Northern Cancer Alliance Follow up guidelines for prostate cancer patients

2019/2020

Developed and endorsed by the Northern Cancer Alliance Urology Pathway Board

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INTRODUCTION

This document provides regional guidelines to prostate teams for the management of follow up for people with localised or locally advanced prostate cancer having radical treatment or on watchful waiting. It also includes a section on management of patients with metastatic disease and advice on how to manage suspected malignant spinal cord compression. The guidance is designed to complement existing national guidelines e.g. National Institute for Health and Care Excellence (NICE) and is part of the Northern Cancer Alliance Urology Clinical Guidelines. This guideline does not override the individual responsibility of healthcare professionals in making decisions appropriate to the circumstances of the individual patient.

It is not anticipated that the guidelines will cover all clinical situations in all patients, but where unusual circumstances exist, it is expected that such treatments would be discussed in the appropriate MDT.

These guidelines were developed by a sub group of the Northern Cancer Alliance Urology Clinical Guidelines takes into account NICE clinical guidelines [NG131] May 2019, Prostate Cancer QS91

The guidelines will be reviewed on an annual basis. Where new treatments are introduced between revisions they will be added as an addendum to the current guideline.

BACKGROUND

Prostate cancer is the most common cancer in men in the UK 1. Majority (84%) of men diagnosed with prostate cancer live beyond 10 years 1. The incidence and prevalence of prostate cancer continues to increase thereby putting pressure on available resources. Moreover, current practice of prostate cancer management is not meeting all of the needs of those living with and beyond cancer.

NHS improvement working as part of the National Cancer Survivorship Initiative (NCSI) to improve the quality and effectiveness of care and support to those living

with and beyond cancer, tested stratified prostate cancer follow up at four test sites. The interesting findings from the pilot were:

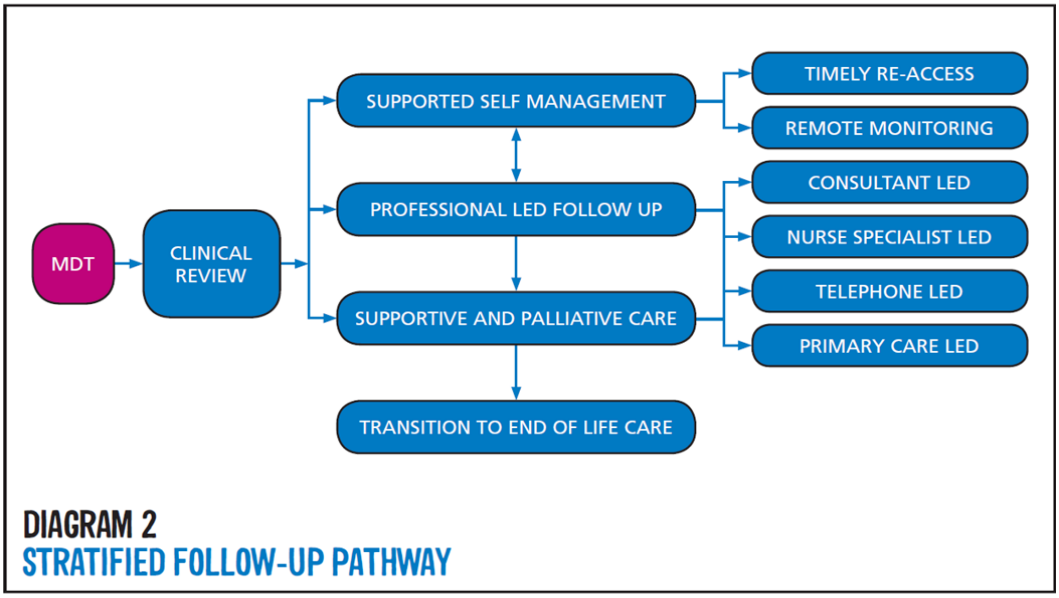
- The majority (80%) of patients felt fairly or very confident in managing their own health
- Patients required better information on signs and symptoms to look out for
- Better management of erectile dysfunction
- Better continence management

These findings add to the existing body of information that strengthens the approach to better inform our patients and primary care practitioners, perform a thorough assessment of patients' needs, risk assess and arrange appropriate follow up.

