A UK NATIONAL AUDIT OF THE LABORATORY INVESTIGATION OF PSA

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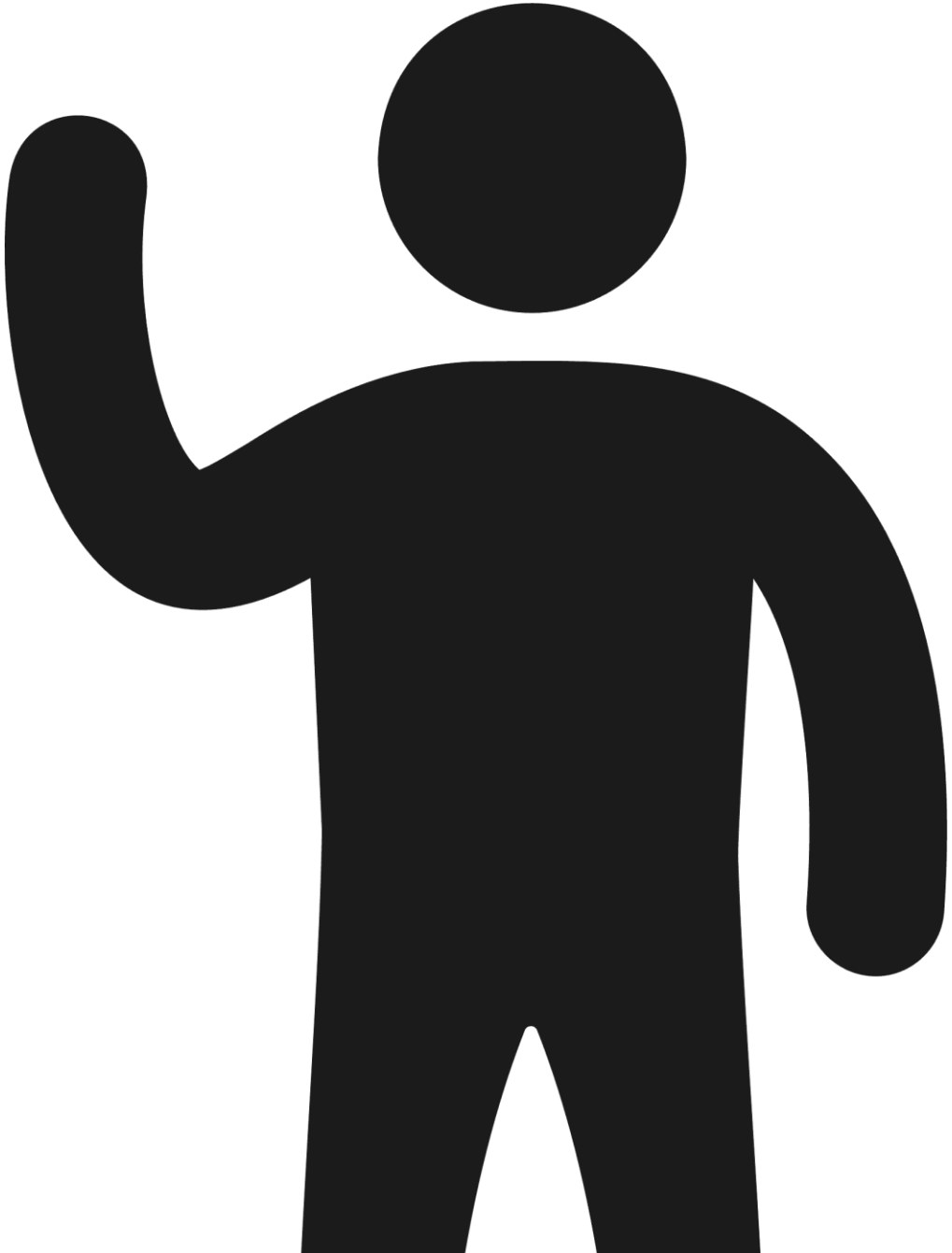
CONFIDENTIAL– PAPER IN PREPARATION



BACKGROUND

PROSTATE CANCER STATS - UK

- **Prostate cancer is the most common cancer among men**, and in England, it is now the most common cancer overall.
- More than **63,000 men get diagnosed** with prostate cancer every year.
- On average, more than **12,000 men die** from prostate cancer every year.
- Around **510,000 men are living with or after** prostate cancer.

