P3 PROSTATE CANCER FORUM 2026

Perspectives, Possibilities, Progress

Delivering Personalised Prostate Cancer Care via Shared Decision-Making

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PP-NUB-GB-2952 | May 2026

Declarations of interest

Honoraria / Advisory Boards / Conference Attendance:

- Bayer, Astellas, Novartis, AstraZeneca, Janssen

American Society of Clinical Oncology (ASCO)

- Member of the Education Board; Member of the Taskforce on International Research Education

The Learning Lab

- Chief Medical Officer

The London Clinic

- Clinical Lead for Radiotherapy; Joint Research Lead

What is shared decision-making (SDM)?

➢Collaboration:

- Patient and family / carers
- Clinical team

➢Discussion:

- Current best clinical evidence
- Clarity over risks and benefits
- Alignment with patient values and preferences

SDM, shared decision-making.
Based on speaker's own personal experience.

Why is SDM essential in prostate cancer?

- Multiple treatment options
- “Grey” comparison data
- Quality of life trade-offs
- Long disease trajectory
- Risk of decisional regret

Considerations:

- Localised Disease
- Metastatic Disease

SDM, shared decision-making.
Based on speaker’s own personal experience.

Localised prostate cancer

Regret associated with:[1–6]

- Less active engagement / satisfaction in the decision-making process
- Worse post-treatment outcomes
  - +ve surgical margins / PSA recurrence
- Lower QoL
- Longer length of time from treatment
- Depressive / anxiety symptoms

+ve, positive; PSA, prostate-specific antigen; QoL, quality of life.

1. Baunacke M. et al. J Urol 2020;203(3):554–561; 2. Link C. Pract Radiat Oncol 2019:9:e516–e527; 3. Lavery H.J. et al. J Urol 2012;188(6):2213–2218;
4. Hoffman R.M. et al. JCO 2017;35(20):2306–2314; 5. Wallis C. et al. JAMA Oncology 2022;8(1):50–59; 6. Szproch A.K. et al. Journal of Psychosocial Oncology 2022;40(1):1–25.

Metastatic prostate cancer

Survey: mHSPC[1]

- 201 men
  - 319 sent the questionnaire
- Median of 2 years post:
  - Orchidectomy 29%
  - LHRH analogue 71%
- 23% expressed regret
- Qualitative analysis (focus groups)
  - Uncertainty about prognosis
  - Uncertainty about the quality of decisions they made

TOPCOP1 Study: mCRPC[2]

- 198 men; aged >65 years
  - 30% non-responders
  - Awaiting docetaxel / ARPI / Radium-223▼
- Decision regret analysed post treatment
- Post-treatment decision regret was low:
  - Higher with baseline pain
  - Higher with early discontinuation of therapy

ARPI, androgen receptor pathway inhibitor; LHRH, luteinising hormone-releasing hormone; mCRPC, metastatic castration-resistant prostate cancer; mHSPC, metastatic hormone-sensitive prostate cancer; TOPCOP1, Towards Optimal Prescription of ChemOtherapy in Prostate cancer.

1. Clark J.A. et al. JCO 2001;19:72–80; 2. Guo S. et al. JGO 2025;16:102240.

Guidelines

NICE Guideline 197: *Published June 2021*[1]

- Acknowledge a decision exists
- Present options clearly and fairly
- Align treatment recommendations with patient values and preferences

NICE Guideline 131: *Updated December 2021*[2]

- Offer people with prostate cancer information tailored to their own needs
- Offer people with prostate cancer advice on how to get information and support from websites, local and national information services, and from cancer support groups
- Choose or recommend information resources for people with prostate cancer that are clear, reliable and up to date. Ask for feedback...

NICE, National Institute for Health and Care Excellence.
1. NICE | Shared decision-making | Guideline 197. Available at: https://www.nice.org.uk/guidance/ng197 (accessed May 2026);
2. NICE | Prostate cancer: diagnosis and management | Guideline 131. Available at: https://www.nice.org.uk/guidance/NG131 (accessed May 2026).

Challenges

- Ageing population
- Multiple comorbidities
- Polypharmacy
- Diversity of preferences and values
- NHS capacity
- Inequity of healthcare access
- Virtual / telephone clinics
- Increasingly complex management options
- Early intensification

NHS, National Health Service.
Based on speaker's own personal experience.

Virtual consultations

Potential benefits[1]

- Flexibility
- Inclusion of relatives / carers
- Reduced travel burden
- Potential to share digital aids on screen

Potential risks[1]

