Living with and beyond cancer programme

Prostate Cancer Risk Stratification Guideline

2018

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Introduction

This document has been drafted based on:

- Four clinical delivery group meetings during 2017/2018, involving clinicians from secondary and primary care, managers and commissioners from across the programme footprint.
- Further conversations outside the meetings with clinicians, managers and commissioners.
- Local experience of risk stratification in prostate cancer to date.
- Research into models and approaches to risk stratification in prostate cancer both regionally and nationally.
- Regional and national policy and guidance on prostate cancer and risk stratification.

Section 1 - Background and current risk stratification of Prostate cancer

The Living with a beyond cancer programme has been working with commissioners, providers and local stakeholders in a programme approach across the cancer alliance since April 2016. The aim of the programme is to implement the nationally specified "Recovery package" and "Risk stratified pathways".

The aims of this programme are to

- Tailor post treatment care to individual patients according to their needs and risk of developing further problems
- Support and empower patients to manage their own follow-up where appropriate
- Ensure follow-up pathways are efficient and value for money, without compromising patient care

In 2016, the Yorkshire and Humber Clinical Network convened a series of meetings for steering groups to develop High Value Pathways (HVP) for the management of Prostate cancer across Yorkshire. Based on the best available evidence, they recommended:

- At diagnosis, men with Prostate cancer should, if clinically appropriate, be assigned to the relevant risk stratified follow up pathway
- Commissioners and providers should review existing resource commitment and adapt and implement risk stratified follow up for stable prostate cancer

Other relevant policy and guidance supporting risk stratification includes:

- NCSI (2011) Innovation to implementation: Stratified pathways of care for people living with or beyond cancer A 'how to guide'.
- Achieving world-class cancer outcomes a strategy for England 2015-2020
- Implementing the cancer taskforce recommendations: commissioning person centred care for people affected by cancer (2016)
- NHSE and NHSI (2018) Refreshing NHS Plans for 2018/19

Why stratify?

- Many outpatient follow up appointments offer little value to the patient. Large proportions are scheduled simply to convey a test result.
- Demand is increasing by at least three per cent per year due to increased incidence and improved survival rates. Additional resources are not available to meet this increasing demand.
- Effective risk stratification releases capacity, which in turn can be used to deliver:
  - timely initial diagnosis and treatment. (This is a particular issue in the Prostate pathway so there is a big incentive to get this right).
  - and supporting those with metastatic and complex disease.
- Needs change as patients move along the pathway demanding a more tailored approach to care in place of the current 'one size fits all' approach.
- The personal cost of follow-up can be significant for patients particularly those with other conditions and illnesses who need to attend other departments. Where the patient cost of care can be reduced it should be.
- Technology is offering many new alternatives to face-to-face follow up.

- Existing clinics are often overbooked and ensuring access times for new patients and urgent follow ups can be challenging.

Current Risk stratified pathways for Prostate cancer

Locally commissioned arrangements are already in place in some of our localities:

CCG Locality	Prostate	Comment
Bassetlaw	None	
Barnsley	None	
Doncaster	X	Primary care – limited activity at this stage
Hardwick	X	Primary care – activity not clear at this stage
North Derbyshire	X	Primary care – activity not clear at this stage
Rotherham	X	Primary care – activity not clear at this stage
Sheffield	X	Primary care – some Hormone drugs
Wakefield	X	Primary care – significant activity +/- 2000 pa

There is a variable system of follow-up in place currently which broadly includes:

- Face to face contact (Acute and or Primary care)
- Other contact eg: telephone
- Surveillance investigations
- Holistic needs assessment (ad hoc), with onward signposting and referral
- Health & wellbeing events/groups

In 2014 Wakefield (364,000 population) implemented seven pathways to support the Risk stratification of men affected by Prostate cancer. Wakefield already had Anti-Androgen Injection pathway in place since 2009. From evaluation (below) **1935 primary care follow ups** were provided in 2015/16, with the majority (85%) being injection therapy. Patient experience is very positive with most patients rating their care as excellent or good.