- **1 in 8 men** will be diagnosed with prostate cancer in their lifetime.
- Black men are more likely to get prostate cancer than other men. In the UK, **1 in 4 Black men** will get prostate cancer in their lifetime. Almost **1,600 Black men** are diagnosed with prostate cancer each year in England.

Reference: Prostate Cancer UK, Data & Evidence Library for Health Improvement (DELHI), latest data for incidence and mortality are presented, reflecting annual averages from 2019 to 2021 unless otherwise specified. (June 2025)

PSA TESTING GUIDELINES

Association for Laboratory Medicine

UK National Screening Committee

Adult screening programme

Prostate cancer

Under review

The prostate is a small gland found in men. It is [illegible] the penis and the bladder. The main function of the prostate is [illegible] production of semen. Prostate cancer is the most common cancer in men and usually affects men over the age of 65.

» Read more about prostate cancer on NHS UK

UK NSC screening recommendation

Based on the last UK NSC review of this condition that occurred in November 2020.

Screening is not currently recommended for this condition.

PCRMP – Asymptomatic

GOV·UK

Home > Health and social care > Public health > Health conditions > Can

Guidance

Prostate cancer risk management programme: overview

This document explains the Prostate Cancer Risk Management Programme (PCRMP), PSA testing and evidence against a national screening programme.

From: Public Health England

Published 1 January 2015

Last updated 29 March 2016 — See all updates

NICE NG12 – Symptomatic

NICE National Institute for Health and Care Excellence

Search NICE... Men

Home › NICE Guidance › Conditions and diseases › Blood and immune system conditions › Blood and bone marrow cancers

Suspected cancer: recognition and referral

NICE guideline

NG12

Published: 23 June 2015

Last updated: 01 May 2025

Table 1 Age-specific PSA thresholds for people with possible symptoms of prostate cancer

Age (years)	Prostate-specific antigen threshold (micrograms/litre)
Below 40	Use clinical judgement
40 to 49	More than 2.5
50 to 59	More than 3.5
60 to 69	More than 4.5
70 to 79	More than 6.5
Above 79	Use clinical judgement

"The PSA test is available to men who request it, including trans women and non-binary people."

PROSTATE CANCER DETECTION / MANAGEMENT

Association for Laboratory Medicine

No screening – men do not get invited for testing

Prostate cancer suspected via GP – Men present with / without symptoms **PSA (+/- DRE)**

