the Quality Standard, it is highly unlikely that increased awareness among healthcare staff of the potential impacts of prostate cancer on gay, bisexual or other men who have sex with men, and trans women will be achieved. This is necessary in order to improve the quality of prostate cancer care. We note that Section 1 of the Equality Analysis refers to “transgender men”, who are not actually at risk of prostate cancer as they will not have a prostate. It is trans women (i.e. women who were identified as male at birth) who are at risk of prostate cancer (as noted in Section 3). The Equality Analysis should be amended to reflect this and the Quality Standard amended to include recognition of the needs of trans women.
28	SH	Wicked Minds Limited	Question 1	Whilst we welcome the 5 quality statements within this draft quality standard, we are disappointed that it does not go further to address the following improvement areas, which we believe would support the overarching indicators and improvement areas from the frameworks highlighted within the introduction:Shared decision-making - Men with prostate cancer have the opportunity to talk through all available treatment options and are provided with comprehensive information on the risks and benefits by members of their multi-disciplinary team (MDT) in order to make an informed decision. *(The decisions taken about treatment options may impact upon*

ID	Type	Stakeholder	Statement No	Comments
				the patient's quality of life long after treatment has finished. The National Cancer Survivorship Initiative (NCSI) suggests offering patients support in making the decisions that best reflect their individual priorities) – this could be incorporated in to QS 2 and 3. Equality of access to all treatments - Men with prostate cancer (regardless of stage of disease) have access to their treatment of choice, including clinical trials if deemed clinically appropriate, regardless of geographical location. *(Prostate cancer is unique in that, without solid evidence of the best treatment option (e.g. of surgery versus radiation), personal choice becomes an important element in selecting treatment options. In the latest national cancer patient experience survey (October 2014) 73% of prostate cancer patients felt their views were taken into consideration when discussing treatment options) – this could be incorporated in to QS3.* Self-management - Men with prostate cancer receive guidance and a package of care to support self- management of the side effects from their treatment, if they wish to do so. *(All cancer survivors who are clinically safe to self-manage should be provided with comprehensive information and be involved in a remote monitoring and/or alert system that prompts screening investigations).* Shared Care - Men living with prostate cancer benefit from an integrated and seamless approach to their care and wellbeing appropriate to their stage of disease for the rest of their lives. This will include clear accountability and responsibility across primary and secondary care. *(According to the National Cancer Patient Experience Survey (2014), 28% of prostate cancer patients mentioned that their GPs and nurses did not support them enough whilst being treated and 34% of prostate cancer patients did not feel different professionals worked well together to give them the best possible care)* Non-curative care - All patients receive and benefit from non-curative care at the appropriate stage of their disease, which is not limited to end of life care or restricted to being associated with hospice care. *(As recommended by NICE clinical guideline (CG 175) palliative care should be made available when needed, and not limited to the end of life nor should it be restricted to being associated with hospice care. NICE also recommends integrating palliative interventions at any stage into coordinated care, and facilitating any transitions between care settings as smoothly as possible).* We believe that this quality standard <u>should cover the whole pathway</u> with a particular focus on key quality improvement areas, as highlighted above. We are particularly concerned that this quality

ID	Type	Stakeholder	Statement No	Comments
				standard has not paid any attention to men living with non-curative cancer (men with 'non-curable' prostate cancer would benefit from having access to 'palliative' care much earlier on in their treatment yet the term palliative more often than not has misleading connotations). It is important to recognise that non-curative care can be offered following treatment or, in the earlier stages of an illness, alongside other treatments. In addition, with more men becoming long term survivors of prostate cancer it is essential follow up care to deliver timely access to treatments as and when necessary and the alleviation of suffering whilst ensuring that no one falls through the cracks. It is clear that primary care providers should play a bigger role, as it is they who inevitably care not only for prostate cancer survivors, but all those affected by prostate cancer. In order to ensure men are adequately supported to manage these needs we believe that there must be a seamless integration of well co-ordinated cancer care across primary (GP), secondary (hospital), and social care. This includes clear lines of responsibility and accountability with staff provided with the necessary training and links to resources.Whilst we appreciate that NICE has to follow a systematic process and there can only be a limited number of statements, we would strongly urge the committee to consider including at the very least <u>2 additional statements relating to non-curative care and shared care.</u>
29	SH	Tackle Prostate Cancer	Question 1	No. The arbitrary restriction to five Quality Statements is not supported by any evidence that there are only five key areas for quality improvement. To be of use, the Standard needs also to address the following areas, which we believe would support the overarching indicators and improvement areas from the frameworks highlighted within the introduction:Shared decision-making - Men with prostate cancer have the opportunity to talk through all available treatment options and are provided with comprehensive information on the risks and benefits by members of their multi-disciplinary team (MDT) in order to make an informed decision. *(The decisions taken about treatment options may impact upon the patient's quality of life long after treatment has finished. The National Cancer Survivorship Initiative (NCSI) suggests offering patients support in making the decisions that best reflect their individual priorities) – this could be incorporated in to QS 2 and 3.* Equality of access to all treatments - Men with prostate cancer (regardless of stage of disease) have access to their treatment of choice, including clinical trials

ID	Type	Stakeholder	Statement No	Comments
				if deemed clinically appropriate, regardless of geographical location. *(Prostate cancer is unique in that, without solid evidence of the best treatment option (e.g. of surgery versus radiation), personal choice becomes an important element in selecting treatment options. In the latest national cancer patient experience survey (October 2014) 73% of prostate cancer patients felt their views were taken into consideration when discussing treatment options) – this could be incorporated in to QS3.* Self-management - Men with prostate cancer receive guidance and a package of care to support self-management of the side effects from their treatment, if they wish to do so. *(All cancer survivors who are clinically safe to self-manage should be provided with comprehensive information and be involved in a remote monitoring and/or alert system that prompts screening investigations).*Shared Care - Men living with prostate cancer benefit from an integrated and seamless approach to their care and wellbeing appropriate to their stage of disease for the rest of their lives. This will include clear accountability and responsibility across primary and secondary care. *(According to the National Cancer Patient Experience Survey (2014), 28% of prostate cancer patients mentioned that their GPs and nurses did not support them enough whilst being treated and 34% of prostate cancer patients did not feel different professionals worked well together to give them the best possible care)*Non-curative care - All patients receive and benefit from non-curative care at the appropriate stage of their disease, which is not limited to end of life care or restricted to being associated with hospice
30	SH	Ipsen Limited	Question 1	Whilst we welcome the 5 quality statements within this draft quality standard, we are disappointed that it does not go further to address the following improvement areas, which we believe would support the overarching indicators and improvement areas from the frameworks highlighted within the introduction:Shared decision-making - Men with prostate cancer have the opportunity to talk through all available treatment options and are provided with comprehensive information on the risks and benefits by members of their multi-disciplinary team (MDT) in order to make an informed decision. *(The decisions taken about treatment options may impact upon the patient's quality of life long after treatment has finished. The National Cancer Survivorship Initiative (NCSI) suggests offering patients support in making the decisions that best reflect their individual priorities) – this could be incorporated in to QS 2 and 3.*Equality of access to all

ID	Type	Stakeholder	Statement No	Comments
				treatments - Men with prostate cancer (regardless of stage of disease) have access to their treatment of choice, including clinical trials if deemed clinically appropriate, regardless of geographical location. *(Prostate cancer is unique in that, without solid evidence of the best treatment option (e.g. of surgery versus radiation), personal choice becomes an important element in selecting treatment options. In the latest national cancer patient experience survey (October 2014) 73% of prostate cancer patients felt their views were taken into consideration when discussing treatment options) – this could be incorporated in to QS3.* Self-management - Men with prostate cancer receive guidance and a package of care to support self-management of the side effects from their treatment, if they wish to do so. *(All cancer survivors who are clinically safe to self-manage should be provided with comprehensive information and be involved in a remote monitoring and/or alert system that prompts screening investigations).*Shared Care - Men living with prostate cancer benefit from an integrated and seamless approach to their care and wellbeing appropriate to their stage of disease for the rest of their lives. This will include clear accountability and responsibility across primary and secondary care. *(According to the National Cancer Patient Experience Survey (2014), 28% of prostate cancer patients mentioned that their GPs and nurses did not support them enough whilst being treated and 34% of prostate cancer patients did not feel different professionals worked well together to give them the best possible care)*Non-curative care - All patients receive and benefit from non-curative care at the appropriate stage of their disease, which is not limited to end of life care or restricted to being associated with hospice care*. (As recommended by NICE clinical guideline (CG 175) palliative care should be made available when needed, and not limited to the end of life nor should it be restricted to being associated with hospice care. NICE also recommends integrating palliative interventions at any stage into coordinated care, and facilitating any transitions between care settings as smoothly as possible).* We believe that this quality standard <u>should cover the whole pathway </u>with a particular focus on key quality improvement areas, as highlighted above. We are particularly concerned that this quality standard has not paid any attention to men living with non-curative cancer (men with 'non-curable' prostate cancer would benefit from having access to 'palliative' care much earlier on in their treatment yet the term palliative more often than not has