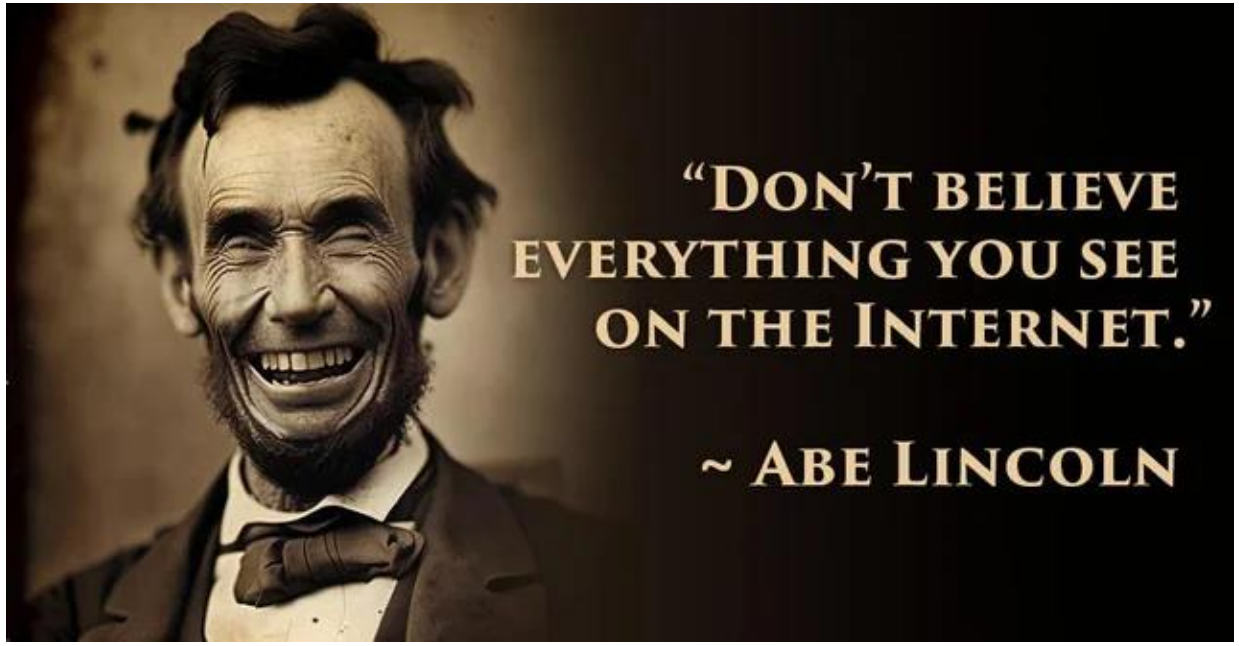
- Missed non-verbal cues
- Difficulty assessing frailty, cognition, distress
- Time compression
- Digital exclusion

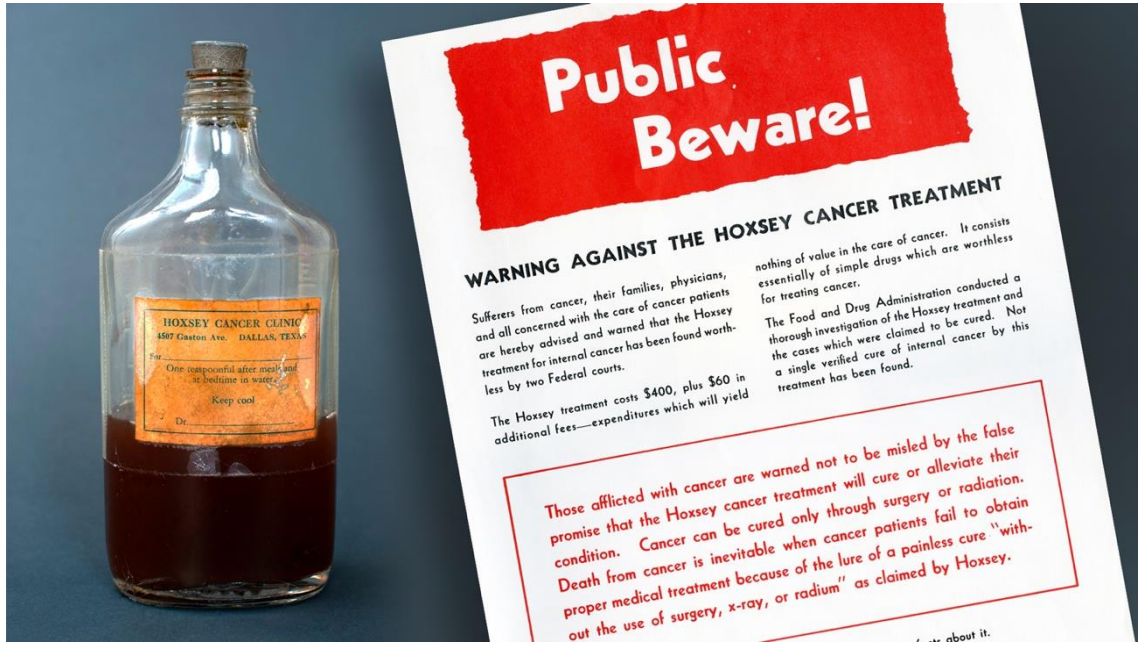
UK Context

- GMC Guidance:[2]
  - Same standards for consent for remote consultations
  - Clinicians must ensure understanding
- NICE Guidance 197:[3]
  - Meaningful SDM – regardless of the format

GMC, General Medical Council; NICE, National Institute for Health and Care Excellence; SDM, shared decision-making; UK, United Kingdom.
1. Based on speaker's own personal experience; 2. The MDU. Conducting remote consultations. Available at: https://www.themdu.com/guidance-and-advice/guides/conducting-remote-consultations (accessed May 2026); 3. NICE | Shared decision-making | Guideline 197. Available at: https://www.nice.org.uk/guidance/ng197 (accessed May 2026).

Social media[1,2]





1. Image available at: https://thefinanser.com/2025/09/everything-on-the-network-is-a-scam-and-why-principles-matter (accessed May 2026); 2. US Food And Drug Administration. Products claiming to "cure" cancer are a cruel deception. Available at: https://www.fda.gov/consumers/consumer-updates/products-claiming-cure-cancer-are-cruel-deception (accessed May 2026).

Social media

Potential benefits

- Increased awareness of treatment options
- Access to peer experiences
- Exposure to survivorship narratives
- Greater confidence to ask questions in clinic
- Signposting to reputable organisations

Potential risks

- Anecdote > evidence
- Overestimation of benefit from highly selected “success stories”
- Over- / under-estimation of toxicity or treatment burden
- Misinformation – non-evidence-based therapies
- Heightened anxiety and decisional conflict

Based on speaker’s own personal experience.

Social media

Impact on consultation dynamics:[1]

- Patients arrive with preformed preferences
- Framing effects
- Time to correct misinformation
- Risk of perceived dismissal in concerns not validated

UK professional context:

- GMC:[2]
  - Doctors must engage respectively with patient-sourced information
- NICE NG197:[3]
  - Decisions must be informed and evidence-based
- NHS England:[4]
  - Personalised care includes supporting health-literacy

GMC, General Medical Council; NHS, National Health Service; NICE, National Institute for Health and Care Excellence; UK, United Kingdom.