→

Secondary care PC diagnosed/ruled out – **PSA / mpMRI / +/- biopsy**

→

Cambridge Prognostic Group based on PSA/MRI/Bx

Early prostate cancer

- CPG 1
- CPG 2
- CPG 3
- CPG 4
- CPG 5

Metastatic

→

Active surveillance – **PSA** / MRI / ± Bx

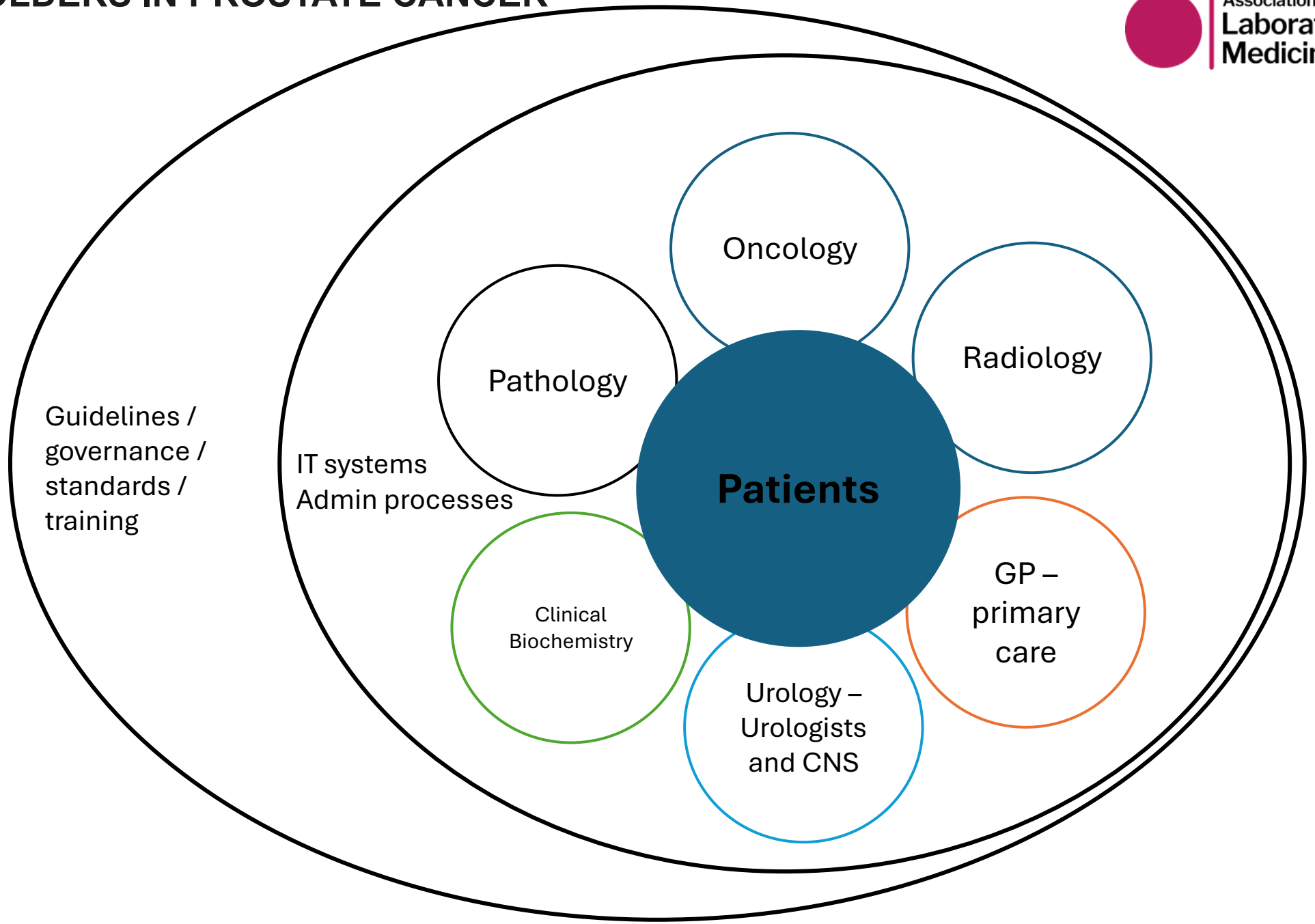
Surgery / radiotherapy

PSA to monitor Tx effectiveness

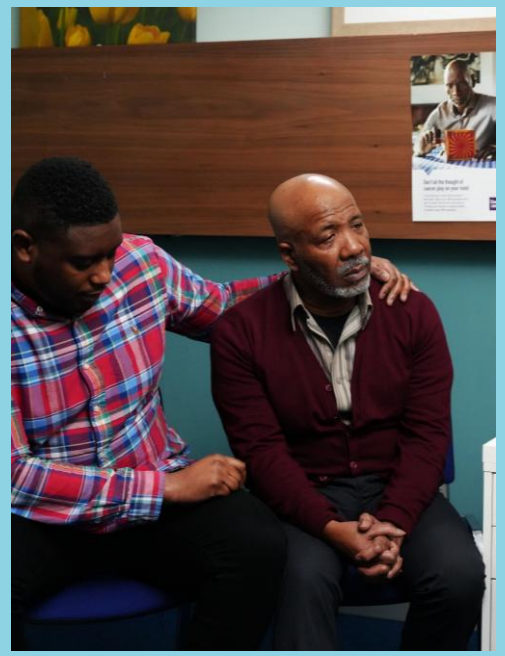
Chemotherapy **PSA** monitoring

Prostate-Specific Antigen (PSA) = important marker in the detection and monitoring of prostate cancer

KEY STAKEHOLDERS IN PROSTATE CANCER



WHY IS THIS SURVEY IMPORTANT?