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				misleading connotations). It is important to recognise that non-curative care can be offered following treatment or, in the earlier stages of an illness, alongside other treatments. In addition, with more men becoming long term survivors of prostate cancer it is essential follow up care to deliver timely access to treatments as and when necessary and the alleviation of suffering whilst ensuring that no one falls through the cracks. It is clear that primary care providers should play a bigger role, as it is they who inevitably care not only for prostate cancer survivors, but all those affected by prostate cancer. In order to ensure men are adequately supported to manage these needs we believe that there must be a seamless integration of well co-ordinated cancer care across primary (GP), secondary (hospital), and social care. This includes clear lines of responsibility and accountability with staff provided with the necessary training and links to resources. Whilst we appreciate that NICE has to follow a systematic process and there can only be a limited number of statements, we would strongly urge the committee to consider including at the very least 2 additional statements relating to non-curative care and shared care. In our view, not doing so would represent a lost opportunity to produce a broader, more far-reaching document.
31	SH	Wicked Minds Limited	Question 2	We believe data collection for the proposed quality measures can be adequately collected through the National Prostate Cancer Audit (NPCA) and the annual National Cancer Patient Experience Survey. Currently the NPCA only captures baseline information, therefore it is imperative that the audit is updated to reflect the measures captured within this quality standard.
32	SH	Tackle Prostate Cancer	Question 2	We believe data collection for the proposed quality measures can be adequately collected through the National Prostate Cancer Audit (NPCA) and the annual National Cancer Patient Experience Survey. Currently the NPCA only captures baseline information, therefore it is imperative that the audit is updated to reflect the measures captured within this quality standard.
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				imperative that the audit is updated to reflect the measures captured within this quality standard.
34	SH	British Association of Urological Surgeons	Question 2	Question 2 – really in order to implement these Quality Standards the structures put in place for national audit would need to be expanded/maintained by NHS England. Outside of the National Prostate Cancer Audit, which is a time limited project, the only national data source available is the BAUS dataset collected by surgeons. We are unsure if radiation oncologists collect the same data. There are several projects underway across the UK that will inform these QS further that NICE should perhaps be aware of: The National Prostate Cancer Audit (NPCA)PCUK's True NTH – patient reported outcomes project PROTECT study results Focusing on how we ensure that good data collection structures are in place once the NPCA is done should be a priority.
35	SH	Wicked Minds Limited	Question 3	Statement 1 – Be specific and add value to the statement by saying there should be a named and contactable urology/oncology CNS for every patient. Statement 2 and 3 – Say more about active surveillance being a viable treatment option i.e. put it on a par with radical treatment options. Ensure patients are involved in an informed discussion around treatment options including risks and benefits and the disadvantages of over-treatment. Statement 4 – Integration within and between MDTs is essential for patients with prostate cancer because the collaboration between prostate cancer MDT members is central to the treatment strategy, with on-going support from wider specialist to manage pain and the adverse effects of therapy. In addition, having the opportunity to meet with other men living with prostate cancer through support groups can offer an immense sense of support and relief that they are not alone. The QS does not make reference to local patient support groups – cancer centres should look to promote, refer and raise awareness of support groups as a valuable asset in helping inform patients about treatment options and long term management of their health include adverse effects. Statement 5 – we are concerned by the resource capacity required to ensure that these men have access to an uro-oncologist (as a minimum requirement) yet alone a complete MDT. All men (regardless of stage of disease) should be discussed at MDT and if resources are limited then further investment should be locally negotiated with their respective

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				commissioners.
36	SH	Tackle Prostate Cancer	Question 3	Statement 1 – Be specific and add value to the statement by saying there should be a named and contactable urology/oncology CNS for every patient. Statement 2 and 3 – Say more about active surveillance being only one viable treatment option i.e. put it on a par with other radical treatment options. Ensure patients are involved in an informed discussion around treatment options including risks and benefits and the disadvantages of over-treatment. Statement 4 – Integration within and between MDTs is essential for patients with prostate cancer because the collaboration between prostate cancer MDT members is central to the treatment strategy, with on-going support from wider specialist to manage pain and the adverse effects of therapy. In addition, having the opportunity to meet with other men living with prostate cancer through support groups can offer an immense sense of support and relief that they are not alone. The QS does not make reference to local patient support groups – cancer centres should look to promote, refer and raise awareness of support groups as a valuable asset in helping inform patients about treatment options and long term management of their health include adverse effects. Statement 5 – we are concerned by the resource capacity required to ensure that these men have access to an uro-oncologist (as a minimum requirement) yet alone a complete MDT. All men (regardless of stage of disease) should be discussed at MDT and if resources are limited then further investment should be locally negotiated with their respective commissioners.
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				support groups can offer an immense sense of support and relief that they are not alone. The QS does not make reference to local patient support groups – cancer centres should look to promote, refer and raise awareness of support groups as a valuable asset in helping inform patients about treatment options and long term management of their health include adverse effects. Statement 5 – we are concerned by the resource capacity required to ensure that these men have access to an uro-oncologist (as a minimum requirement) yet alone a complete MDT. All men (regardless of stage of disease) should be discussed at MDT and if resources are limited then further investment should be locally negotiated with their respective commissioners.
38	SH	British Association of Urological Surgeons	Question 3	Question 3 – supporting improvement and helping to overcome barriers. Having enough nurse specialists and lengthening the MDT to ensure patient with relapsing disease are all discussed would help.
39	SH	Wicked Minds Limited	Question 4	Having spoken to several men with prostate cancer it would be difficult to highlight one specific adverse effect that is currently not properly managed as this varies between centres and individual experiences. Instead it is important to ensure that regardless of what adverse effect a man is suffering from that the service is set up to manage this effectively and adequately. Some key facts to also consider are: Whilst the numbers of people affected by chronic gastrointestinal (GI) symptoms is lower than for other adverse effects (30% of those who have been treated with pelvic radiotherapy for urological cancers are estimated to be impacted – figures taken from Throwing Light on the Consequences of Cancer and its Treatment), PROMS tell us that of all pelvic consequences bowel problems had the most effect on quality of life (in the NCSI PROMS study individuals reporting any difficulty controlling their bowels were more than twice as likely to report lower EQ5D QoL scores). Whilst not all CCGs are equipped to deliver the full range of recommended ED rehabilitation strategies it is generally clear who is responsible for managing ED and lower urinary tract symptoms when they arise. Whereas support for managing GI symptoms after prostate cancer treatment is a neglected area of healthcare, which falls between two specialisms (urology and gastroenterology), neither of which has taken

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				real responsibility for improvement. Culturally they are so separate that the likelihood of patients getting the right referral through to a gastroenterologist is low, and if that referral is made the likelihood of that gastroenterologist being equipped to manage their symptoms effectively is equally low. [source: Andreyev HJN, Davidson SE, Gillespie C, et al. Practice guidance on the management of acute and chronic gastrointestinal problems arising as a result of treatment for cancer. Gut (2011)]. We would welcome a specific measure to address this issue. Suggested measure:Proportion of patients who have a named gastroenterologist to manage their GI side effects Numerator – the number of patients in the denominator who have a named gastroenterologist Denominator – the number of patients requiring a named gastroenterologist
40	SH	Tackle Prostate Cancer	Question 4	This is a question that should not be asked. It is our experience, based on discussion with a very large number of men with prostate cancer, that it is impossible to highlight one specific adverse effect that is currently not properly managed as this varies widely between centres and individual experiences. Instead it is important to ensure that, regardless of what adverse effect a man is suffering from, the service is set up to manage this effectively and adequately. In this regard, our comment below on the list of effects in the definitions section of QS4, is important.
41	SH	National LGB&T Partnership	Question 4	As noted in our previous response, one specific adverse effect in which men currently not being properly supported is addressing the psychosexual needs of gay, bisexual and other men who have sex with men diagnosed with prostate cancer. Patient-centred, holistic care is a cornerstone of the NHS service model and NHS constitution. Providing information and treatment that is responsive to patient need will be more effective in the long term and lead to better patient outcomes. The side effects of treatment for prostate cancer can affect gay and bisexual and other men who have sex with men differently to heterosexual men, particularly in relation to how they see themselves and their sexuality. Often they tell us that their concerns are not addressed in the quest to deal with their cancer or remove their prostate and whenever a question is raised about issues such as incontinence, or erectile dysfunction e.g. they are told that the most important thing is that their cancer has been dealt with. This often leaves these men to become very isolated and withdrawn and affects their personal relationships as well as their self-esteem.

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42	SH	Ipsen Limited	Question 4	Having spoken to several men with prostate cancer it would be difficult to highlight one specific adverse effect that is currently not properly managed as this varies between centres and individual experiences. Instead it is important to ensure that regardless of what adverse effect a man is suffering from that the service is set up to manage this effectively and adequately. Some key facts to also consider are:Whilst the numbers of people affected by chronic gastrointestinal (GI) symptoms is lower than for other adverse effects (30% of those who have been treated with pelvic radiotherapy for urological cancers are estimated to be impacted – figures taken from Throwing Light on the Consequences of Cancer and its Treatment), PROMS tell us that of all pelvic consequences bowel problems had the most effect on quality of life (in the NCSI PROMS study individuals reporting any difficulty controlling their bowels were more than twice as likely to report lower EQ5D QoL scores). Whilst not all CCGs are equipped to deliver the full range of recommended ED rehabilitation strategies it is generally clear who is responsible for managing ED and lower urinary tract symptoms when they arise. Whereas support for managing GI symptoms after prostate cancer treatment is a neglected area of healthcare, which falls between two specialisms (urology and gastroenterology), neither of which has taken real responsibility for improvement. Culturally they are so separate that the likelihood of patients getting the right referral through to a gastroenterologist is low, and if that referral is made the likelihood of that gastroenterologist being equipped to manage their symptoms effectively is equally low. [source: Andreyev HJN, Davidson SE, Gillespie C, et al. Practice guidance on the management of acute and chronic gastrointestinal problems arising as a result of treatment for cancer. Gut (2011)]. We would welcome a specific measure to address this issue. Suggested measure:Proportion of patients who have a named gastroenterologist to manage their GI side effects Numerator – the number of patients in the denominator who have a named gastroenterologist Denominator – the number of patients requiring a named gastroenterologist
43	SH	The Royal College of Radiologists / British	Question 4	The RCR suggests that the one specific adverse effect that men are not currently being supported with, that the statement should focus on, is radiation induced enteropathy.