1. Based on speaker's own personal experience; 2. GMC | Decision Making and Consent. Available at: https://www.gmc-uk.org/cdn/documents/gmc-guidance-for-doctors---decision-making-and-consent-english_pdf-84191055.pdf (accessed May 2026); 3. NICE | Shared decision-making | Guideline 197. Available at: https://www.nice.org.uk/guidance/ng197 (accessed May 2026); 4. NHS England | Enabling people to make informed health decisions. Available at: https://www.england.nhs.uk/personalisedcare/health-literacy/ (accessed May 2026).

Resources

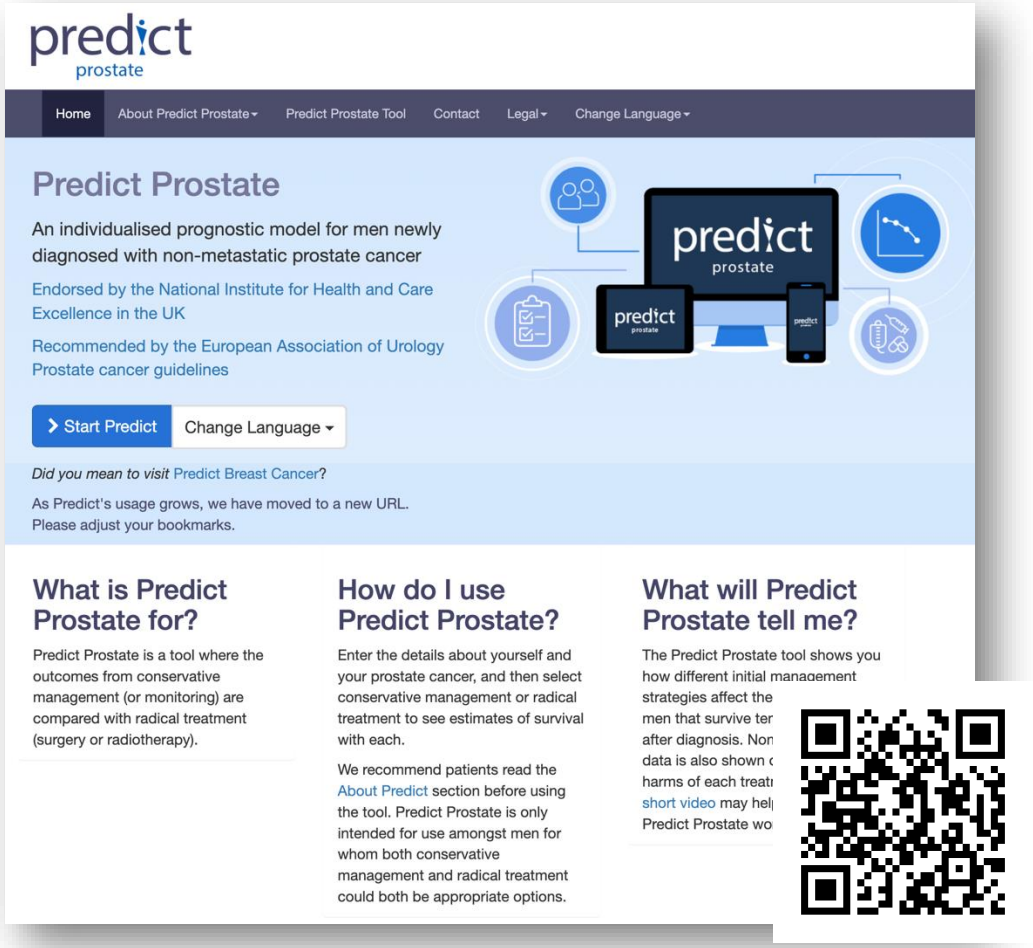
Clinical Nurse Specialist (CNS) support

- Single point of contact
- Personalised management approach
- Information translation from diagnosis (patient and family)
- Decision coaching
- Side effect support
- Signposting to specialist support services