The NHS Long Term Plan (2019) states that the traditional model of outpatient follow up is outdated and unsustainable and aims to redesign services so that patients avoid unnecessary face-to-face outpatient visits; putting them in charge of their own survivorship with all the necessary assurances in place regarding re-entry to specialist care when absolutely necessary. This vision was secured in the NHS Operational and Planning Guidance 2019/20 which placed requirements on Cancer Alliances to help roll out commissioned remote stratified follow up pathways for prostate cancer patients by April 2021. Following completion of radical treatment suitably informed patients who fulfil the necessary criteria outlined below, as part of standard of care from April 2021 will be provided with the necessary support and tools needed to safely self-manage their condition. It is incumbent on all CCGs and hospital trusts across the alliance to find a way to commission and facilitate a safe remote follow up strategy with the necessary governance and support structures in place to assure patients are appropriately safety-netted at all times and have access back into specialist uro-oncology services in a timely manner. This is in line with NICE guideline [NG131]. In May 2019 the NICE guidance committee agreed that based on their expertise, patients who successfully completed radical treatment (radical prostatectomy, or radiotherapy based), should be counselled regarding a remote follow-up strategy. From April 2021 it is recommended that patients are counselled for remote monitoring according to the criteria set below.

It also advised to follow up people with prostate cancer who have chosen a watchful waiting regimen with no curative intent in primary care if protocols for this have been agreed between the local urological cancer MDT and the relevant primary care organisation(s).

STRATIFIED FOLLOW UP PATHWAYS



Following clinical assessment of their needs, both low and high risk patients can be supported to manage their own follow-up, with back up from the clinical team as needed. Under this system patients will no longer have routine follow up appointments; instead they are educated and encouraged to contact the cancer specialist nurses when they have a new concern or problem regarding their prostate cancer. PSA testing will take place as per recommendations from these guidelines. It will be up to individual CCGs and Hospital Trusts caring for the respective patients to decide on where PSA tests are performed, (ideally at a location most convenient to the patient). We recommend that PSA results are monitored and acted upon accordingly by the relevant secondary care site. The details of the implemented safety-netted system may vary from each locality dependent upon the agreed commissioned service deployed. It is expected that all patients who fulfil the remote follow up remit across the Norther Cancer Alliance will routinely be offered this from April 2021.

The patients follow up plan will be discussed with the patient when they attend the consultant's clinic. A urologist or specialist nurse should discuss the purpose, duration, frequency and location of follow-up with each person with localised and locally advanced prostate cancer, and if they wish, their partner or carers. Any patient anxieties and concerns about support should be addressed prior to embarking on remote follow-up. It is also important to note that not all patients will be

suitable for a remote follow up strategy and should not feel coerced into it. In addition, patients despite fulfilling the criteria for remote follow up, but develop significant complications post-treatment are likely to need more face-to-face consultation time. We should however avoid a paternalistic approach and with appropriate patient counselling (for example in a post-treatment remote follow up patient workshop) patients should be encouraged to confidently embark upon this pathway.

There are many working models already operational around the country demonstrating ways to develop and implement a remote follow up strategy. It is expected that an IT based solution is essential.

VISION

The aim of Norther Cancer Alliance is aligned to National Cancer Survivorship Initiatives supported by NHS Improvement (Cancer) and NICE guidance, is to ensure

- All individuals diagnosed with prostate cancer receive personalised information and appropriate support to enable them to live actively and well following the end of their cancer treatment.
- A safe, robust and transparent system is utilised to manage prostate cancer surveillance and ongoing care/support.
- Timely, safe and appropriate systems back into specialist services are in place in the event that a concern arises. Patients should not be left feeling isolated or uncertain who to contact at any point after their definitive treatment has ended.
- Each individual is provided with verbal and written guidance about exactly when and who to contact if they have any concerns in the future.