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		Society for Urogenital Radiology		
44	SH	British Association of Urology Nurses	1	Our concern is that the provision of a named CNS does not always mean that men will have access to one. We know that there are insufficient numbers of Prostate cancer CNSs nationally and this has been highlighted in the NPCA first report. This is particularly true for men diagnosed with advanced prostate cancer. This measure needs to be measurable with evidence of a service provided by an appropriately trained CNS who follows the patient pathway from diagnosis though treatment and beyond.
45	SH	Wicked Minds Limited	1	We welcome this quality statement as having a key clinical contact such as a clinical nurse specialist (CNS) is vital to ensuring that the patient and their carer/family members are able to speak to a single point of contact to discuss any questions or concerns they may have during the course of their care. In addition to having a named clinical contact it is also important to ensure patients and their carers have access and are able to contact their named CNS (i.e. contact details are provided). We specifically welcome the point around providing men with a personalised care plan, as this offers an opportunity to discuss and be assured that the patient is aware of all treatment expectations and consequences such as erectile dysfunction, incontinence and bone health, and have access to care and wider social care support they could need as part of their care plan. According to the 2014 National Cancer Patient Experience Survey (NCPES), only 20% of prostate cancer patients were offered a written care plan. The survey also highlighted that 88% of men diagnosed with prostate cancer were given the name of a CNS compared to 93% of people diagnosed with breast cancer (Available at: Cancer Patient Experience Survey 2014. http://www.quality-health.co.uk/surveys/national-cancer-patient-experience-survey). For this reason we would suggest that NICE add a specific measure to ensure all men diagnosed with prostate cancer are provided with a personalised care plan, which can be measured through the NCPES.Suggested measures include: Evidence of local arrangements to support coordinated care through clear and accurate information exchange (written and shared through a personalised care plan) between patient and relevant

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				health and social care professionals. Proportion of patients receiving a personalised care plan Numerator – the number of patients in the denominator receiving a personalised care plan Denominator – the number of patients diagnosed with prostate cancer Proportion of patients who receive personalised information and support, including a written care plan and details on how to contact a named health or social care professional relevant to their wellbeing needs Numerator – the number of people in the denominator receiving personalised information and support, including a written follow-up care plan and details on how to contact a named health or social care professional relevant to their wellbeing needs. Denominator – the number of people having treatment for prostate cancer.
46	SH	Association for Palliative Medicine of Great Britain and Ireland	1	Agree with having a named nurse for patients – essential to have a clear point of contact for patients. It is also essential for a patient to have a direct phone number for the named nurse
47	SH	Society and College of Radiographers	1	The SCoR questions the recommendation specifically for a CNS. The SCoR would disagree that this role could only be fulfilled by a CNS and feel this recommendation is too prescriptive. An expert consultant or advanced therapeutic radiographer practitioner could fulfil this role, as they also give patients advice about treatment options and adverse effects. These roles are emerging and we understand many centres who offer radiotherapy have already established these roles and there is currently a project being led jointly between Prostate Cancer UK and the College of Radiographers further exploring and promoting the importance of this role. We think it would offer greater flexibility if this statement in the standard stated a CNS or other non-medical practitioner with core clinical skills related to prostate cancer, such as therapeutic radiographers.
48	SH	Prostate Cancer UK	1	We support the inclusion of a Quality Statement relating to the role of the Clinical Nurse Specialist (CNS) as we know from the National Cancer Patient Experience Survey (NCPES) that patients with access to a CNS report better experiences of care (1). In addition, both the NCPES and the specialist adult cancer nurse census (1,2) indicate variability in the provision of

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				a CNS. The Quality Standard will play a valuable role in ensuring equity of provision. However, the NCPES also tells us that being given the name of a CNS does not equate to genuine access to a CNS. In the 2014 survey (1), whilst 88% of prostate cancer patients were given the name of a CNS, only 72% found it easy to contact their CNS. This standard should therefore focus on whether men were able to access a named CNS. Due to the discrepancy between provision and access, the Quality Measures should be based on data sources that are patient reported, such as the NCPES or local surveys as appropriate. Although this statement makes reference to the role of the CNS in providing information and support on treatment options and their adverse effects, supported patient decision making does not appear to be a central requirement within this statement. Levels of decision regret can be high for men with prostate cancer (3), particularly in men with localised disease who face a choice between several very different management options (4). Although the CNS will have a critical role, supported decision making goes beyond this to incorporate information provision, including written information; the opportunity to discuss options with the relevant specialists; and explanation of all of the impacts that a particular treatment may have. The phrase, 'who can provide' should be replaced with 'and have sufficient'. Supported decision making should also be assessed through the quality measures for this statement. These should include measures that assess whether men felt that their information needs were met, and whether they felt fully supported in their decision making. The data for these measures must come from patient reported sources such as the NCPES.
49	SH	NHS England	1	This is measurable, but should read ' cancer nurse specialist' - collectable
50	SH	Tackle Prostate Cancer	1	We welcome this quality statement; having a key clinical contact such as a clinical nurse specialist (CNS) is <u>vital</u> to ensuring that the patient and their carer/family members are able to speak to a single point of contact to discuss any questions or concerns they may have during the course of their care. In addition to having a named clinical contact it is also important to ensure patients and their carers have <u>access</u> and are able to contact their named CNS (i.e. contact details are provided). We specifically welcome the point around providing men with a personalised care plan, as this offers an opportunity to discuss and be assured that the patient is aware of all treatment expectations and consequences such as erectile dysfunction,

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				incontinence and bone health, and have access to care and wider social care support they could need as part of their care plan. According to the 2014 National Cancer Patient Experience Survey (NCPES), only 20% of prostate cancer patients were offered a written care plan. The survey also highlighted that 88% of men diagnosed with prostate cancer were given the name of a CNS compared to 93% of people diagnosed with breast cancer (Available at: Cancer Patient Experience Survey 2014. http://www.quality-health.co.uk/surveys/national-cancer-patient-experience-survey). For this reason we would suggest that NICE add a specific measure to ensure all men diagnosed with prostate cancer are provided with a personalised care plan, which can be measured through the NCPES. Suggested measures include: Evidence of local arrangements to support coordinated care through clear and accurate information exchange (written and shared through a personalised care plan) between patient and relevant health and social care professionals. Proportion of patients receiving a personalised care plan Numerator – the number of patients in the denominator receiving a personalised care plan Denominator – the number of patients diagnosed with prostate cancer Proportion of patients who receive personalised information and support, including a written care plan and details on how to contact a named health or social care professional relevant to their wellbeing needs Numerator – the number of people in the denominator receiving personalised information and support, including a written follow-up care plan and details on how to contact a named health or social care professional relevant to their wellbeing needs. Denominator – the number of people having treatment for prostate cancer.
51	SH	National LGB&T Partnership	1	The National LGB&T Partnership is very concerned to see that there is no mention of the specific needs of gay, bisexual or other men who have sex with men, and of trans women, in relation to prostate cancer. Without this, the draft quality standard does not accurately reflect the key areas for quality improvement; please see the appendix for our response to the engagement exercise for this quality standard held in Aug-Sept 2014 which outlines these key issues. In order to fully understand whether the needs of these communities are being met by services, sexual orientation and gender identity monitoring should be implemented across the healthcare system.

