

1 **NATIONAL INSTITUTE FOR HEALTH AND CARE**
2 **EXCELLENCE**

3 **Guideline**

4 **Suspected cancer: recognition and referral**

5 **Draft for consultation, October 2021**
6

This is an update to NICE guideline NG12 (published June 2015). We have:

- reviewed the evidence on fixed and age-adjusted thresholds for prostate-specific antigen testing
- updated recommendation 1.6.3

Who is it for?

- Healthcare professionals
- People involved in clinical governance in both primary and secondary care
- People with suspected cancer and their families and/or carers.

What does it include?

- the recommendation that has been updated
- related recommendations that have not been updated (shaded in grey and marked **[2015]**), included here for context
- recommendations for research
- rationale and impact sections that explain why the committee made the 2021 recommendation and how it might affect services
- the guideline context.

Information about how the guideline was developed is on the [guideline's webpage](#). This includes the evidence reviews, the scope, details of the committee and any declarations of interest.

Commenting on this update

We have only reviewed the evidence for recommendation 1.6.3, marked **[2021]**. You are invited to comment on the updated recommendation.

Recommendations in section 1.6 that have not been updated have been shaded in grey and we will not be accepting comments on them.

Sections of the guideline that have had no changes at all have been temporarily removed for this consultation and will be re-instated when the final guideline is published. See the [existing short version of the guideline](#).

See [update information](#) for a full explanation of what is being updated.

Full details of the evidence and the committee's discussion on the 2021 recommendations are in the [evidence reviews](#).

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1 Recommendations organised by site of cancer

Use this guideline to guide referrals. If still uncertain about whether a referral is needed, consider contacting a specialist (see the recommendations on [the diagnostic process](#)). Consider a review for people with any symptom associated with increased cancer risk who do not meet the criteria for referral or investigative action (see the recommendations on [safety netting](#)).

2

3 1.6 Urological cancers

4 Prostate cancer

5 1.6.1 Refer people using a [suspected cancer pathway referral](#) (for an
6 appointment within 2 weeks) for prostate cancer if their prostate feels
7 malignant on digital rectal examination. **[2015]**

8 1.6.2 Consider a prostate-specific antigen (PSA) test and digital rectal
9 examination to assess for prostate cancer in people with:

- 10
- 11 • any lower urinary tract symptoms, such as nocturia, urinary frequency,
hesitancy, urgency or retention **or**
 - 12 • erectile dysfunction **or**
 - 13 • visible haematuria. **[2015]**

14 1.6.3 Consider referring people with possible symptoms of prostate cancer, as
15 specified in recommendation 1.6.2, using a suspected cancer pathway
16 referral (for an appointment within 2 weeks) for prostate cancer if their
17 PSA levels are above the threshold for their age in table 1. Take into
18 account the person's preferences and any comorbidities when making the
19 decision. **[2021]**

1 **Table 1 Age-specific PSA thresholds**

Age (years)	Prostate serum antigen threshold (micrograms/litre)
40 to 49	2.5
50 to 59	3.5
60 to 69	4.5
70 to 79	6.5

2

For a short explanation of why the committee made the 2021 recommendation and how it might affect practice, see the [rationale and impact section on PSA testing for prostate cancer](#).

Full details of the evidence and the committee's discussion are in [evidence review A: PSA testing for prostate cancer](#).

3

4 **Recommendations for research**

5 The guideline committee has made the following recommendations for research.

6 **Key recommendations for research**

7 **Prostate specific antigen testing**

8 What is the diagnostic accuracy and cost effectiveness of using age-adjusted
9 prostate specific antigen thresholds for people with symptoms of prostate cancer,
10 including those at high risk of developing prostate cancer?

For a short explanation of why the committee made this recommendation see the rationale section on Prostate serum antigen testing for prostate cancer.

Full details of the evidence and the committee's discussion are in [evidence review A: PSA testing for prostate cancer](#).

1 **Rationale and impact**

2 These sections briefly explain why the committee made the recommendations and
3 how they might affect practice.

4 **Prostate serum antigen testing for prostate cancer**

5 [Recommendation 1.6.3](#)

6 **Why the committee made the recommendations**

7 The evidence on the diagnostic accuracy of fixed and age-specific prostate serum
8 antigen (PSA) thresholds was very uncertain because all of the studies were based
9 on a population that had already been referred to secondary care. The 2019
10 recommended referral if PSA levels were above the age-specific reference range.

11 The committee agreed that referral should be considered based on PSA thresholds,
12 but did not make a stronger recommendation because of the uncertainty in the
13 evidence and the likely low positive predictive value of the PSA test for prevalence
14 estimates based on UK population data. The committee noted that many prostate
15 cancers are slow growing and might never impact a person's life expectancy. Some
16 people might choose not to be referred to secondary care to avoid invasive
17 investigations and treatment that might not benefit them. Therefore the committee
18 agreed that a patient-centred approach to referral is important and recommended
19 that the person's preferences and any comorbidities should be taken into account.