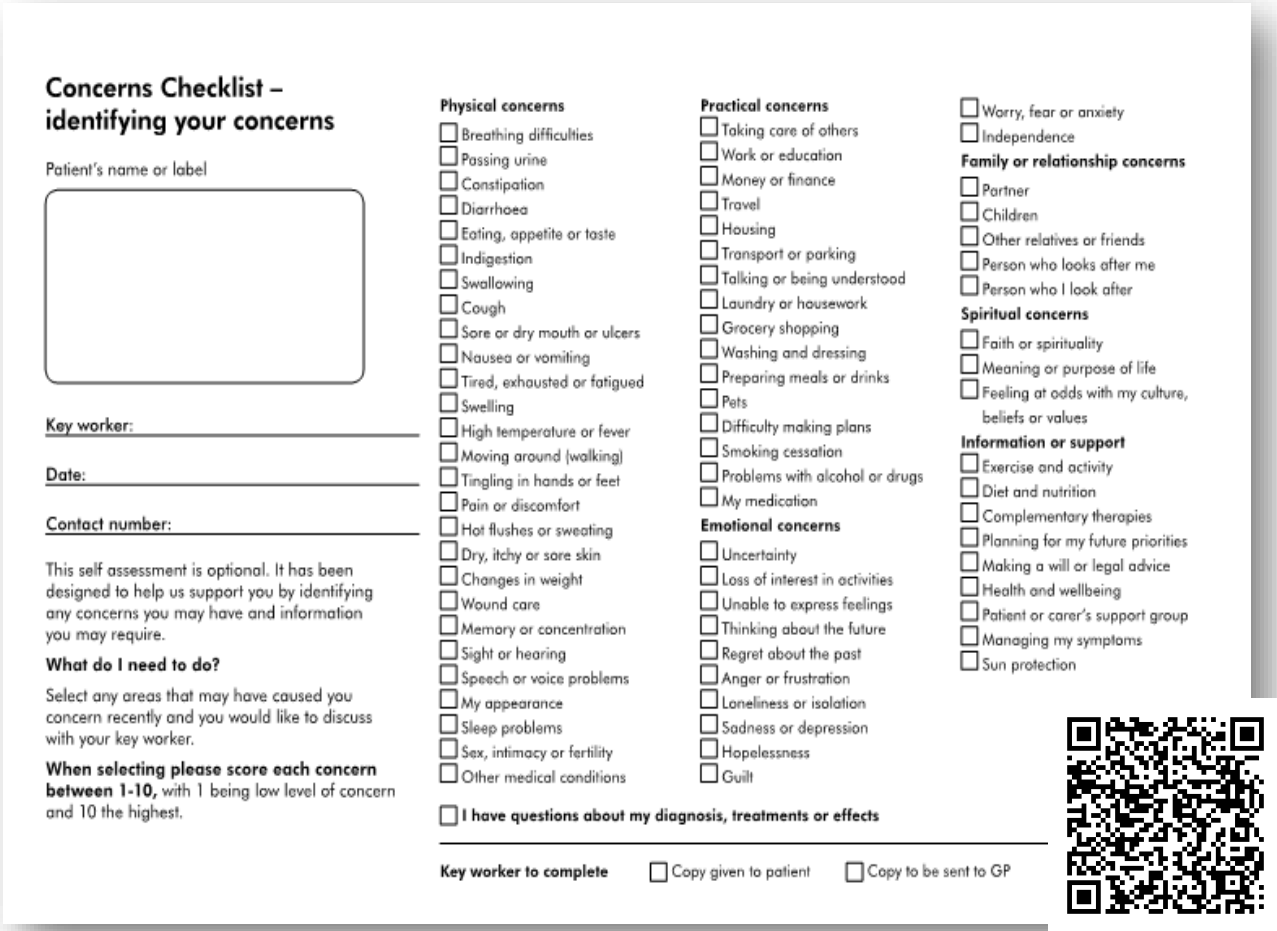
CNS, Clinical Nurse Specialist.
Based on speaker's own personal experience.

Decision support tools

Non-metastatic prostate cancer[1]



All patients with a cancer diagnosis[2]



1. Predict prostate. Available at: https://prostate.predict.cam/ (accessed May 2026); 2. Holistic Needs Assessment (HNA) | Macmillan Cancer Support. Available at: https://www.macmillan.org.uk/healthcare-professionals/innovation-in-cancer-care/holistic-needs-assessment (accessed May 2026).

Peer support and education programmes

Advanced Prostate Cancer Club[1,2]

- Healthy hormone events
- Education events
- Weekly online exercise class
- Fortnightly walking group
- Monthly relaxation classes/ Qi gong
- Monthly cinema club
- Quarterly art courses
- Christmas and summer socials
- Grave talks
- Look good Feel better
- Days out
- Partners meet-up / support
- Acupuncture

ADVANCED PROSTATE CANCER CLUB

SUPPORT • INFORMATION • ACTIVITIES

The Androgen Deprivation Therapy Educational Programme[3]

1. Advanced Prostate Cancer Club – APCC - For Men on Hormone Therapy for Prostate Cancer. Cancer Care Map. Available at: https://www.cancercaremap.org/advanced-prostate-cancer-club-apcc/2 (accessed May 2026); 2. Based on speaker's own personal experience; 3. The Androgen Deprivation Therapy Educational Programme. Available at: https://www.lifeonadt.com/ (accessed May 2026).

Geriatric oncology: Comorbidity optimisation

Comprehensive Geriatric Assessment:[1,2]

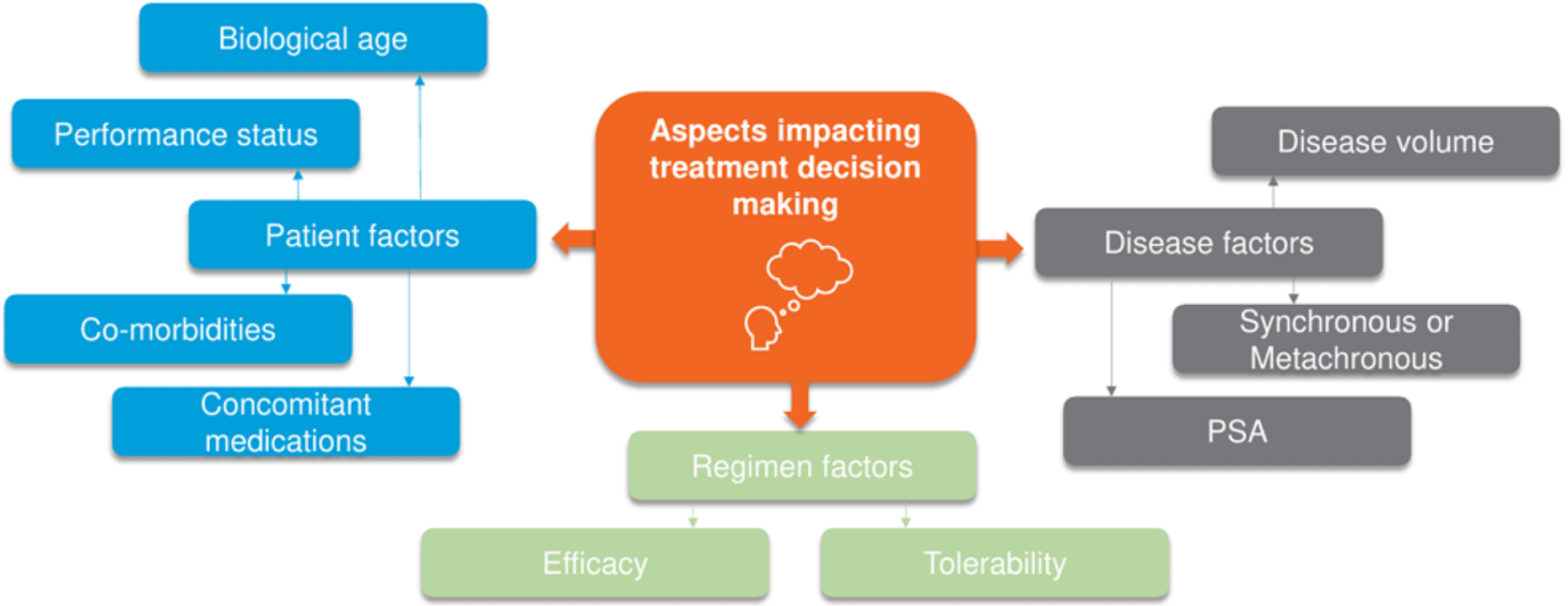
- Screening:
  - Identify areas for further assessment and support
- Assessment:
  - Fitness / vulnerabilities / goals / scope for intervention
- Optimisation / support plan:
  - Optimise fitness
  - Anticipate / mitigate toxicity
  - Improve support