Pathway	FU	New	Housebound
Injection Therapy	1344	150	131
Oral Hormone Therapy	14		
Radiotherapy - Intermediate/Locally Advanced	4		
Persistently Raised PSA	1		
Radical Prostatectomy	38	15	
Radiotherapy - Post External Beam	46	23	
Radiotherapy - Primary	5	3	
Watchful Waiting	144	17	
Total	1596	208	131
Grand Total	1,935		

Section 2 – Who is suitable for risk stratification

Shared principles in the delivery of follow up care

No matter who or how follow up care is provided there are shared principles we would expect. Tailoring follow-up to individuals will require more than one approach to the delivery of follow-up pathways in the future. Some patients will have less direct secondary care contact, whilst retaining the same level of care and support. Effective risk stratification will be dependent upon the presence of other key components of the pathway. These include:

- a system to ensure on-going surveillance tests happen at the right time
- effective holistic needs assessments that identify and address any outstanding needs and ensure the patient has the knowledge and confidence to self-manage; '**person centred conversation with a meaningful shared care plan'**
- good communication between specialist and primary care teams; and
- a system that allows timely re-access to the specialist team if needed
- **pathway choice is a joint decision between the individual and the clinician**
- expectations need to be clear at the start – patients and clinicians should be clear on how long they may be followed up in a particular setting, this may be earlier, but it will be based on their needs.
- follow-up after treatment for prostate cancer comprises two key elements
    - Clinical care / Psychosocial support
    - Surveillance tests to look for recurrence of disease
- These two elements are not necessarily interdependent. Some patients may not be appropriate for surveillance monitoring, but may require ongoing review for clinical or psychosocial concerns. Conversely, many patients in an active surveillance programme will not require regular clinical review.

Patients suitable for risk stratified follow up including surveillance for recurrence

- Following treatment, patients should be assessed for suitability to participate in post treatment surveillance programmes based on clinical factors and patient choice.
- Post treatment surveillance does not require regular clinical contact with patients and can be delivered remotely or via primary care, as long as a robust system is in place to ensure that tests are being correctly requested and reviewed.
- The risk of developing recurrence varies with known risk factors and a stratified approach to surveillance tests is appropriate.

There are five groups of men who are suitable for risk stratified follow up:

1. **Adjuvant Anti Androgen Injection**
2. **Long Term Anti Androgen Treatment**
3. **Radical Prostatectomy**
4. **Radiotherapy**
5. **Watchful wait**

1. **Adjuvant Anti Androgen Injection** - Anti Androgen Hormone Injections are prescribed by Secondary Care Clinicians and can be delivered to the patient in Primary Care. In some cases these patients remain under secondary care as receiving other treatments. The duration of hormones and the frequency of GP review including PSA as specified in management plan. Considered from 3 months post treatment. Where men remain under secondary care they may be suitable for remote PSA monitoring.
   Red flags - A rising PSA as specified in individual management plan, Significant or deteriorating IPSS, Haematuria or recurring UTI, GP Concern, Cardiac Event

2. **Long Term Anti Androgen Treatment** – (As above) The treatment is for men who have been diagnosed with prostate cancer and the progression is stable. The duration of hormones, the frequency of GP review including PSA is specified in management plan. Considered from 3 months post treatment.
   Red flags – Advice: PSA doubling time of less than 6 months, Significant or deteriorating IPSS, GP Concern, Acute admission: Urinary retention, Bone pain and concern of spinal cord compression, 2 week wait: Haematuria or recurring UTI