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52	SH	NHS Dorset CCG	1	Having a Nurse specialist can play a vital role in patient care but as a locality it would be essential to provide information for the patient, Primary and Secondary care teams as to: 1) how to contact them 2) when to contact them and 3) what reason to contact them
53	SH	NHS Dorset CCG	1	Proportion of men receiving information is not necessarily concordant with satisfaction with information provided
54	SH	NHS Dorset CCG	1	Elderly men with prostate cancer and f/u needs to be appropriate to patient wishes and ensure good information is given to a patient in regard to benefits of wait and see approach as opposed to invasive investigations.
55	SH	Ipsen Limited	1	We welcome this quality statement as having a key clinical contact such as a clinical nurse specialist (CNS) is vital to ensuring that the patient and their carer/family members are able to speak to a single point of contact to discuss any questions or concerns they may have during the course of their care. In addition to having a named clinical contact it is also important to ensure patients and their carers have access and are able to contact their named CNS (i.e. contact details are provided). We specifically welcome the point around providing men with a personalised care plan, as this offers an opportunity to discuss and be assured that the patient is aware of all treatment expectations and consequences such as erectile dysfunction, incontinence and bone health, and have access to care and wider social care support they could need as part of their care plan. According to the 2014 National Cancer Patient Experience Survey (NCPES), only 20% of prostate cancer patients were offered a written care plan. The survey also highlighted that 88% of men diagnosed with prostate cancer were given the name of a CNS compared to 93% of people diagnosed with breast cancer (Available at: Cancer Patient Experience Survey 2014. http://www.quality-health.co.uk/surveys/national-cancer-patient-experience-survey). For this reason we would suggest that NICE add a specific measure to ensure all men diagnosed with prostate cancer are provided with a personalised care plan, which can be measured through the NCPES. Suggested measures include: Evidence of local arrangements to support coordinated care through clear and accurate information exchange (written and shared through a personalised care plan) between patient and relevant health and social care professionals. Proportion of patients receiving a

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56	SH	British Association of Urological Surgeons	1	Question 1 – Yes this QS accurately reflects a key area for quality improvement.
57	SH	British Association of Urological Surgeons	1	Question 2 – Yes, if the systems and structures were available, it would be possible to collect the data for the proposed quality measure.
58	SH	Bayer	1	Statements 1 and 5 both cover the discussion of treatment options. We suggest that an additional key area for quality improvement that should be covered by the quality standard is the discussion of all relevant management options recommended in NICE guidance with men with prostate cancer and their partners or carers, irrespective of whether they are available through local services. This is based on a recommendation from NICE clinical guideline CG175, Prostate Cancer: diagnosis and treatment,1 to discuss all relevant management options recommended in the guideline with men with prostate cancer and their partners or carers, irrespective of whether they are available through local services. This is an important issue as not all management options may be available all localities. It is essential that patients are not disadvantaged on the basis of their location, and are referred for appropriate treatment where necessary. The significance of this topic is evidenced by the fact that the aforementioned recommendation was assigned as a key priority for implementation in the

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				clinical guideline. Proposed quality statement: Men with prostate cancer and their partners or carers, are given the opportunity to discuss all relevant management options recommended in NICE guidance irrespective of whether they are available through local services. (1) National Collaborating Centre for Cancer - Commissioned by the National Institute for Health and Care Excellence. Prostate Cancer: diagnosis and treatment. Jan. 2014. Available from: http://www.nice.org.uk/guidance/cg175/resources/cg175-prostate-cancer-full-guideline3. (Last accessed: 30/1/2015).
59	I	John Graham	1	Article on the importance of a CNS for a patient with prostate cancer.
60	SH	Royal College of Physicians	1	We would urge caution here. The NPCA comments in this area were specifically related to 'Oncology Trained Nurses'. There was some discussion in the NPCA group about this as many 'Urology specialist' nurses have a great deal of experience in oncology but they are not in the main trained in the use of chemotherapy (or radiotherapy). We believe that consideration should be given to tightening up the definition and also referencing the exact NPCA quote.
61	SH	NHS Dorset CCG	1 & 4	The need for 'access' to specialist nurses and specialist services to manage complications does not create any obligation to refer all patients to these services - but help should be available locally when required. This help could be provided in community settings rather than hospitals.
62	SH	British Association of Urology Nurses	2	BAUN believes that this statement needs to put emphasis on the need to include the patient in the process of treatment decision making when a number of treatment options are available to them
63	SH	Wicked Minds Limited	2	As a quality improvement area we would challenge the relative importance of this statement in relation to other aspects of the care pathway. In order for this statement to be aspirational and inline with the NHS Constitution and the Outcome Frameworks we would welcome an emphasis on patient choice and involvement in shared-decision making. Prostate cancer is unique in that, without solid evidence of the best treatment option, personal choice (e.g. of surgery versus radiation) becomes an important element in selecting treatment options. In the latest national cancer patient experience survey (October 2014) 73% of prostate cancer patients felt their views were taken into consideration when discussing treatment options. If this

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				statement is to remain we strongly request that the wording of the statement is reconsidered. We suggest: Men with low-risk localised prostate cancer should have the opportunity to talk through all available treatment options with their healthcare professional, including the risk and benefits of active surveillance, radical prostatectomy, or radical radiotherapy in order to make an informed decision on their treatment.
64	SH	Wicked Minds Limited	2	The patient and his partner, family and/or other carers should be fully informed about care and treatment options and therefore able to make appropriate decisions based upon the choices offered by their healthcare professionals. For example, the choice between radical treatment and active surveillance may be influenced by a patient's desire to retain sexual activity, physical energy and quality of life (QoL). Patients should also be informed of their nearest prostate cancer support group as well as other support mechanisms to help aid decision-making. Healthcare professionals should be encouraged to use Patient Decision Aids, which are specially designed information resources that help men make decisions about different healthcare options. They will help patients think about why one option maybe better than another. It is important to recognise however that patients are given a plethora of information leaflets etc. but there is no explicit responsibility on the giver to check the patient's level of understanding or confusion. Agreeing on the "treatment of choice" may require staff trained in counselling, and access must be available and offered when appropriate. It is also important to bear in mind that men's views change over time depending on their experiences and who they talk to. We would ask NICE that the above points are included within the rationale.
65	SH	Wicked Minds Limited	2	In light of our comments to expand the scope of this statement we would suggest the following measures are also included: a) Evidence of local arrangements to ensure that patients are supported to make informed choices using risk communication and decision support, such as patient decision aids. b) Evidence of local arrangements to ensure that information provided to facilitate shared decision-making is evidence-based, understandable and clearly communicated. c) Evidence from patient experience surveys and feedback that patients found that the information provided to facilitate shared decision-making was understandable and clearly communicated. d) Evidence from patient experience surveys and feedback that patients

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				feel able to make decisions that reflect what is important to them.
66	SH	Prostate Cancer UK	2	The wording of this statement does not make it clear that active surveillance should be offered as one treatment option alongside others. The statement should emphasise patient choice. An alternative wording might be:*“Men with low-risk localised prostate cancer for whom radical prostatectomy or radical radiotherapy is suitable are also offered the option of active surveillance and given information and support to help make their decision.”*
67	SH	Galil Medical	2	Comment about Quality Statement 2. In addition to Active Surveillance, Focal Prostate cryotherapy treatments (NICE Guidance IPG423) are an appropriate treatment option. . Focal cryotherapy offers men a less invasive option and carries a very low risk profile, when patients seek a treatment that is not invasive such as radical prostatectomy and/or radical radiotherapy.
68	SH	Galil Medical	2	Comment about Statement 2. Focal therapies should be listed as a quality standard in the same way that the quality standard for Active Surveillance is being listed as it is appropriate for this same group of patients. Focal cryotherapy offers a treatment with a very low risk profile to patients seeking a treatment. NICE Guidance IPG423 covers the use of Focal Cryotherapy.
69	SH	Galil Medical	2	Comment about Quality Statement 2. Cryotherapy is also a recognised NICE Primary treatment (NICE Guidance IPG145)
70	SH	Tackle Prostate Cancer	2	This recommendation is unsafe and unworkable. Until the protocols for the conduct of Active Surveillance and, in particular, the trigger conditions for intervention, are more clearly specified (and NICE Guidance CG175 is vague on this) the widespread adoption of Active Surveillance, though undoubtedly welcome to avoid over-treatment, is unsafe, and not yet justified by the evidence. Furthermore we would challenge the relative importance of this statement in relation to other aspects of the care pathway. In order for this statement to be aspirational and inline with the NHS Constitution and the Outcome Frameworks we would welcome an emphasis on <u>patient choice</u> and involvement in shared-decision making. Prostate cancer is unique in that, without solid evidence of the best treatment option, personal choice (e.g. of surgery versus radiation) becomes an important element in selecting treatment options. In the latest national cancer patient experience survey (October 2014) 73% of prostate cancer patients felt their views were taken into consideration when discussing treatment options. We strongly advise

ID	Type	Stakeholder	Statement No	Comments
				that the wording of the statement is changed to address all treatment modalities for low risk disease. We suggest: Men with low-risk localised prostate cancer should have the opportunity to talk through all available treatment options with their healthcare professional, including the risk and benefits of active surveillance, radical prostatectomy, or radical radiotherapy in order to make an informed decision on their treatment.
71	SH	Tackle Prostate Cancer	2	The patient and his partner, family and/or other carers should be fully informed about care and treatment options and therefore able to make appropriate decisions based upon the choices offered by their healthcare professionals. For example, the choice between radical treatment and active surveillance may be influenced by a patient's desire to retain sexual activity, physical energy and quality of life (QoL). Patients should also be informed of their nearest prostate cancer support group as well as other support mechanisms to help aid decision-making. Healthcare professionals should be encouraged to use Patient Decision Aids, which are specially designed information resources that help men make decisions about different healthcare options. They will help patients think about why one option maybe better than another. It is important to recognise however that patients are given a plethora of information leaflets etc. but there is no explicit responsibility on the giver to check the patient's level of understanding or confusion. Agreeing on the "treatment of choice" may require staff trained in counselling, and access must be available and offered when appropriate. It is also important to bear in mind that men's views change over time depending on their experiences and who they talk to. We would suggest that the above points are included within the rationale.
72	SH	Tackle Prostate Cancer	2	In light of our comments to expand the scope of this statement we would suggest the following measures are also included: a) Evidence of local arrangements to ensure that patients are supported to make informed choices using risk communication and decision support, such as patient decision aids. b) Evidence of local arrangements to ensure that information provided to facilitate shared decision-making is evidence-based, understandable and clearly communicated. c) Evidence from patient experience surveys and feedback that patients found that the information provided to facilitate shared decision-making was understandable and clearly communicated. d) Evidence from patient experience surveys and feedback that patients