Lived experience of:

Delays in referral

Delay in re-investigation for prostate cancer recurrence

Concerns from within the Biochemistry community:

Seeking clarity around guidelines

Concerns around communication between secondary care, primary care and the laboratory setting.

Collaboration between Prostate Cancer UK, ALM, and UK NEQAS to understand current practice, variation, and gaps to help inform policy and recommendations.

AIMS OF THIS STUDY

- Are men experiencing variation in PSA testing depending on where they live in the UK?
- Could variation have an impact on clinical decision-making and subsequently the treatment men receive for prostate cancer?
- Which standards/areas of practice require improvement/change and where is education/training required?

Achieve this through:

- Audit
- Data analysis, reporting / publication of results
- Development of recommendations to improve
- Collaboration with key stakeholder to implement recommendations and continual learning

SURVEY CONTEXT

ABOUT THE SURVEY

Association for Laboratory Medicine

31

Number of questions

MCQs = proportions sum >100%

57

Number of Responders

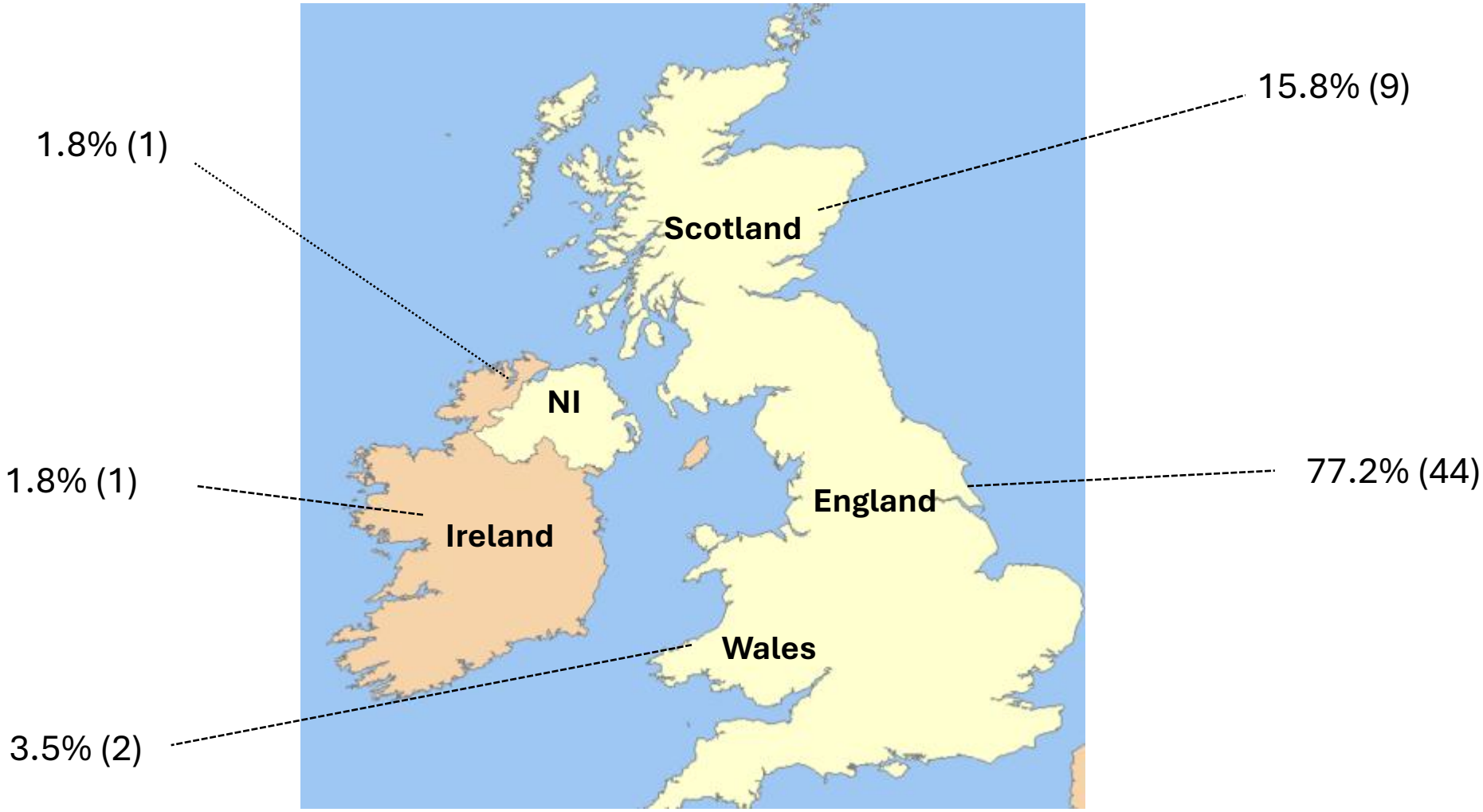
Maximum respondents to a question

48

Number of Trusts and Health Boards

(23%; UK)