- The pathway incorporates the NCSI Recovery Package interventions (Holistic Needs Assessment and care plan, Treatment Summary, Cancer Care Review, Health and Wellbeing event) to improve outcomes and co-ordination of care. (see Appendix 1 & 2).

To this effect, following risk stratification and clinical parameters were discussed and agreed between the representatives from regional units.

PROCESS

1. Patients after radical prostatectomy

It is understood that patients undergoing prostatectomy will be looked after as currently with more formal needs assessment and stratified follow up. If discharge criteria are met then care will be transferred over to primary care for ongoing follow up. The criteria is as follows:

1.1 Discharge criteria

- PSA <0.1 or PSA stable under 0.1 (depending on the analyser), with no rise during the hospital follow up
- Functional, social and psychological issues are addressed and satisfied
- No new symptoms to address
- Understands the follow schedule required
- Holistic needs assessment repeated
- Treatment completion summary given to patient and GP

1.2 Risk stratification following final histology

Locally agreed low and high risk criteria have been described below. These help shape the type of remote follow up that should be offered

- Low risk
  - All patients with organ confined prostate cancer with negative margins and focal positive margins (pT2 R0 and focal R1)
  - All patients with extracapsular extension with negative margins (pT3a R0)
  - All patients with negative nodes (N0)

- High risk
  - All patients with organ confined prostate cancer with extensive positive margin (pT2 R1, >3mm positive margin)
  - All patients with extracapsular extension with any positive margin (pT3a R1)
  - All patients with seminal vesicle invasion irrespective of margins positivity
  - All patients with positive nodes (N1)

1.3 Follow up

- Low risk
  - First outpatient appointment (OPA) at a maximum of 3 months for histology and to discuss local remote stratified follow up option for risk group (It is understood that local units may manage this differently either via a letter or CNS led clinic etc.)
    - Second OPA and third OPA at 4 monthly intervals if patient declines risk assessed remote follow up.
    - Discharge to GP or placed on remote monitoring platform, where available, at 12 months post op, if stratified follow up criteria met, with following recommendation
    - PSA to be measured 6 monthly for further 2 years and yearly for 7 years
    - Any PSA rise should be followed up by a further measurement between 6-8 weeks.

- High risk
  - First outpatient appointment (OPA) at 3 months for histology and to discuss the local remote stratified follow up option for risk group
  - Subsequent OPA at 4 monthly intervals for two years in total
  - Discharge to GP or placed on remote monitoring platform, where available, at 24 months, (after 6th post op OPA) if stratified follow up criteria met and with following recommendation
  - PSA to be measured on a 6 monthly for further 3 years and then yearly for 5 further years

- Any PSA rise should be followed up by a further measurement between 6-8 weeks.

1.4 Remote Follow up Notes

- Please follow recommended schedule at stratified follow up for PSA monitoring
- Any PSA rise should be followed up by a further measurement between 6-8 weeks
- Following criteria should prompt a referral via urgent referral to the respective units (not a 2WW referral)
  a. If PSA rises to 0.2 ng/ml (confirmed by a further test in 6 weeks)
  b. Any new frank haematuria, new lower urinary tract symptoms not controlled by conventional treatment
  c. New unexplained bone pain lasting more than 6 weeks that has not improved with analgesia
  d. Please refer to individualized end of treatment summary for your patients

2. Patients after Radical Radiotherapy

With advances in radiology in general and evidence emerging to support aggressive local treatment, increasing number of patients are being treated with radiotherapy. Although risk stratification according to stage of disease is practical, given the various salvage treatment options available, including evidence to support improvements in disease free survival with the earlier recognition and treatment of “oligometastatic disease” to improve our patient outcomes, it is essential to diagnose recurrence as early as possible.

2.1 Stratified follow up

On completion of RT and first post RT appointment with oncology, patients are transferred on to urology follow up. The recommended standard will be remote follow up. It is therefore essential to have an end of treatment summary and HNA performed at discharge from oncology to identify any ongoing urgent needs and length of hormonal treatment.

At first outpatient appointment (OPA) with oncology, to discuss personalised remote follow up strategy.