ID	Type	Stakeholder	Statement No	Comments
				feel able to make decisions that reflect what is important to them.
73	SH	National LGB&T Partnership	2	The National LGB&T Partnership is very concerned to see that there is no mention of the specific needs of gay, bisexual or other men who have sex with men, and of trans women, in relation to prostate cancer. Without this, the draft quality standard does not accurately reflect the key areas for quality improvement; please see the appendix for our response to the engagement exercise for this quality standard held in Aug-Sept 2014 which outlines these key issues. In order to fully understand whether the needs of these communities are being met by services, sexual orientation and gender identity monitoring should be implemented across the healthcare system.
74	SH	NHS Dorset CCG	2	Dorset stakeholders agreed that we need to ensure good database compatible across county.
75	SH	NHS Dorset CCG	2	The only other point here is what gold standard method is being used to inform patients of the staging of their disease.
76	SH	Ipsen Limited	2	As a quality improvement area we would challenge the relative importance of this statement in relation to other aspects of the care pathway. In order for this statement to be aspirational and inline with the NHS Constitution and the Outcome Frameworks we would welcome an emphasis on patient choice and involvement in shared-decision making. Prostate cancer is unique in that, without solid evidence of the best treatment option, personal choice (e.g. of surgery versus radiation) becomes an important element in selecting treatment options. In the latest national cancer patient experience survey (October 2014) 73% of prostate cancer patients felt their views were taken into consideration when discussing treatment options. If this statement is to remain we strongly request that the wording of the statement is reconsidered. We suggest: Men with low-risk localised prostate cancer should have the opportunity to talk through all available treatment options with their healthcare professional, including the risk and benefits of active surveillance, radical prostatectomy, or radical radiotherapy in order to make an informed decision on their treatment.
77	SH	Ipsen Limited	2	The patient and his partner, family and/or other carers should be fully informed about care and treatment options and therefore able to make appropriate decisions based upon the choices

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				offered by their healthcare professionals. For example, the choice between radical treatment and active surveillance may be influenced by a patient's desire to retain sexual activity, physical energy and quality of life (QoL). Patients should also be informed of their nearest prostate cancer support group as well as other support mechanisms to help aid decision-making. Healthcare professionals should be encouraged to use Patient Decision Aids, which are specially designed information resources that help men make decisions about different healthcare options. They will help patients think about why one option maybe better than another. It is important to recognise however that patients are given a plethora of information leaflets etc. but there is no explicit responsibility on the giver to check the patient's level of understanding or confusion. Agreeing on the "treatment of choice" may require staff trained in counselling, and access must be available and offered when appropriate. It is also important to bear in mind that men's views change over time depending on their experiences and who they talk to. We would ask NICE that the above points are included within the rationale.
78	SH	Ipsen Limited	2	In light of our comments to expand the scope of this statement we would suggest the following measures are also included: a) Evidence of local arrangements to ensure that patients are supported to make informed choices using risk communication and decision support, such as patient decision aids. b) Evidence of local arrangements to ensure that information provided to facilitate shared decision-making is evidence-based, understandable and clearly communicated. c) Evidence from patient experience surveys and feedback that patients found that the information provided to facilitate shared decision-making was understandable and clearly communicated. d) Evidence from patient experience surveys and feedback that patients feel able to make decisions that reflect what is important to them.
79	SH	British Association of Urological Surgeons	2	Q1 - Yes this QS accurately reflects a key area for quality improvement.
80	SH	British Association	2	Question 2 – Yes, if the systems and structures were available, it would be possible to collect the data for the proposed quality measure. In terms of the data source referred to in this

ID	Type	Stakeholder	Statement No	Comments
		of Urological Surgeons		statement, the NPCA collects this data we are not sure anyone uses the NICE prostate cancer clinical audit tool.
81	SH	The Royal College of Radiologists / British Society for Urogenital Radiology	2	The draft Quality Standard states that 'Active surveillance follows the protocol outlined in table 2 in prostate cancer (NICE guideline CG175). This table recommends mpMRI if not previously performed but does not mention what action is to be taken on the results – ie the patient could have a low Gleason score biopsy, putting them into the low risk group, but mpMRI may have shown a potentially high score lesion anteriorly that may not have been biopsied - therefore the patient has been classed as low risk incorrectly.
82	SH	Royal College of Physicians	2	A minor comment: Brachytherapy may be used with external beam as HDR. It is not an either or.
83	SH	Royal College of Physicians	2 & 3	Again, surgery is a possibility. There does not seem to be a consideration of this with or without adjuvant radiotherapy for high risk post op.
84	SH	British Association of Urology Nurses	3	There is good evidence that men should not receive EBRT without androgen deprivation therapy. Patients may not be aware of the evidence so this statement should be worded to reflect that the gold standard should be to have combined treatment of EBRT and Androgen deprivation therapy. Patients should also be offered radical prostatectomy and have the discussion about the risks and benefits of both options.
85	SH	Wicked Minds Limited	3	As a quality improvement area we would challenge the relative importance of this statement in relation to other aspects of the care pathway. Particularly issues relating to equality of access to treatment regardless of a man's stage of disease and geographical location. The NHS Constitution sets out patients' right to treatment, right to NICE approved drugs and right to complain about their care. The constitution gives the patient the right to ask their doctor and hospital for the right care. For cancer drugs that have not been approved by the NICE the Government has set up the Cancer Drugs Fund (CDF) to pay for cancer drugs that haven't been approved and aren't available within the NHS in England. There is a national list of drugs

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				available through the Fund and if a patient meets the conditions for a drug that is on the list, he should be able to have it on the NHS regardless of geographical location within England. Patients should also have the opportunity to speak to their specialist about whether there are any other treatments they can access such as trials of new experimental treatments going on and their eligibility to take part in one of them. Cancer Research UK publishes a clinical trials database (http://www.cancerresearchuk.org/about-cancer/trials/) listing trials both open and closed. We suggest rewording the statement as follows: Men with prostate cancer (regardless of stage of disease) have access to their treatment of choice including radical prostatectomy, combination of radical radiotherapy and androgen deprivation therapy, and where clinically appropriate access to clinical trials, regardless of geographical location.
86	SH	Society and College of Radiographers	3	Men with intermediate - or high-risk - localised prostate cancer are offered a combination of radical radiotherapy and androgen deprivation therapy. This is to ensure that men are offered the two together, and not androgen deprivation (ADT) alone- which has been reported as often happening especially in older men, and strong evidence showing the benefit of the combined therapies. Our concern is that it could be turned the other way around and that radiotherapy must be offered with ADT. Presumably when radiotherapy is stated this means any form of radiotherapy, including brachytherapy? In the case of prostate HDR brachytherapy as monotherapy for the intermediate risk cases, there is now a national protocol - agreed at the UK and Ireland prostate brachytherapy meeting, for a 19Gy single dose with no EBRT. The protocol for this treatment is not to give ADT and there would be no evidence to show that ADT improves outcomes as it is a fairly new treatment and not done with ADT. And how will this be measured? We understand that often men see a surgeon and choose prostatectomy without meeting the clinical oncologist. If a clinic appt is made for this, they sometimes cancel as they have made their minds up for surgery. So what will the measure be? That they attend an appt with oncologist?
87	SH	Prostate Cancer UK	3	The statement should make it clearer that the intention for this statement is to ensure that men with intermediate- or high-risk localised prostate cancer should not receive radical radiotherapy or androgen deprivation therapy alone. The use of the word ‘offered’ in this context is

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				misleading. The wording of the statement does not make it clear that a combination of radical radiotherapy and androgen deprivation therapy is not the only option that men can be presented with. Radical prostatectomy is a treatment option for these men, and active surveillance is an option for men who do not wish to receive immediate radical treatment. We believe the statement is intending to ensure that men get offered a combination of radical radiotherapy and androgen deprivation therapy, rather than either alone and this should be clarified. As with Quality Statement 2, the statement should also emphasise patient choice more strongly. An alternative wording might be:*“Men with intermediate- or high-risk localised prostate cancer receiving radical radiotherapy and androgen deprivation therapy should only have these treatments in combination and not alone. This combination should be offered alongside other treatment options.”*
88	SH	Galil Medical	3	Comment about Quality Statement 3. Alternative treatments i.e. Cryotherapy are also covered by Nice Guidelines (NICE Guidance IPG145), and should be included in the quality standard for men with intermediate – to high risk localised prostate cancer.
89	SH	Galil Medical	3	Comment about Quality Statement 3. Patients with Intermediate – High risk, can be offered other treatments. Cryotherapy is very suitable for this group of patients and has NICE Guidance (NICE guidance IPG145).
90	SH	NHS England	3	Some patients in this group will also receive surgery. The denominator here may be best as number of men with int- and high risk disease having radiotherapy - collectable
91	SH	Takeda UK	3	Suggest listing all luteinising hormone-releasing hormone agonists: Androgen deprivation therapy Bilateral orchidectomy or treatment with a luteinizing hormone-releasing hormone agonist such as goserelin, leuprorelin and triptorelin to lower testosterone levels.
92	SH	Tackle Prostate Cancer	3	As a quality improvement area we would challenge the relative importance of this statement in relation to other aspects of the care pathway. The statement as it stands is incompatible with current treatment options for men with intermediate or high-risk localised PCa, which include, prostatectomy, radiotherapy with ADT, and brachytherapy. The concentration of the statement on the RT option, and the now standard use of adjuvant ADT, gives an unbalanced picture of the areas where quality improvement is required, particularly issues relating to equality of