3. **Radical Prostatectomy** - Radical prostatectomy is used in men with localised or locally advanced prostate cancer. Men should generally have a 10 year life expectancy. Shared care with Primary care would be for men who have a stable PSA<0.05ng/ml. They would have no ongoing post-operative problems requiring tertiary care input. Consultant review at 3 and 6 months, if stable, Nurse Led follow-up for 18 months. The tertiary care team may also choose remote PSA surveillance from 6 weeks. From 2 years GP may provide 6 monthly reviews up to 5 years following date of treatment, including PSA testing and then annual GP reviews ongoing Including PSA testing.
   Red flags: Advice: PSA 2 consecutive rises and PSA >0.1ng/ml, LUTS, Increase in urinary incontinence, GP Concern, Acute admission: Urinary retention, Bone pain and concern of spinal cord compression

4. **Radiotherapy** -
   a. **Intermediate/Locally Advanced** - External beam radiotherapy along with adjuvant androgen deprivation therapy is used in the management of intermediate and locally advanced non metastatic prostate cancer. It influences both local control and has a small survival benefit in patients of appropriate performance status and life expectancy from co morbidities. Management of PSA rise is expectant, with re introduction of androgen deprivation therapy as the mainstay of treatment. These patients are not usually suitable for other prostate directed therapies.
   Acute hospital review for 3 years in total, who may choose remote PSA surveillance from 6 weeks. From year 4 or 5 GP can provide annual reviews up to 10 years following date of treatment, including PSA testing.
   Red flags: Advice: 6 month doubling time of PSA, GP Concern, PSA > 10, Acute admission: Urinary retention, Bone pain and concern of spinal cord compression

   b. **Post Salvage External Beam Radiotherapy** – Out with the current Radicals trial, patients undergo salvage radiotherapy plus or minus androgen deprivation

therapy for post operative PSA rise. The purpose of follow up is to detect toxicities and longer term PSA rise which may warrant systemic therapy. Acute hospital review for 5 years in total. The acute trust may also choose remote PSA surveillance from 6 weeks. From year 5 GP can provide 6 monthly reviews up to 15 years following date of treatment, including PSA testing and then annual GP review from year 15.
Red flags: Advice: PSA >0.4, GP Concern, Acute admission: Urinary retention, Bone pain and concern of spinal cord compression

c. **Primary Radiotherapy of Brachytherapy or External Beam Radiotherapy** - External beam radiotherapy or brachytherapy is used in men with early stage prostate cancer. Men should generally have a 10 year life expectancy. Shared care would be for men who have a stable PSA <2ng/ml. They would have no ongoing post radiotherapy problems requiring secondary care input. These patients may be suitable for salvage prostate directed therapies preferably within clinical trials.
Acute hospital review for 2,3 or 5 years depending on risk. The acute trust may also choose remote PSA surveillance from 6 weeks.
'Low risk' patients can be discharged back to GP at years 2 or 3; if the locality has an arrangement in place with Primary care. The onus has been on CCG/localities to communicate with Oncologists when this is set up. GP can provide 6 monthly reviews up to 5 years following date of treatment, including PSA testing and then annual GP reviews ongoing Including PSA testing.
'High risk' are discharged at year 5 for annual PSA.
Red Flags: Advice: 3 consecutive rises in PSA, PSA >2, GP Concern, Acute admission: Urinary retention, Bone pain and concern of spinal cord compression

5. **Watchful Waiting** - Watchful waiting involves the conscious decision to avoid treatment unless symptoms of progressive disease develop. Often for older men or those with significant co-morbidities and thought unlikely to have significant cancer progression.
Patient can be transferred to shared care with Primary Care with an individual management plan or the acute trust may also choose remote PSA surveillance. Patient will require blood tests at 6 months whether followed up remotely or via Primary care.
Red Flags: Advice: PSA of 50 or doubling of 6 months or less, Significant or deteriorating IPSS, GP Concern, Acute admission: Urinary retention, Bone pain and concern of spinal cord compression, 2 week wait: Haematuria or recurring UTI

<u>Supporting the whole person - the Recovery package</u>

- All patients should be reviewed face to face post surgery/completion of treatment to determine a follow-up/care plan
- A Holistic needs assessment should be performed around the time of diagnosis and following treatment to detect concerns that may require addressing. Where patients do raise concerns a care plan will be developed and appropriate signposting/referral will be made.