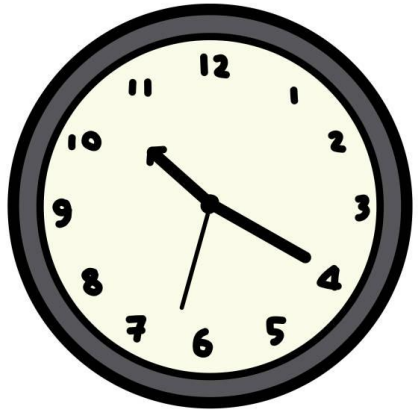
MOST RESPONDERS/LABORATORIES WERE BASED IN ENGLAND AND SCOTLAND



UK LABORATORY PRACTICE: SAMPLE RECEIPT AND TESTING

Sample Receipt and Testing

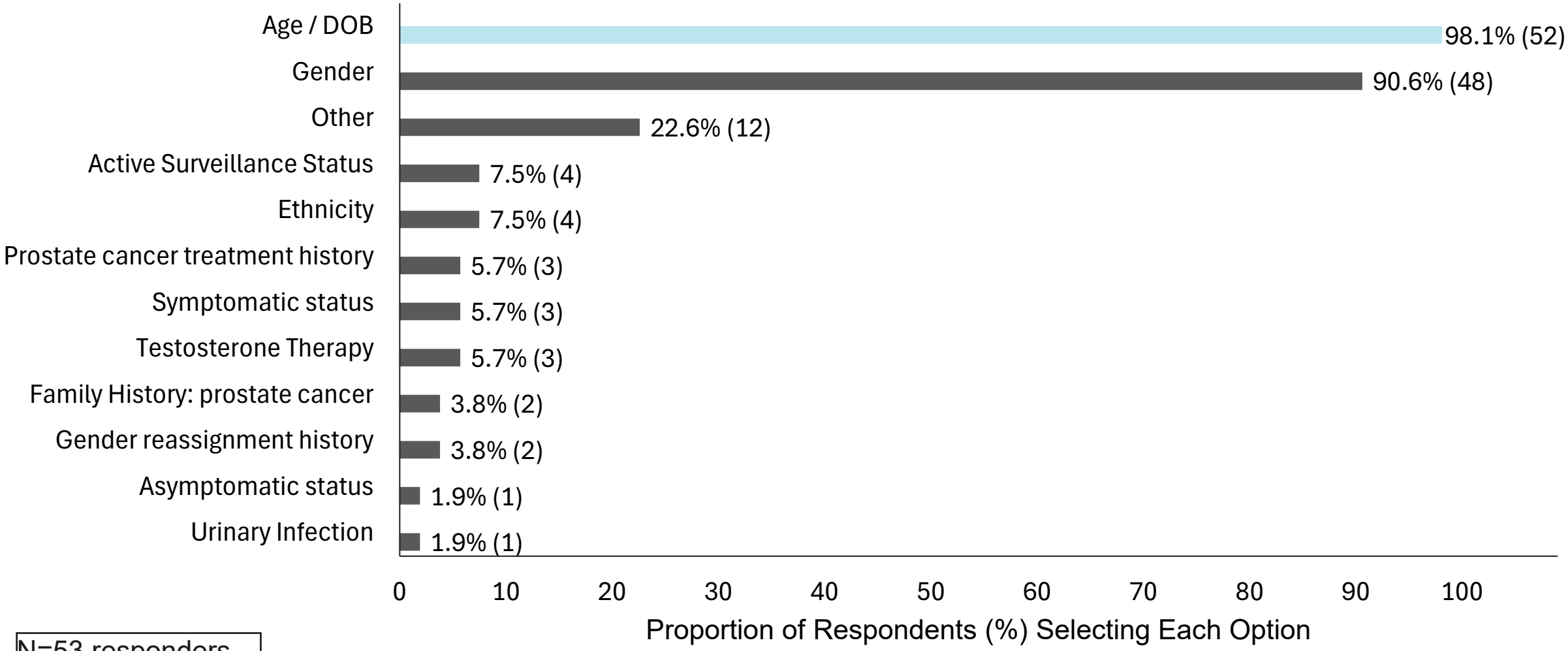
MAJORITY OF LABORATORIES USE A 24-HOUR CUT-OFF TIME FOR DELAYED SAMPLE RECEIPT



Responses (including free text)	Proportion of Respondents (%)	Number of Respondents
24 hours	**46**	**23**
No cut off	28	14
48 hours	18	9
Greater than 48 hours	8	4