1. Department of Health, Age UK and Macmillan. Cancer Services Coming of Age: Learning from the Improving Cancer Treatment Assessment and Support for Older People Project. Available at: https://assets.publishing.service.gov.uk/media/5a7b7e4e40f0b62826a03f0c/DH_Macmillan_Age-UK_Report_Final.pdf (accessed May 2026); 2. Based on speaker's own experience.

SDM and mHSPC

mHSPC, metastatic hormone-sensitive prostate cancer; SDM, shared decision-making.

mHSPC treatment intensification



Note:

- Not everyone benefits equally
- Are we over-treating low-volume metastatic prostate cancer with indolent biology?

mHSPC, metastatic hormone sensitive prostate cancer; PSA, prostate-specific antigen.
Based on speaker's own personal experience.

Case illustration 1*

Fit 60-year-old man

mHSPC

- De novo
- High-volume
- High-grade

Priority: Maximum survival

Initial management options:

- Observation
- ADT alone
- ADT + ARPI
- ADT + docetaxel + ARPI

*This is a fictional patient case based on the speaker's own clinical experience.
ADT, androgen deprivation therapy; ARPI, androgen receptor pathway inhibitor.

How do we portray the evidence?*

What is the evidence for triplet vs. doublet therapy (ARPI)?

Considerations:

- Fitness for docetaxel
- Cancer characteristics:
  - High-volume / synchronous / high-grade
- Portrayal of evidence:
  - Hazard ratio vs. absolute % benefit vs. relative % benefit
- Patient preference

*This is a fictional patient case based on the speaker's own clinical experience.
ARPI, androgen receptor pathway inhibitor.

Case illustration 2*

60-year-old man

IHD, T2DM, TIA, AF
- DOAC

mHSPC
- De novo
- High-volume
- High-grade

Priority: Maximum survival

Initial management options:

- Observation
- ADT alone
- ADT + ARPI
- ADT + docetaxel + ARPI

*This is a fictional patient case based on the speaker's own clinical experience.
ADT, androgen deprivation therapy; AF, atrial fibrillation; ARPI, androgen receptor pathway inhibitor; DOAC, direct oral anticoagulant; IHD, ischaemic heart disease; T2DM, type 2 diabetes mellitus; TIA, transient ischaemic attack.

How do we portray the evidence?*

What is the evidence for triplet vs. doublet therapy (ARPI)?

- Would this patient have been eligible for trials?

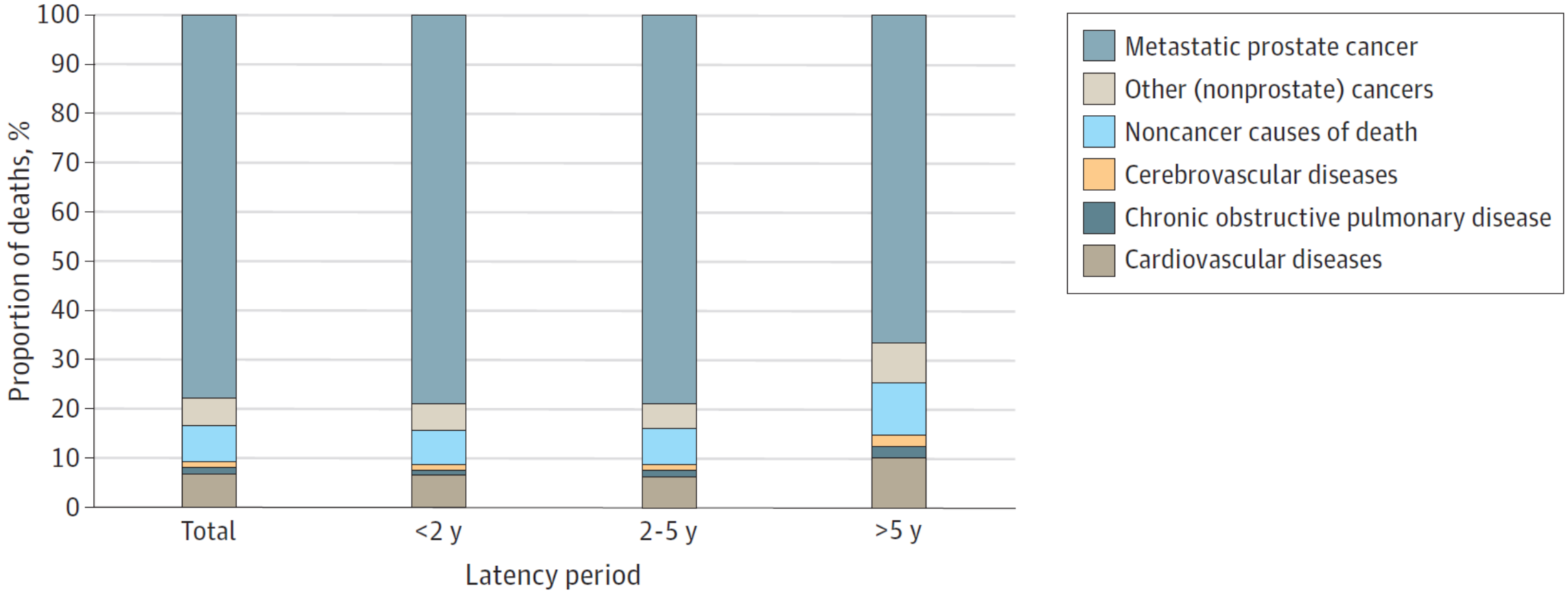
Considerations:

- Fitness for docetaxel / LHRH analogue
- Cancer characteristics:
  - High-volume / synchronous / high-grade
- Portrayal of evidence:
  - Hazard ratio vs. absolute % benefit vs. relative % benefit
- Patient preference

*This is a fictional patient case based on the speaker's own clinical experience.
ARPI, androgen receptor pathway inhibitor; LHRH, luteinising hormone-releasing hormone.

Competing mortality

Causes of death during each latency period after diagnosis of metastatic prostate cancer



y, years.

Elmehrath A.O. et al. JAMA Netw Open 2021;4(8):e2119568.

Practical framework for mHSPC

1) CLARIFY PROGNOSIS

- Patient preference for level of information
- Stage / burden / risk
- Competing mortality
- Be honest about uncertainty

2) PRESENT REASONABLE TREATMENT OPTIONS

- Evidence-based
- Treatment benefits
- Toxicity trade-offs
- Avoid framing bias

3) QUANTIFY BENEFIT CLEARLY

- Use absolute numbers / percentages
- Avoid relative risks

4) EXPLORE VALUES

- What matters to you most over the next few years?
- Longevity vs. QoL
- Independence / work / caregiving roles

mHSPC, metastatic hormone-sensitive prostate cancer; QoL, quality of life.
Based on speaker's own personal experience.

Document a shared plan

- Explicitly record the patient's priorities
- Confirm understanding
- Offer time to reflect
- Signpost to CNS and other resources

CNS, Clinical Nurse Specialist.
Based on speaker's own personal experience.

Any questions?

NUBEQA (darolutamide) Prescribing Information

NUBEQA® (darolutamide) 300 mg film-coated tablets
Prescribing Information – United Kingdom
(Refer to full Summary of Product Characteristics (SmPC) before prescribing)