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				access to treatment regardless of a man’s stage of disease and geographical location. Patients should also have the opportunity to speak to their specialist about whether there are any other treatments they can access such as trials of new experimental treatments going on and their eligibility to take part in one of them. Cancer Research UK publishes a clinical trials database (cancerresearchuk.org/about-cancer/trials/) listing trials both open and closed. We suggest rewording the statement as follows: Men with prostate cancer (regardless of stage of disease) have access to their treatment of choice including radical prostatectomy, combination of radical radiotherapy and androgen deprivation therapy, and where clinically appropriate access to clinical trials, regardless of geographical location.
93	SH	Tackle Prostate Cancer	3	This is one of a number of cases where the QS is repeated verbatim as a “what this means for …” statement. It adds nothing to the standard, and suggests that inadequate thought has been given to why the statement has been included. We suggest the team give more thought to the issue, or consult those who have.
94	SH	National LGB&T Partnership	3	The National LGB&T Partnership is very concerned to see that there is no mention of the specific needs of gay, bisexual or other men who have sex with men, and of trans women, in relation to prostate cancer. Without this, the draft quality standard does not accurately reflect the key areas for quality improvement; please see the appendix for our response to the engagement exercise for this quality standard held in Aug-Sept 2014 which outlines these key issues. In order to fully understand whether the needs of these communities are being met by services, sexual orientation and gender identity monitoring should be implemented across the healthcare system
95	SH	NHS Dorset CCG	3	The data outcome of this approach should reflect patient informed decisions rather than targets for surgical or non-surgical options.
96	SH	Ipsen Limited	3	As a quality improvement area we would challenge the relative importance of this statement in relation to other aspects of the care pathway. Particularly issues relating to equality of access to treatment regardless of a man’s stage of disease and geographical location. The NHS Constitution sets out patients’ right to treatment, right to NICE approved drugs and right to complain about their care. The constitution gives the patient the right to ask their doctor and

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				hospital for the right care. For cancer drugs that have not been approved by NICE, the Government has set up the Cancer Drugs Fund (CDF) to pay for cancer drugs that haven't been approved and aren't available within the NHS in England. There is a national list of drugs available through the Fund and if a patient meets the conditions for a drug that is on the list, he should be able to have it on the NHS regardless of geographical location within England. Patients should also have the opportunity to speak to their specialist about whether there are any other treatments they can access such as trials of new experimental treatments going on and their eligibility to take part in one of them. Cancer Research UK publishes a clinical trials database (http://www.cancerresearchuk.org/about-cancer/trials/) listing trials both open and closed. We suggest rewording the statement as follows: Men with prostate cancer (regardless of stage of disease) have access to their treatment of choice including radical prostatectomy, combination of radical radiotherapy and androgen deprivation therapy, and where clinically appropriate access to clinical trials, regardless of geographical location.
97	SH	British Association of Urological Surgeons	3	We seek clarification of this statement that all men with intermediate or high risk PCa are offered radiotherapy and hormone manipulation. This implies that these men should not be offered surgery as a treatment option. Obviously this is not evidence based if that is the suggestion. This statement should be reworded to state that these men should be offered surgery or a combination of radiotherapy and hormones. If not reworded it should be removed.
98	SH	National Osteoporosis Society	3	Men with prostate cancer on androgen deprivation therapy are at risk of osteoporosis and attendant fragility fractures, however, the risk can be reduced with appropriate bone active therapy. We feel the review team should consider whether to include the additional requirement for the nurse specialist to discuss ways to mitigate also against any adverse effects due to therapy. In the case of osteoporosis this would include a discussion about the potential impact of bone active therapy in reducing the risk. As the standard is currently written there is no requirement to do this and the concern is that the fear of adverse effects may put some men off taking therapy.
99	SH	Royal College of	3	This must include greater emphasis on the role of surgery.

ID	Type	Stakeholder	Statement No	Comments
		Physicians		
100	SH	Royal College of Physicians	3	See comments above regarding surgery as an option.
101	SH	British Association of Urology Nurses	4	I is impossible to identify one side effect over another. Who are we to say that incontinence is more important than erectile dysfunction or Gynacomastia, or Loss of libido. The side effects are vast and will vary in the degree depending on individual patients. At a minimum, the standards should specify the services and interventions needed for the management of erectile dysfunction, and urinary and bowel incontinence
102	SH	Wicked Minds Limited	4	We believe this is an important issue to raise within this quality standard since an estimated one in five of all prostate cancer patients do not raise, or really understand, the potential issues and associated side-effects of treatments and alternatives that may be available to them [House of Commons Committee of Public Accounts 2006]. The 2014 national cancer patient experience survey highlighted that before treatment, 44% of patients were not fully informed about side effects that could affect them in the future. Patients who continue to survive with cancer complications may be better supported through access to an MDT at the point of diagnosis, with subsequent on-going MDT support to manage their side effects and consequences of cancer treatment. NICE CG 175 recommends the need for specialists such as gastroenterologists and dieticians to be part of the multi-disciplinary team to help men with bowel problems after prostate radiotherapy and was given ‘Key priority for implementation’ status, but as yet there is little evidence this is happening. By being familiar with the complete spectrum of management strategies, MDTs can assist patients in making treatment decisions that are specific for their individual disease state, co-morbid conditions, age and lifestyle [source: British Uro-oncology Group (BUG) and British Association of Urological Surgeons (BAUS) Section of Oncology. Interim MDT (Multi-disciplinary Team) Guidance for Managing Prostate Cancer (September 2013)]. We would ask NICE that the above points are included within the rationale.
103	SH	Wicked	4	All cancer survivors, wherever they live, can and should expect to have informed choices in

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		Minds Limited		relation to the services on offer to them through an established aftercare MDT [Source: Living with & Beyond Cancer: Taking Action to Improve Outcomes (an update to the 2010 The National Cancer Survivorship Initiative Vision). http://www.ncsi.org.uk/wp-content/uploads/Living-with-and-beyond-2013.pdf]. We would request the following measures are considered for inclusion: Evidence of local arrangements to provide patients with access to specialist MDTs to manage their side effects and main complications of treatment Evidence from patient experience surveys and feedback that patients are aware of their side effects and main complications of their treatment and know when and who to access for specialist support. Evidence from patient experience surveys and feedback that patients feel that their side effects and main complications in relation to their condition are adequately managed with access to specialist support when needed.
104	SH	Wicked Minds Limited	4	Under the list of adverse effects we suggest psychological distress, depression and anxiety are added to the list as common side effects associated with prostate cancer treatment [Source: Prostate Cancer UK. Research into wellbeing services for men with prostate cancer – final report. August 2014].
105	SH	Society and College of Radiographers	4	Men with prostate cancer have access to specialist services and interventions to manage the adverse effects of treatment. There was concerns raised at the Prostate Cancer advisory group meeting that the standard will select just one adverse effect to measure. It was widely felt that patients should have access to help for all the most common adverse effects, as there is no clear evidence which is the most worrying or distressing side effect. This varies hugely between individuals.
106	SH	Prostate Cancer UK	4	Whilst there is a need for more specificity in this statement on the services and interventions that men should have access to, focusing on one adverse effect alone in order to achieve this, as suggested in consultation question 4, is not a helpful approach. There are many different treatment options available to men with prostate cancer, with different side effect profiles. Men with prostate cancer can experience side effects including erectile dysfunction, urinary and bowel incontinence, aches and pains and hot flushes (5,6). We understand from conversations with clinicians that side effects such as incontinence and erectile dysfunction are best managed

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				together. Furthermore, different men assign different levels of importance to the different side effects according to their values, life stage and circumstances. For example, qualitative research commissioned by Prostate Cancer UK (7) found that, in general, younger men tended to see erectile dysfunction and its subsequent effect on sex life as having a more significant impact on their lives than urinary incontinence; whilst for older men, the reverse was true. In addition, men in relationships worried about the impact a change in physical relationships will have on their partner; and traditional conceptions of masculinity in Afro-Caribbean culture made the emasculating impact of erectile dysfunction particularly difficult both to come to terms with. We recommend that the Quality Standards should specify the services and interventions needed for the management of erectile dysfunction, urinary and bowel incontinence and the psychosocial impacts of prostate cancer and its treatment. Prostate Cancer UK and Macmillan have developed quick guides (8,9) on the management of erectile dysfunction following prostatectomy and radiotherapy, based on guidelines punished in the International Journal of Clinical Practice (10,11). The interventions specified in this guidance should be included in the Quality Standard.
107	SH	NHS England	4	Erectile dysfunction is poorly managed, and would be a good measure. It would also ensure that patients are actually asked this question regularly and that they receive appropriate expert input.
108	SH	Tackle Prostate Cancer	4	We believe this is an important issue to raise within this quality standard since an estimated one in five of all prostate cancer patients do not raise, or really understand, the potential issues and associated side-effects of treatments and alternatives that may be available to them [House of Commons Committee of Public Accounts 2006]. The 2014 national cancer patient experience survey highlighted that before treatment, 44% of patients were not fully informed about side effects that could affect them in the future. Patients who continue to survive with cancer complications may be better supported through access to an MDT at the point of diagnosis, with subsequent on-going MDT support to manage their side effects and consequences of cancer treatment. By being familiar with the complete spectrum of management strategies, MDTs can assist patients in making treatment decisions that are