To have 6 monthly remote PSA assessments for at least 5 years, then annually. ***PSA trigger values requiring an urgent referral for a face-to-face secondary care appointment to be agreed locally.***

Patients who decline or are not suitable for remote stratified follow-up should have 6 monthly PSA tests until 1 year after hormone manipulation has been stopped. Then offer remote PSA monitoring if suitable or local agreement with primary care to discharge. If PSA measurements have not shown an increase (nadir PSA value to be clearly stated on discharge summary) and HNA satisfactory and treatment summary completed

2.2 **Primary care follow up**

For patients who have either declined remote follow up or are outside a remote follow up programme and under primary care, a prompt referral via an urgent referral pathway (not a 2WW referral) should be made if:

a. The PSA is 2ng/ml more than the nadir PSA (nadir= the lowest PSA reading following RT). Please do note that the patients have their prostates in situ and need to ensure there is no UTI or any instrumentation that could rise PSA level prior to re-referral
b. Please refer to end of treatment plan for alternative PSA threshold for your patient
c. Any new frank haematuria, new lower urinary tract symptoms not controlled by conventional treatment
d. New unexplained bone pain lasting more than 6 weeks that has not improved with analgesia

Please refer to individualized end of treatment summary for your patients

3. Active surveillance

This area of practice felt to be the most complex and quite varied practices prevail amongst urologists. It is recognised that approximately 50% of patients under active surveillance will go on to receive radical treatment within 5 years.

Secondary care based remote follow up can be performed and decisions surrounding scheduled face-to-face appointments +/- further mpMRI and prostate biopsies will be made by each local urology team in tandem to the individual patient's

PSA dynamics. It was agreed that there will be local variations and the broad concept of stratified follow up was agreed.

3.1 Follow up schedule

- PSA testing 4 monthly for 2 years, 6 monthly for 3 further years
- Yearly DRE
- mpMRI with or without biopsies at local unit discretion depending on the initial biopsy strategy. The frequency between 1 and 4 years (taking into account MRI capacity available locally)
- Assess patient wishes, choice of treatment suitable for that particular patient and plan discharge
- Offer personalised remote follow up or discharge to primary care dependent on local arrangements with individualized PSA threshold (PSA density, doubling time, PSA velocity could be used)
- Please refer to individualized end of treatment summary for your patients

4. Watchful waiting

Following diagnosis, a HNA, patient wishes, treatment modalities discussed with patient.

4.1 Follow up schedule

- OPA at 6 month from diagnosis
- Assess HNA, discuss end of treatment summary
- Discharge if PSA < 20% increase, no symptoms to palliate

4.2 Primary care follow up for watchful waiting

- Assess PSA on a 6 monthly basis, could be every year depending the rate of rise

- Any of the following criteria should prompt an urgent (not a 2WW referral)
  a. If the PSA is >50ng/ml. Please do note that the patients have their prostates in situ and need to ensure there is no UTI or any instrumentation that could rise PSA level prior to rereferral
  b. Alkaline phosphatase >200u and rising, associated with bone pain
  c. Any new frank haematuria, new lower urinary tract symptoms not controlled by conventional treatment
  d. New unexplained bone pain lasting more than 6 weeks that has not improved with analgesia
- Please refer to individualized end of treatment summary for your patients

5. Hormone manipulation

Majority of patients with metastatic disease require hormones. Many of these patients will need to and should be followed up face-to-face during time on hormone therapy. This is because many patients will receive further systemic therapies including chemotherapy and oral anti-cancer agents and are likely to develop signs and symptoms of clinical progression. Despite this, there will be a group of patients who will benefit from a remote follow up strategy. This would include asymptomatic patients with metastatic disease who were deemed:

1. Not suitable for up-front Docetaxel chemotherapy in the metastatic hormone sensitive setting with a favourable* PSA response after 6 months of hormone therapy
2. Completed up-front docetaxel chemotherapy and have had a favourable* PSA response prior to developing castrate-resistant disease.
3. Asymptomatic patients with performance status of 0-1

*to be agreed locally – e.g. PSA > 90% reduction from presentation or < 4ug/L

It will be incumbent on the local discharging urology and oncology team to decide on the PSA value that triggers referral back to secondary care for re-staging and further treatment.