Presentation: Each film-coated tablet contains 300 mg of darolutamide. **Indication(s):** NUBEQA is indicated for the treatment of adult men with non-metastatic castration resistant prostate cancer (nmCRPC) who are at high risk of developing metastatic disease or with metastatic hormone-sensitive prostate cancer (mHSPC) in combination with androgen deprivation therapy or with mHSPC in combination with docetaxel. **Posology & method of administration:** Treatment should be initiated and supervised by a specialist physician experienced in treatment of prostate cancer. Medical castration with a luteinising hormone-releasing hormone (LHRH) analogue should be continued during treatment of patients not surgically castrated. For oral use. The tablets should be taken whole with food. ***Adults:*** 600 mg darolutamide (two tablets of 300 mg) taken twice daily, equivalent to a total daily dose of 1200 mg. When used in combination with docetaxel in mHSPC patients, the first of 6 cycles of docetaxel should be administered within 6 weeks after the start of darolutamide treatment. Treatment with darolutamide should be continued until disease progression or unacceptable toxicity even if a cycle of docetaxel is delayed, interrupted, or discontinued. If a patient experiences a ≥ Grade 3 toxicity or an intolerable adverse reaction related to darolutamide, dosing should be withheld or reduced to 300 mg twice daily until symptoms improve. Treatment may then be resumed at a dose of 600 mg twice daily. ***Children & adolescents:*** There is no relevant use of darolutamide in the paediatric population. ***Elderly:*** No dose adjustment is necessary. ***Renal Impairment:*** No dose adjustment is necessary for patients with mild or moderate renal impairment. For patients with severe renal impairment (eGFR 15-29 mL/min/1.73 m2) not receiving haemodialysis, the recommended starting dose is 300 mg twice daily. ***Hepatic Impairment:*** No dose adjustment is necessary for patients with mild hepatic impairment. The available data on darolutamide pharmacokinetics in moderate hepatic impairment is limited. Darolutamide has not been studied in patients with severe hepatic impairment. For patients with moderate and severe hepatic impairment (Child-Pugh Classes B and C), the recommended starting dose is 300 mg twice daily. **Contra-indications:** Hypersensitivity to the active substance or to any of the excipients. Women who are or may become pregnant. **Warnings & precautions:** Monitor for signs and symptoms of ischaemic heart disease. Optimise management of cardiovascular risk factors. Discontinue darolutamide for Grade 3-4 ischaemic heart disease. Seizure occurred in patients receiving darolutamide. Advise patients of the risk of developing a seizure while receiving darolutamide. Consider discontinuation of darolutamide in patients who develop a seizure during treatment. Cases of idiosyncratic drug-induced liver injury (DILI) with increases in alanine aminotransferase (ALT) and/or aspartate aminotransferase (AST) to ≥5 and ≥20 x upper limit of normal (ULN) have been reported. Idiosyncratic DILI has been reported in clinical trials and the post-marketing setting. Liver function test abnormalities were reversible upon darolutamide discontinuation. In case of liver function test abnormalities suggestive of idiosyncratic drug-induced liver injury, permanently discontinue darolutamide. The available data in patients with severe renal impairment are limited. As exposure might be increased those patients should be closely monitored for adverse reactions. The available data in patients with moderate hepatic impairment are limited, and darolutamide has not been studied in patients with severe hepatic impairment. As exposure might be increased those patients should be closely monitored for adverse reactions. Patients with clinically significant cardiovascular disease in the past 6 months including stroke, myocardial infarction, severe/unstable angina pectoris, coronary/peripheral artery bypass graft, and symptomatic congestive heart failure were excluded from the clinical studies. Therefore, the safety of darolutamide in these patients has not been established. Use of strong CYP3A4 and P-gp inducers during treatment with darolutamide may decrease the plasma concentration of darolutamide and is not recommended, unless there is no therapeutic alternative. Selection of an alternate concomitant medicinal product with less potential to induce CYP3A4 or P-gp should be considered. Patients should be monitored for adverse reactions of BCRP, OATP1B1 and OATP1B3 substrates as co-administration with darolutamide may increase the plasma concentrations of these substrates. Co-administration with rosuvastatin should be avoided unless there is no therapeutic alternative. In patients with a history of risk factors for QT prolongation and in patients receiving concomitant medicinal products that might prolong the QT interval, physicians should assess the benefit-risk ratio including the potential for Torsade de pointes prior to initiating NUBEQA. NUBEQA 300mg film-coated tablets contains lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose galactose malabsorption should not take this medicinal product. **Interactions:** For the effect of other medicinal products on the action of darolutamide (e.g CYP3A4, P-gp inducers and CYP3A4, P-gp and BCRP inhibitors, UGT1A9 inhibitors and docetaxel) and the action of darolutamide on other medicinal products (BCRP, OATP1B1, OATP1B3 substrates, P-gp substrates, docetaxel, CYP3A4 substrates and other medicinal products that prolong the QT interval) refer to the relevant SmPCs. **Pregnancy & lactation:** Darolutamide is not indicated in women of childbearing potential, and it is not to be used in women who are, or may be, pregnant or breast-feeding. Unknown whether darolutamide or its metabolites are present in semen. If the patient is engaged in sexual activity with a woman of childbearing potential, a highly effective contraceptive method (<1% failure rate per year) should be used during and for 1 week after completion of treatment. Unknown whether darolutamide or its metabolites are excreted in human milk. No studies in animals have been conducted to evaluate the excretion of darolutamide or its metabolites into milk. A risk to the breast-fed child cannot be excluded. There are no human data on the effect of darolutamide on fertility. Based on animal studies, darolutamide may impair fertility in males of reproductive potential. **Effects on ability to drive and use machines:** Darolutamide has no or negligible influence on the ability to drive and use machines. **Undesirable effects:** *Adverse reactions observed in patients with nmCRPC and mHSPC* *Very common:* fatigue/asthenic conditions, neutrophil count decreased, bilirubin increased, ALT increased, AST increased, anaemia. *Common:* ischaemic heart disease, heart failure, rash, pain in extremity, fractures. *Serious adverse reactions:* cardiac arrhythmias, urinary retention, urinary tract infection, pneumonia, fractures, seizure. *Adverse reactions observed in patients with mHSPC treated with darolutamide in combination with docetaxel*. *Very common:* hypertension, rash, blood bilirubin increased, ALT increased, AST increased. *Serious adverse reactions:* fractures, ischaemic heart disease, seizure, febrile neutropenia, neutrophil count decreased, pneumonia. Prescribers should consult the SmPC in relation to other side effects (see section 4.8 of SmPC). **Overdose:** In the event of intake of a higher than recommended dose, treatment with darolutamide can be continued with the next dose as scheduled. There is no specific antidote for darolutamide and symptoms of overdose are not established. **Legal Category:** POM**. Package Quantities & Basic NHS Costs:** Pack of 112 film-coated tablets, £4,040. **MA Number(s):** PLGB 00010/0677. **Further information available from:** Bayer plc, 400 South Oak Way, Reading RG2 6AD, United Kingdom. Telephone: 0118 206 3000. **Date of preparation:** June 2025

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Adverse events should also be reported to Bayer plc.
Tel: 0118 206 3500, Fax: 0118 206 3703, Email: pvuk@bayer.com

Xofigo▼ (radium-223 dichloride) Prescribing Information

▼ Xofigo® 1100 kBq/mL solution for injection (radium223 dichloride)
Prescribing Information (Refer to full Summary of Product Characteristics (SmPC) before prescribing)