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				specific for their individual disease state, co-morbid conditions, age and lifestyle [source: British Uro-oncology Group (BUG) and British Association of Urological Surgeons (BAUS) Section of Oncology. Interim MDT (Multi-disciplinary Team) Guidance for Managing Prostate Cancer (September 2013)]. We believe that the above points should be included within the rationale.
109	SH	Tackle Prostate Cancer	4	All cancer survivors, wherever they live, can and should expect to have informed choices in relation to the services on offer to them through an established aftercare MDT [Source: Living with & Beyond Cancer: Taking Action to Improve Outcomes (an update to the 2010 The National Cancer Survivorship Initiative Vision). http://www.ncsi.org.uk/wp-content/uploads/Living-with-and-beyond-2013.pdf]. We would request the following measures are considered for inclusion: Evidence of local arrangements to provide patients with access to specialist MDTs to manage their side effects and main complications of treatment Evidence from patient experience surveys and feedback that patients are aware of their side effects and main complications of their treatment and know when and who to access for specialist support. Evidence from patient experience surveys and feedback that patients feel that their side effects and main complications in relation to their condition are adequately managed with access to specialist support when needed.
110	SH	Tackle Prostate Cancer	4	It is the experience of our members that, in addition to the common side effects associated with prostate cancer treatment listed, the following are not uncommon: psychological distress, and depression and anxiety, sometimes leading to collapse of personal relationships. They should be added to the list as [Source: Prostate Cancer UK. Research into wellbeing services for men with prostate cancer – final report. August 2014].
111	SH	National LGB&T Partnership	4	The National LGB&T Partnership is very concerned to see that there is no mention of the specific needs of gay, bisexual or other men who have sex with men, and of trans women, in relation to prostate cancer. Without this, the draft quality standard does not accurately reflect the key areas for quality improvement; please see the appendix for our response to the engagement exercise for this quality standard held in Aug-Sept 2014 which outlines these key issues. In order to fully understand whether the needs of these communities are being met by services, sexual orientation and gender identity monitoring should be implemented across the

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				healthcare system.
112	SH	Association of Chartered Physiotherapists in Oncology and Palliative Care	4	In the first paragraph regarding rationale is there enough evidence to suggest "effect management at the point of diagnosis and throughout treatment" of adverse effects. The gold standard care is to provide physiotherapy input prior to treatments to minimise and prevent incontinence and sexual dysfunction. However, routine care in the majority of places appears to be reactive and provided after treatments.
113	SH	Association of Chartered Physiotherapists in Oncology and Palliative Care	4	Specialist Services and interventions. Under specialist services and interventions physiotherapy should be there. It does come under the umbrella of continence services but often this can be seen as just nursing. It may be important to highlight both.
114	SH	Association of Chartered Physiotherapists in Oncology and Palliative Care	4	Question for Consultation: Is the evidence strong enough to resource proactive physiotherapy/exercise prior to treatments rather than just post treatments? So in response to the direct question – are men supported with incontinence or sexual dysfunction as efficiently and in line with the evidence based research around proactive care?
115	SH	NHS Dorset CCG	4	As discussed with key stakeholders, many of these investigations and symptoms could, should and are already being managed in primary care. The outcome that we discussed was ensuring that GPs and patients had good access back into specialist care if needed.
116	SH	Ipsen Limited	4	We believe this is an important issue to raise within this quality standard since an estimated one in five of all prostate cancer patients do not raise, or really understand, the potential issues and associated side-effects of treatments and alternatives that may be available to them

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				[House of Commons Committee of Public Accounts 2006]. The 2014 national cancer patient experience survey highlighted that before treatment, 44% of patients were not fully informed about side effects that could affect them in the future. Patients who continue to survive with cancer complications may be better supported through access to an MDT at the point of diagnosis, with subsequent on-going MDT support to manage their side effects and consequences of cancer treatment. NICE CG 175 recommends the need for specialists such as gastroenterologists and dieticians to be part of the multi-disciplinary team to help men with bowel problems after prostate radiotherapy and was given 'Key priority for implementation' status, but as yet there is little evidence this is happening. By being familiar with the complete spectrum of management strategies, MDTs can assist patients in making treatment decisions that are specific for their individual disease state, co-morbid conditions, age and lifestyle [source: British Uro-oncology Group (BUG) and British Association of Urological Surgeons (BAUS) Section of Oncology. Interim MDT (Multi-disciplinary Team) Guidance for Managing Prostate Cancer (September 2013)]. We would ask NICE that the above points are included within the rationale.
117	SH	Ipsen Limited	4	All cancer survivors, wherever they live, can and should expect to have informed choices in relation to the services on offer to them through an established aftercare MDT [Source: Living with & Beyond Cancer: Taking Action to Improve Outcomes (an update to the 2010 The National Cancer Survivorship Initiative Vision). http://www.ncsi.org.uk/wp-content/uploads/Living-with-and-beyond-2013.pdf]. We would request the following measures are considered for inclusion: Evidence of local arrangements to provide patients with access to specialist MDTs to manage their side effects and main complications of treatment Evidence from patient experience surveys and feedback that patients are aware of their side effects and main complications of their treatment and know when and who to access for specialist support. Evidence from patient experience surveys and feedback that patients feel that their side effects and main complications in relation to their condition are adequately managed with access to specialist support when needed.
118	SH	Ipsen Limited	4	Under the list of adverse effects we suggest psychological distress, depression and anxiety are

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				added to the list as common side effects associated with prostate cancer treatment [Source: Prostate Cancer UK. Research into wellbeing services for men with prostate cancer – final report. August 2014].
119	SH	British Association of Urological Surgeons	4	Question 4 - Difficult for us as clinicians to answer this - although the management of ED associated with treatment of PCa is something that could perhaps be improved. The patient groups will be better able to tell us. At a meeting in November the Chairman of the English Prostate Cancer patient groups stated that the side effects of hormone manipulation therapy were the biggest issue that bothered the members of the various groups. So perhaps this is the area to look at, and perhaps strategies to ensure that the treatments that we offer minimise the use of hormone treatment would be something that comes from this.
120	SH	National Osteoporosis Society	4	We welcome this statement. Androgen deprivation therapy is an important and under-recognised cause of bone loss and fractures and we welcome the requirement for patients to have access to the appropriate specialist services for prevention and management of androgen deprivation therapy related bone loss.
121	SH	National Osteoporosis Society	4	In contrast to women taking aromatase inhibitors for breast cancer, there is much less awareness about the potential impact of androgen therapy on bone health, and the fact that it is preventable. Consequently many affected men on these therapies remain at risk of unnecessary and preventable fractures. We would support focusing this standard on the identification and prevention of osteoporosis.
122	SH	The Royal College of Radiologists / British Society for Urogenital Radiology	4	Please see response to Page 7, Question 4 (line 2 above).
123	SH	Royal College of	4	The QS should make it clear that the role of radiotherapy is to prevent gynaecomastia, otherwise it is not clear what role radiotherapy has here.

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		Physicians		
124	SH	The British Pain Society	5	This could be broadened so that specialist services are made available for disease as well as treatment related problems (Statement 4). We suggest: Men with biochemical evidence of hormone-relapsed metastatic prostate cancer have their treatment options discussed by a multidisciplinary team (MDT) with referral access to other specialist services e.g. Palliative Medicine and pain clinics.
125	SH	British Association of Urology Nurses	5	Urology MDTs do not just cover Prostate cancer. Urology is a 5 cancer site speciality. In addition to a local MDT there will be specialist MDTs for Prostate, Renal and Bladder. To enable teams to take on an additional MDT will require significant investment. MDT capacity is already compromised, so meeting this standard will be particularly challenging and will set up many department to fail an unachievable standard. The standard should state that men with advanced disease are being offered all the available treatment options and have the opportunity to see the appropriate expert to have the treatment discussion.
126	SH	Association for Palliative Medicine of Great Britain and Ireland	5	Agree – essential for palliative care to be involved in some patients with hormone-relapsed metastatic prostate cancer. However, under rationale the consultation does not make clear which patients should be referred to oncology and which to palliative care – it merely says “men with biochemical evidence of hormone-relapsed metastatic prostate cancer have their care discussed at the urological MDT, with a view to seeking an opinion from an oncologist and/or palliative care specialist”. It should be much clearer which of these patients are to be referred to oncology and which to palliative care. Palliative care does not see patients according to diagnosis, but rather according to symptom need in the context of advanced disease. This should be made clearer to provide guidance for urological MDTs.
127	SH	Prostate Cancer UK	5	We have heard from clinicians that MDT capacity is already compromised, so meeting this standard will be particularly challenging. However, we strongly believe that men with hormone-relapsed metastatic prostate cancer should have their treatment options discussed by, at a minimum, an oncologist, a CNS and a urologist if required. This may not be in a formal MDT setting, but should entail a multidisciplinary approach. Furthermore, as it is currently written the standard does not address the fundamental issue of whether treatment options are then