20 The committee agreed that more research is needed in this area to better
21 understand the most appropriate thresholds that should prompt referral to secondary
22 care for each age group. The committee noted that ethnicity and family history are
23 important factors that affect the risk of prostate cancer. Therefore, they
24 recommended that the data from research be stratified by these factors to determine
25 whether different PSA levels should prompt referral in these groups.

26 There was no strong evidence to differentiate between using age-specific or fixed
27 PSA thresholds. The committee also noted that no cost-effectiveness evidence
28 comparing age-specific and fixed thresholds was identified. However, because PSA
29 levels increase naturally with age, the committee agreed a lower fixed PSA threshold
30 would detect more cases of prostate cancer but also lead to unnecessary biopsies

1 and overtreatment in some age groups. This would also result in more referrals to
2 secondary care and have a significant impact on NHS resources. The committee
3 therefore recommended the use of age-specific thresholds, which are already
4 established in current practice and were recommended in the previous version of the
5 guideline. Because of regional variations in practice (particularly in the 50 and 69
6 age range), the committee decided to define the age-specific PSA thresholds. The
7 committee agreed that the thresholds used in the reviewed studies on people with
8 symptoms of possible prostate cancer should be used in the absence of evidence to
9 support alternative values, because these studies were most applicable to the
10 population that the recommendation applies to.

11 **How the recommendations might affect practice**

12 Referral based on age-specific PSA thresholds is already recommended, so practice
13 should not change significantly. Also, clarifying the age-specific thresholds will help
14 standardise care. Taking into account patient preferences and comorbidities should
15 also lead to a more patient-centred approach to referral.

16 [Return to recommendations](#)

17 **Finding more information and committee details**

18 You can see everything NICE says on this topic in the [NICE Pathways on suspected](#)
19 [cancer recognition and referral](#) and [lung cancer](#).

20 To find NICE guidance on related topics, including guidance in development, see our
21 [topic page on cancer](#).

22 For full details of the evidence and the guideline committee's discussions, see the
23 [full guideline](#). You can also find information about [how the guideline was developed](#),
24 including [details of the committee](#).

25 NICE has produced [tools and resources](#) to help you put this guideline into practice.
26 For general help and advice on putting NICE guidelines into practice, see [resources](#)
27 [to help you put guidance into practice](#).

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4 **Update information**

5 **January 2021:** We amended recommendation 1.3.4 to include the full list of criteria
6 for faecal testing. Faecal testing should also be offered to people without rectal
7 bleeding aged 50 or over with unexplained abdominal pain or weight loss, or to
8 adults under 60 with changes in bowel habit or iron-deficiency anaemia. The tables
9 of symptoms and findings have been updated to match these changes.

10 **September 2020:** Recommendation 1.3.4 was amended to clarify when to offer
11 faecal testing for colorectal cancer to adults without rectal bleeding. The tables on
12 abdominal and pelvic pain, change in bowel habit and primary care investigations
13 were updated in line with this. The wording in some recommendations was edited to
14 incorporate text previously in footnotes.

15 **July 2017:** Recommendation 1.3.4 was replaced by NICE diagnostics guidance on
16 quantitative faecal immunochemical tests to guide referral for colorectal cancer in
17 primary care. Recommendation 1.3.1 was amended to remove a link to
18 recommendation 1.3.4. In December 2017, the wording of 1.3.4 was clarified, and
19 the tables on abdominal and pelvic pain, change in bowel habit and primary care
20 investigations updated in line with this.

21 **June 2016:** Recommendations 1.3.1 and 1.3.2 have been changed to say ‘adults’
22 instead of ‘people’ to more accurately reflect the populations they cover.

23 **June 2015:** This guideline updates and replaces NICE guideline CG27 (published
24 June 2005).

25 Recommendations are marked as **[2021]**, **[2020]**, **[2015]**, **[2011]**, **[2011, amended**
26 **2020]** or **[2005]**:

- 27 • **[2021]** indicated that the evidence has been reviewed and the recommendation
28 has been updated in 2021.

- 1 • **[2020]** indicates that the evidence has been reviewed and the recommendation
2 has been added or updated in 2020.
- 3 • **[2011, amended 2020]** indicates that the wording has been changed but the
4 evidence has not been reviewed since 2020.
- 5 • **[2015], [2005] or [2011]** indicates the date that the evidence was last reviewed.
6 Recommendations that have been deleted, or changed without an evidence
7 review

8 **October 2021**

9 We have:

- 10 • reviewed the evidence on fixed and age-adjusted thresholds for PSA testing
11 • updated recommendation 1.6.3.

12 For recommendations shaded in grey, we have not reviewed the evidence. In some
13 cases minor changes have been made – for example, to update language and style
14 – without changing the intent of the recommendation.

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