Presentation: Each vial contains 6 mL of solution (6.6 MBq radium223 dichloride at the reference date). Each mL of solution contains 1100 kBq radium Ra 223 dichloride (radium-223 dichloride), corresponding to 0.58 ng radium-223 at the reference date. **Indication(s):** Xofigo monotherapy or in combination with luteinising hormone releasing hormone (LHRH) analogue is indicated for the treatment of adult patients with metastatic castration-resistant prostate cancer (mCRPC), symptomatic bone metastases and no known visceral metastases, in progression after at least two prior lines of systemic therapy for mCRPC (other than LHRH analogues), or ineligible for any available systemic mCRPC treatment. **Posology & method of administration:** Xofigo should be administered only by persons authorised to handle radiopharmaceuticals in designated clinical settings, and after evaluation of the patient by a qualified physician. Xofigo is for intravenous use and must be administered by slow injection (generally up to 1 minute). The intravenous access line or cannula must be flushed with isotonic sodium chloride 9 mg/mL (0.9%) solution for injection before and after injection of Xofigo. ***Adults:*** The dose regimen of Xofigo is an activity of 55 kBq per kg body weight, given at 4 week intervals for 6 injections. ***Hepatic impairment:*** No dose adjustment is considered necessary in patients with hepatic impairment. ***Renal impairment:*** No dose adjustment is considered necessary in patients with renal impairment. ***Elderly patients:*** No dose adjustment is considered necessary in elderly patients. ***Children & adolescents:*** There is no relevant use of this medicinal product in the paediatric population for prostate cancer. **Contra-indications:** Xofigo is contraindicated in combination with abiraterone acetate and prednisone/prednisolone. **Warnings & precautions:** The safety and efficacy of Xofigo in combination with cancer therapies other than LHRH analogues have not been established; an increased risk of mortality and fractures is possible. The combination of radium-223 with other systemic cancer therapies other than LHRH analogues is not recommended. The use of Xofigo is not recommended for treatment of adults with CRPC and only asymptomatic bone metastases. In adults with CRPC and mildly symptomatic bone metastases the benefit of treatment should be carefully assessed to outweigh the risks considering that high osteoblastic activity is likely to be required for treatment benefit. In clinical studies, patients with fewer than 6 bone metastases had an increased risk of fractures and did not have a statistically significant survival benefit. A pre-specified subgroup analysis also showed that overall survival was not significantly improved in patients with a total ALP < 220 U/L. Therefore, in patients with a low level of osteoblastic bone metastases treatment with radium-223 is not recommended. Bone marrow suppression, notably thrombocytopenia, neutropenia, leukopenia and pancytopenia, have been reported in patients treated with Xofigo. Haematological evaluation of patients must be performed at baseline and prior to every dose of Xofigo. In case there is no recovery in values for absolute neutrophil count (ANC), platelets and haemoglobin within 6 weeks after the last administration of Xofigo despite receiving standard of care, further treatment with Xofigo should only be continued after a careful benefit/risk evaluation. Patients with evidence of compromised bone marrow should be treated with caution. Safety and efficacy of Xofigo have not been studied in patients with Crohn's disease and ulcerative colitis. Due to faecal excretion of Xofigo, radiation may lead to aggravation of acute inflammatory bowel disease. Therefore, Xofigo should only be administered after a careful benefit-risk assessment in patients with acute inflammatory bowel disease. In patients with untreated imminent or established spinal cord compression, treatment with standard of care, as clinically indicated, should be completed before starting or resuming treatment with Xofigo. Xofigo increases the risk of bone fractures, especially in patients with medical history of osteoporosis and in patients with <6 bone metastases. Prior to starting radium-223 bone status and baseline risk of fractures of patients (e.g. osteoporosis, less than 6 bone metastases, medication increasing fracture risk, low body mass index) should be carefully assessed, and closely monitored for at least 24 months. Preventive measures should be considered before starting or resuming treatment with Xofigo. In patients with a high baseline risk of fracture, the benefit of treatment should be carefully assessed to outweigh the risk. In patients with bone fractures, orthopaedic stabilisation of fractures should be performed before starting or resuming treatment with Xofigo. In patients treated with bisphosphonates and Xofigo, an increased risk of development of osteonecrosis of the jaw (ONJ) cannot be excluded. Xofigo contributes to a patient's overall long-term cumulative radiation exposure which may be associated with an increased risk of cancer and hereditary defects. In particular, the risk for osteosarcoma, myelodysplastic syndrome and leukaemias may be increased. Xofigo increases the incidence of diarrhoea, nausea, and vomiting which may result in dehydration. Oral intake and fluid status of patients should be carefully monitored. Patients should be advised to seek medical advice if they experience severe or persistent diarrhoea, nausea, vomiting. Patients who display signs or symptoms of dehydration or hypovolemia should be promptly treated. This medicinal product can contain up to 2.35 mmol (54 mg) sodium per dose, depending on the required volume, and must be taken into consideration by patients on a controlled sodium diet. **Interactions:** No clinical interaction studies have been performed. Interactions with calcium and phosphate cannot be excluded. Safety and efficacy of concomitant chemotherapy with Xofigo have not been established. **Fertility, pregnancy & lactation:** Xofigo is not indicated in women. Results from animal studies, indicate there is a potential risk that radiation from Xofigo could cause adverse effects on fertility. Male patients should seek advice on conservation of sperm prior to treatment. Due to potential effects on spermatogenesis associated with radiation, men should be advised to use effective contraceptive methods during and up to 6 months after treatment with Xofigo. **Effects on ability to drive and use machines:** There is no evidence, nor is it expected, that Xofigo will affect the ability to drive or use machines. **Undesirable effects:** Very common: Thrombocytopenia, diarrhoea, vomiting, nausea, bone fracture. Common: Neutropenia, pancytopenia, leukopenia and injection site reactions. Uncommon: Lymphopenia, osteoporosis. Serious: Thrombocytopenia and neutropenia. Prescribers should consult the SmPC in relation to other side effects. **Overdose:** No specific antidote. In the event of an inadvertent overdose, general supportive measures, including monitoring for potential haematological and gastrointestinal toxicity should be undertaken. **Incompatibilities:** Do not mix with other medicinal products. **Special Precautions for Storage:** Store in accordance with national regulation on radioactive materials. **Legal Category:** POM. **Package Quantities & Basic NHS Costs:** Single vial pack £4040. **MA Number(s):** PLGB 00010/0710. **Further information available from:** Bayer plc, 400 South Oak Way, Reading, Berkshire, RG2 6AD United Kingdom. Telephone: 0118 206 3000. **Date of preparation: February 2025**

Xofigo® is a trademark of the Bayer Group

Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk or search for MHRA Yellow Card in Google Play or Apple App Store.
Adverse events should also be reported to Bayer plc.
Tel: 0118 206 3500, Fax: 0118 206 3703, Email: pvuk@bayer.com