- Patients without any on-going clinical or psycho-social concerns do not require regular clinical contact with the secondary care team as long as a robust system is in place to identify problems and allow patient to access back to the secondary care team as needed.
- All patients should have a Treatment summary and an individual management plan if care is to be shared with primary care.

Section 3 – How, delivering risk stratified follow up

The programme is working towards the ICS/Cancer Alliance integration level ***(ii)*** *Single system level commissioning framework to improve connectivity with contracting and delivery at place (ACP).* Therefore if the same outcome is achieved, the delivery method does not need to be the same in each local place. It is also clear that when considering the different options for the delivery of risk stratified follow up there will be local place based issues/needs which require consideration.

The need for regular clinical follow-up in secondary care ("face to face" or "phone") is not dependent on risk of recurrence or site of disease, but whether patients have ongoing issues to address. i.e. decision based on:

- Clinical issues
- Persons individual needs, identified through a Holistic needs assessment
- General fitness
- Functional problems
- Psycho-social issues

Patients and health professionals need to have confidence in ongoing care and surveillance whoever is providing that care. Consequently, a defined period of follow-up after which patients would be discharged if there are no current issues is recommended.

Currently, no trust has a system in place whereby surveillance tests can be requested remotely (i.e. independently from patient follow-up) with the full confidence that no patient will be lost to follow-up. Without such a system, it is likely that patients in surveillance would need ongoing regular face to face contact with secondary care for the first two years on average.

However from the work undertaken to date it is clear that there is the opportunity for a joint model of care provided by both secondary and primary care. Based on the five groups of men suitable for risk stratified follow up we can say in general terms to <u>maximise</u> the benefits of risk stratification for Prostate cancer there is scope in:

- **Secondary care** for remote PSA surveillance combined with clinical led follow up as necessary
- **Primary care** for shared/discharged follow up care including PSA testing and Hormone injections

This would look something like:

Secondary care - remote PSA surveillance combined with clinical led follow up as necessary
Primary care - shared/discharged follow up care including PSA testing and Hormone injections

	3 months	6 months	year 1	year 2	year 3	year 4	year 5	year 10	year 15
1. Adjuvant Anti Androgen Injection									
2. Long Term Anti Androgen Treatment									
3. Radical Prostatectomy									
4. Radiotherapy a									
Radiotherapy b									
Radiotherapy c*									
5. Watchful wait									

***** 2, 3, or 5 years depending on risk

Sample pathways/protocols for both are available;

Secondary care remote PSA surveillance from Wessex University Hospital. Many hospitals now use remote monitoring systems based on either additional software in systems like Infoflex or recording a PSA range within the current system. Bloods can be taken in primary care and the PSA result goes directly to the secondary care clinical team. The results are reviewed often by band 4 'support worker' with any deviation from the individual patients' normal range being highlighted to a clinician for action.

Primary care shared care from Wakefield can be found in Appendix 1 - where primary care is currently commissioned the tasks required, the quality standards and monitoring requirements are detailed in a service specification.

Section 4 - Recommendations & Actions

1. All clinical teams in acute provider trusts, across the LWABC programme footprint should adopt the guidelines in Section 2 - Who is suitable for risk stratification.

2. For those localities where they already have local arrangement in place, the programme will support local commissioners and providers evaluate their current approach to risk stratification for prostate cancer and explore the opportunities to maximise the benefits of risk stratification based on this guidance.

3. For those localities where they don't currently have local arrangements in place the programme will support local commissioners and providers to agree the appropriate delivery model for risk stratification for prostate cancer in their locality based on this guidance.

4. Local commissioners should include this guidance in commissioning intentions for 2019/20 contracts (August 2018), which will be commissioned within provider contracts in 2019/20.

Appendix 1 - Primary care shared care specification Wakefield

Wakefield - Prostate
Cancer Share Care Fo