5.1 Follow up schedule

- OPA at 6 month from diagnosis

- Assess HNA, discuss end of treatment summary
- Discharge if PSA shows >90% reduction, no symptoms to palliate

5.2 Primary care follow up

- Please refer to individualized end of treatment summary for your patients
- Assess PSA on a 6 monthly basis, could be every year depending the rate of rise. Please do note that the patients have their prostates in situ and need to ensure there is no UTI or any instrumentation that could rise PSA level prior to re-referral
- Any of the following criteria should prompt an urgent referral (not a 2WW referral)
- If the PSA shows 3 consecutive rises (please refer to end of treatment plan for alternative PSA threshold)
- Alkaline phosphatase >200u
- Any new frank haematuria, new lower urinary tract symptoms not controlled by conventional treatment
- New unexplained bone pain lasting more than 6 weeks that has not improved with analgesia

6. Malignant Spinal Cord Compression

Patients on both remote follow up strategies and those who are eventually discharged to primary care need to be cognisant of the risks of malignant spinal cord compression. Those at the highest risk are those with metastatic disease, on hormone therapy and those who are on a watchful-waiting strategy. Patients in these groups should be given patient information regarding red flag symptoms and signs to look out for as well as appropriate contact details and be told to seek immediate advice.

Both Primary and secondary healthcare staff responsible for these patients should know to alert the malignant spinal cord coordinator at their relevant hospital site for further advice and management. This guidance should be made available in the GP discharge letter when necessary.

Signs and Symptoms

1. Unexplained Neck Pain
2. Numbness / Pins and Needles in hands and feet buttocks
3. Unsteady on Feet
4. Problems passing urine
5. Faecal incontinence

7. Re-Access to Prostate services

Re access to services should be made as an urgent GP referral to the respective department if disease specific re referral criteria are met. This should not be a 2ww referral. Summary treatment plan prepared at the end of treatment would also include the re-referral route with appropriate contact details. This may vary for different units in the region. Going forward this may change to allow for a separate referral route e.g via cancer care coordinator.

REFERENCES:

1. https://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/prostate-cancer
2. https://www.nice.org.uk/guidance/ng131

APPENDIX 1

Treatment Summary

Patient details……

Dear Dr

Your patient has now completed their initial treatment for cancer and a summary of their diagnosis; treatment and ongoing management plan are outlined below. The patient will be sent/given a copy of this summary.

<table>
<tr><td>Diagnosis:

Date of diagnosis :</td><td>Consultant Surgeon</td><td>Histology</td></tr>
<tr><td colspan="2">Summary of Treatment and relevant dates:

Summary of recent examination</td><td>Endocrine therapy Yes/no
Name and dose of endocrine therapy

Date to complete</td></tr>
<tr><td colspan="2" rowspan="3"></td><td>Health needs assessment complete Yes/No

Action required</td></tr>
<tr><td>Contacts for re referrals or queries:

Cancer Nurse Specialist

Name

Contact no</td></tr>
<tr><td>Other service referrals made:</td></tr>
<tr><td colspan="2">Written information given including information on lifestyle and support needs/access back into service

Date</td><td></td></tr>
<tr><td colspan="3">Any other comments/advice

Discharge from service to GP Date</td></tr>
<tr><td colspan="3">Completing clinician name /contact no:
Date:</td></tr>
</table>

APPENDIX 2

Holistic Needs Assessment

Patient details:

This self-assessment is **optional**; however it may help us to understand the concerns and feelings you have. It will also help us identify any information and support you may need in the future.

If any of the problems below have caused you concern and you wish to discuss them with a health care professional please tick the box.

Social

Coping with dependants
Work hobbies/leisure activities
Finances
Parking/travel
Support

Physical

Difficulties communicating
Sleep
Pain
Menopausal symptoms
Tiredness/fatigue
Erectile dysfunction

Psychological/Emotional

Anxiety
Depression
Fear
Body image issues
Emotional support
Stress
Relationship issues including sexual/intimacy

Action

Clinical Nurse Specialist **Date**