ID	Type	Stakeholder	Statement No	Comments
				discussed with men. As there may not be a role for the full MDT in the management of biochemical relapse, a more feasible and meaningful alternatives to this standard might be: *"Men with biochemical evidence of hormone-relapsed metastatic prostate cancer should be able to discuss their treatment options with all relevant specialists, including an oncologist with a prostate cancer specialty for discussion of their treatment options."*
128	SH	Galil Medical	5	Comment about Quality Statement 5: Hormone relapsed organ confined Prostate Cancer, is also a substantial group and salvage treatments are available. Salvage Cryotherapy for organ confined Prostate Cancer is a NICE recognised treatment. Covered by NICE guidance IPG119.
129	SH	Tackle Prostate Cancer	5	All cases of PCa should have their treatment discussed by an MDT. Wording this statement this way suggests that only those with HRPC should be covered by MDT. We are concerned that the restriction of this statement to cases of HRPC will encourage commissioning groups to close down MDTs for other stages of the disease. This statement would be acceptable if it was preceded by words such as "In addition to newly diagnosed cases …"
130	SH	National LGB&T Partnership	5	The National LGB&T Partnership is very concerned to see that there is no mention of the specific needs of gay, bisexual or other men who have sex with men, and of trans women, in relation to prostate cancer. Without this, the draft quality standard does not accurately reflect the key areas for quality improvement; please see the appendix for our response to the engagement exercise for this quality standard held in Aug-Sept 2014 which outlines these key issues. In order to fully understand whether the needs of these communities are being met by services, sexual orientation and gender identity monitoring should be implemented across the healthcare system.
131	SH	NHS Dorset CCG	5	Such patient groups should rightly be discussed at MDT but there should be a greater emphasis regarding referral to Palliative Care team given minimal Urological, Oncological or Radiological intervention going to be possible.
132	SH	NHS Dorset CCG	5	The addition to Quality 5 of greater emphasis on involvement of Palliative Care: • With a good database the data could be easily collected for these quality measures. Ensuring all interested parties are aware of its importance and responsibility for collecting the data is assigned

ID	Type	Stakeholder	Statement No	Comments
				appropriately then data collection should be straight forward. • Interpretation of the data is then key as this will provide the feedback needed to maintain interest and motivation for continued data collection.
133	SH	Bayer	5	We agree that this is an important statement to include in the quality standard. Metastatic hormone-relapsed prostate cancer is associated with reduced survival and a poor quality of life.[1,2] In a systematic review of epidemiological observational studies, median survival ranged from 9 to 30 months in HRPC populations, shortening to 9-13 months in HRPC patients with metastatic disease, although various diagnostic criteria were used to define HRPC.[2]HRPC with bone metastases is not curable and so the goals of treatment are to improve survival and quality of life, and to control symptoms. At this stage in the disease the control of symptoms and measures that improve quality of life can become as important as treatments that prolong life. The prognosis for HRPC patients with bone metastases is worsened if the patient has also experienced one or more SRE.[3,4]This is an significant area for quality improvement, a 2013 publication of a survey by the British Uro-oncology Group to society members (2010, n=77) reported that key areas for variance in clinical practice compared to the guidelines and uncertainty among clinicians relate to best practice for management of hormone relapsed patients following treatment with docetaxel, and also the use of bisphosphonates.[5]¶(1) Smith HS. Painful osseous metastases. Pain Physician 2011;14(4):E373-E403.(2) Kirby M, Hirst C, Crawford ED. Characterising the castration-resistant prostate cancer population: a systematic review. Int J Clin Pract 2011;65(11):1180-92. (3) Sathiakumar N, Delzell E, Morrisey MA, Falkson C, Yong M, Chia V, et al. Mortality following bone metastasis and skeletal-related events among men with prostate cancer: a population-based analysis of US Medicare beneficiaries, 1999-2006. Prostate Cancer Prostatic Dis 2011 Jun;14(2):177-83.(4) Norgaard M, Jensen AO, Jacobsen JB, Cetin K, Fryzek JP, Sorensen HT. Skeletal related events, bone metastasis and survival of prostate cancer: a population based cohort study in Denmark (1999 to 2007). J Urol 2010 Jul;184(1):162-7.(5) Payne H, Clarke N, Huddart R, Parker C, Troup J, Graham J. Nasty or Nice? Findings from a UK Survey to evaluate the impact of the National Institute for Health and Clinical Excellence (NICE) clinical guidelines on the management of

ID	Type	Stakeholder	Statement No	Comments
				prostate cancer. Clin Oncol (R Coll Radiol) 2013 Mar;25(3):178-89.
134	SH	Royal College of Physicians	5	This should define whether it refers to the specialist or local MDT. Many local MDT's are ill equipped to make decisions on modern combinations
135	SH	Royal College of Physicians	5	This should be called CRPC, in keeping with the international consensus. While recognising that patients do not like this term, and acknowledging that fact, it needs to be clear that this is what is being referred to (otherwise, to a professional, it could mean neuro-endocrine prostate cancer - quite different). Again it should be clarified whether the MDT should be local or specialist. The discussion may not really address the quality issue. No reference is made to timing, from which it could be assumed that the standard must be met within the calendar year in which the first PSA rise on castration therapy is documented. This is rarely the point at which complexity is recognised - discussion at this point, which concludes 'give the patient bicalutamide and carry on' would not really impact on the quality of care for many men. (although 'don't give them bicalutamide, send them to a specialty clinic to take things forwards' would). What is really required is that their care is managed by the appropriate members from an MDT from this point onwards. There is also a lack of consistency in this standard regarding metastatic disease. It would be quite appropriate to include M0 in this recommendation: they feature in the title, but not the denominator. This should be made explicit either way.
136	SH	Royal College of Physicians	5	This should include more on skeletal preservation and, earlier, about metabolic / cardiovascular issues and ADT
137	SH	NHS Dorset CCG	5	The second major deficiency in these quality standards is the lack of an obligation to involve both GPs and Palliative Care specialists in decision-making for hormone-relapsed metastatic disease - a conventional 'urological MDT' is not sufficient.

Appendix 2: Quality standard consultation comments table (non-registered stakeholders)

ID	Type	Statement No	Comments
138	Individual	General	Why has a figure of 150 patients been taken for robotic surgery for prostate cancer. There are many centres in the UK that perform over 100 cases per year but very few more than 150 cases. Surely, it is the number of cases per surgeon that is important. There is no evidence to support the number of 150 and this will lead to legal challenge by trusts who invested a lot of money in robotic surgery and training?
139	Individual	General	Why is there no mention of alternate treatment such as Cryosurgery? A lot of work has been done since the previous guidelines recommended cryotherapy in clinical trials only but none of this is included.
140	Individual	General	Why is the concept of focal therapy in prostate cancer not addressed? This is now a developing area with a lot of interest and considerable advantages to selected patients. Guidelines should include at least a discussion and opinion on this important treatment option.
141	Individual	2 & 3	Radiotherapy seems to have a disproportionate place as a treatment of choice for prostate cancer patients. This is not a balanced view and undermines the credibility of the guidelines.
142	Individual	3	Why should intermediate and high risk patients be offered radiotherapy and hormones only? Surgery has an important place in the management of intermediate and high risk disease and is the only treatment with level 1 evidence data to support its use, particularly in intermediate and high risk patients?

Stakeholders who submitted comments at consultation

- Association of Chartered Physiotherapists in Oncology and Palliative Care
- Association for Palliative Medicine of Great Britain and Ireland
- Bayer
- British Association of Urology Nurses
- British Association of Urological Surgeons
- Damien Greene
- Department of Health
- Digital Assessment Service, NHS Choices
- Galil Medical
- HQT Diagnostics
- Ipsen Limited
- John Graham
- National LGB&T Partnership
- National Osteoporosis Society
- NHS Dorset CCG
- NHS England
- Prostate Cancer UK
- Royal College of General Practitioners
- Royal College of Nursing
- Royal College of Pathologists
- Royal College of Physicians
- Society and College of Radiographers
- Tackle Prostate Cancer
- Takeda UK
- The British Pain Society
- The Royal College of Radiologists/British Society for Urogenital Radiology
- Wicked Minds Limited

Appendix 3: Quality standard consultation comments table (internal)

Internal NICE team	Statement No	Comments Please insert each new comment in a new row.
QS team	1	Suggestion to check consistency stating a 'named nurse specialist' against past published Quality Standards. Need to also consider the resource implications of this specialist and check the evidence strength on this specialist role in the full guideline. Suggestion to change the statement wording to 'Men with prostate cancer have a named nurse specialist' rather than stating what they should specifically do.
QS team	2	Query on the use of 'offer' for the statement. Suggestion to state 'have the option' of active surveillance rather than 'offered the option of active surveillance' and then accordingly change the process measure to 'receive'.
QS team	3	As per statement 2, query on the use of 'offer' for this statement. Agreed to retain this process measure as 'receive'.
QS team	4	Suggestion to focus on one specific action- be it access to specialist services, interventions or management of adverse treatment effects? Suggestion that if one adverse effect is possible we can then break this down in the measures. A consultation question on specifying one adverse effect has been asked at consultation stage.
QS team	5	Suggestion to ask the SCMs at the post-consultation QSAC what is currently happening at the urological cancer MDTs to make this a key quality improvement area. Suggestion to further the examine the National Prostate Cancer Audit for any further information as stated in the data sources.