N=50 responders

AGE/DOB AND GENDER WERE THE MOST FREQUENTLY PROVIDED PATIENT INFORMATION WITH PSA TEST REQUESTS

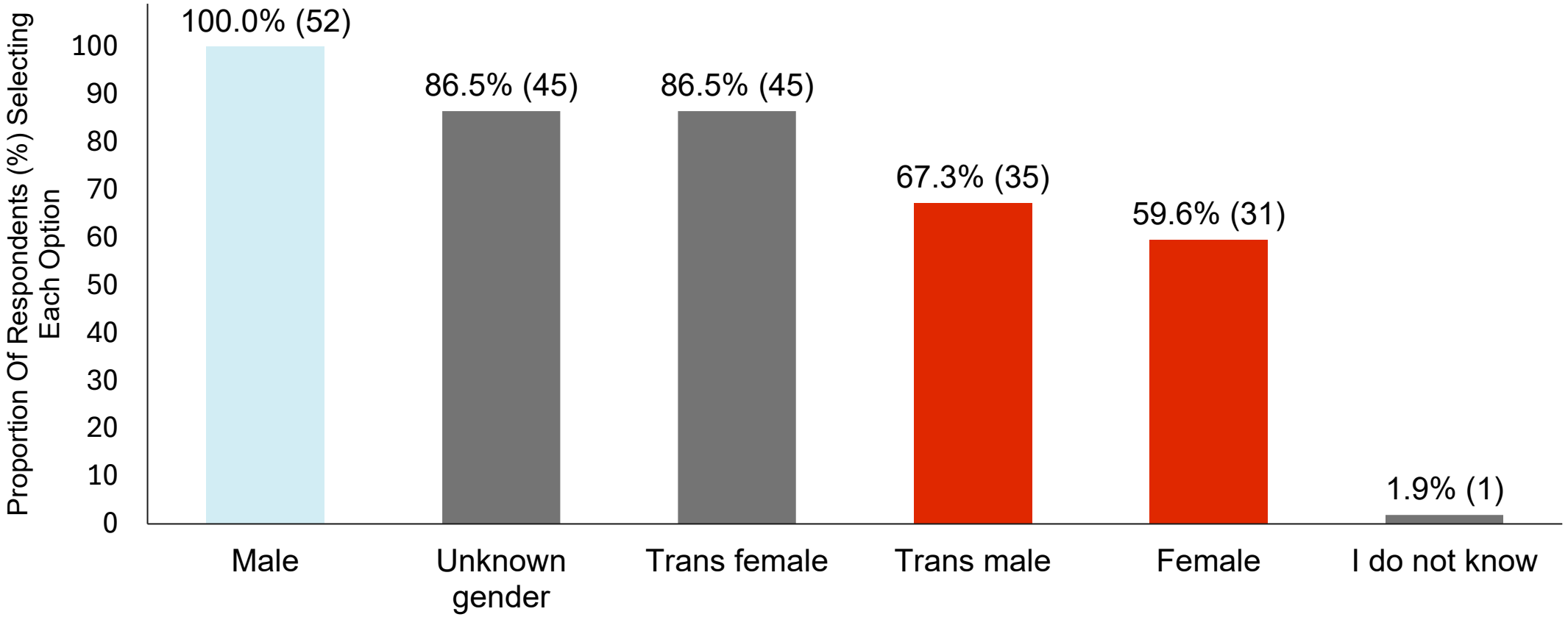


N=53 responders

PSA TESTS ARE PROVIDED EVEN IF PATIENTS DO NOT IDENTIFY AS MALE

Association for Laboratory Medicine

Patient Groups for Whom PSA Testing Is Conducted

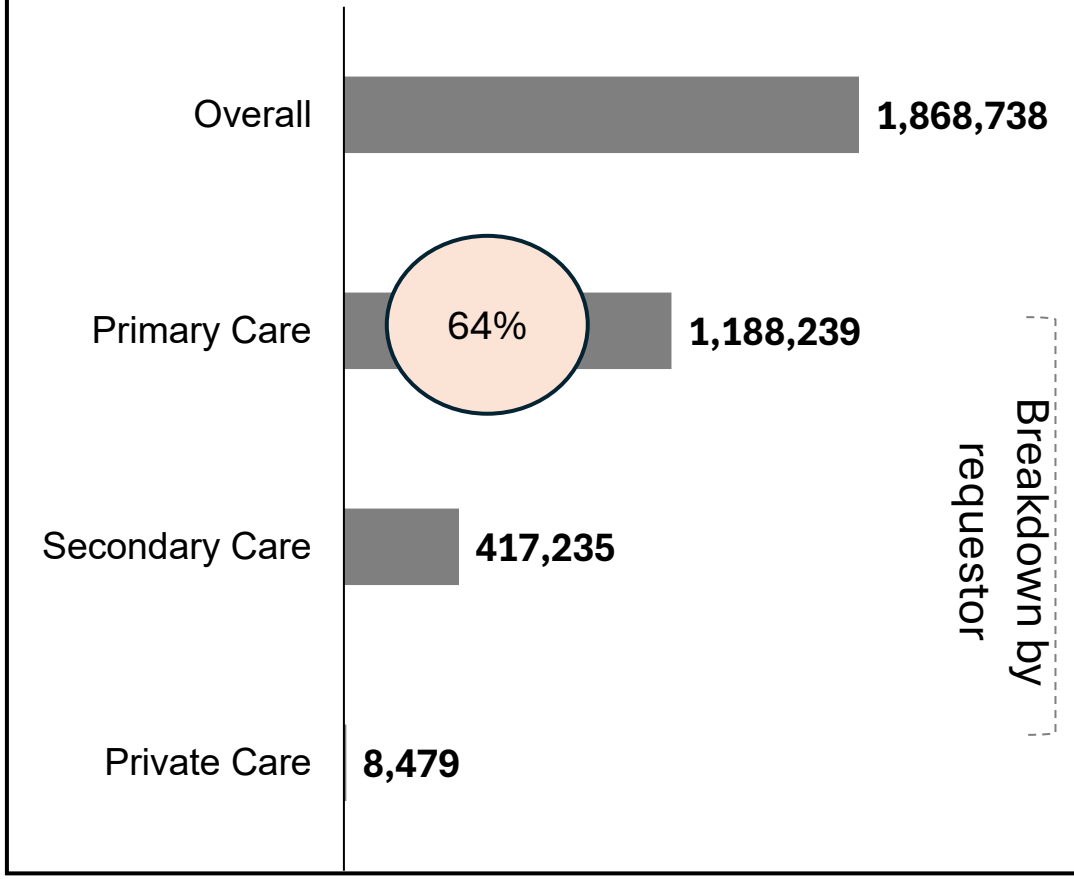


N=52 responders

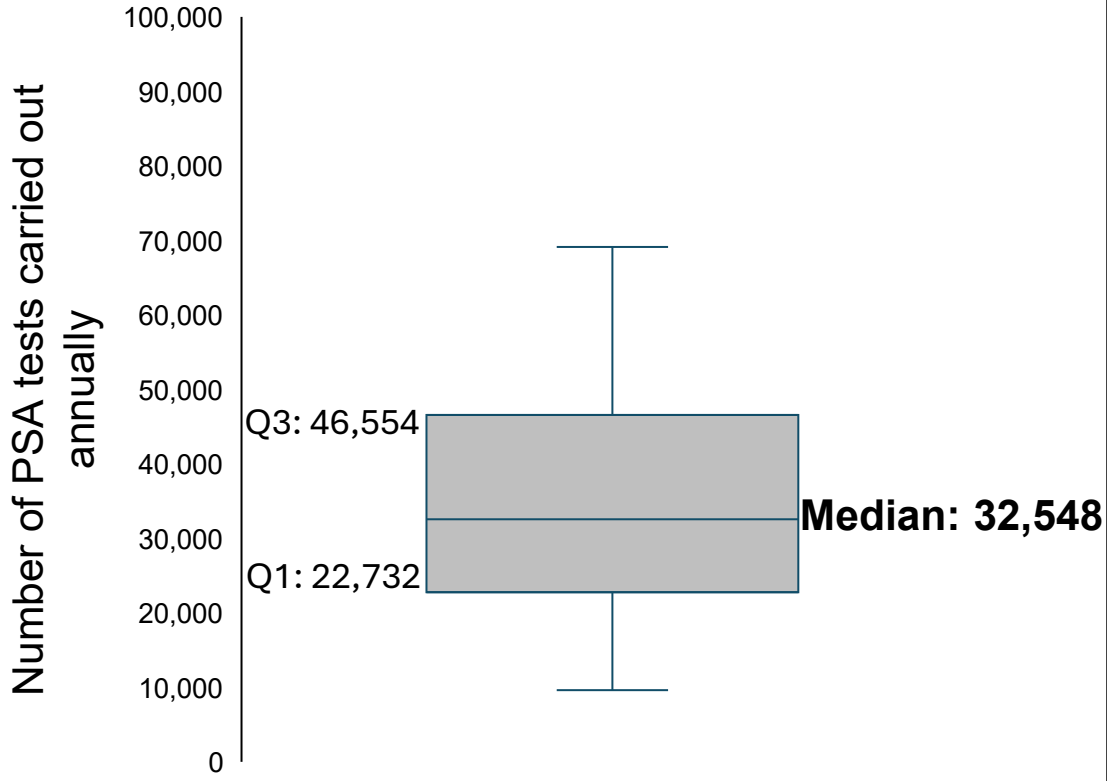
ALMOST 2 MILLION TESTS CONDUCTED ANNUALLY BY 49 LABORATORIES, PREDOMINATELY IN RESPONSE TO PRIMARY CARE TEST REQUESTS

Association for Laboratory Medicine

Total Number of PSA Tests Carried Out Annually By Laboratories Included In Survey



Median Number of All PSA Tests Carried Out Annually by Laboratories Included In Survey



N=49 responders

SUMMARY OF UK LABORATORY PRACTICE: SAMPLE RECEIPT AND TESTING

1. There is need for greater communication of patient status by requestor including:

i) Symptom status

ii) treatment history

iii) gender reassignment history - impacts PSA result interpretation e.g. normal PSA for transwomen is under 1 µg/L if had feminising hormones or an orchidectomy

2. Almost 2 million tests conducted every year across 49 laboratories, with the majority of requests coming from primary care

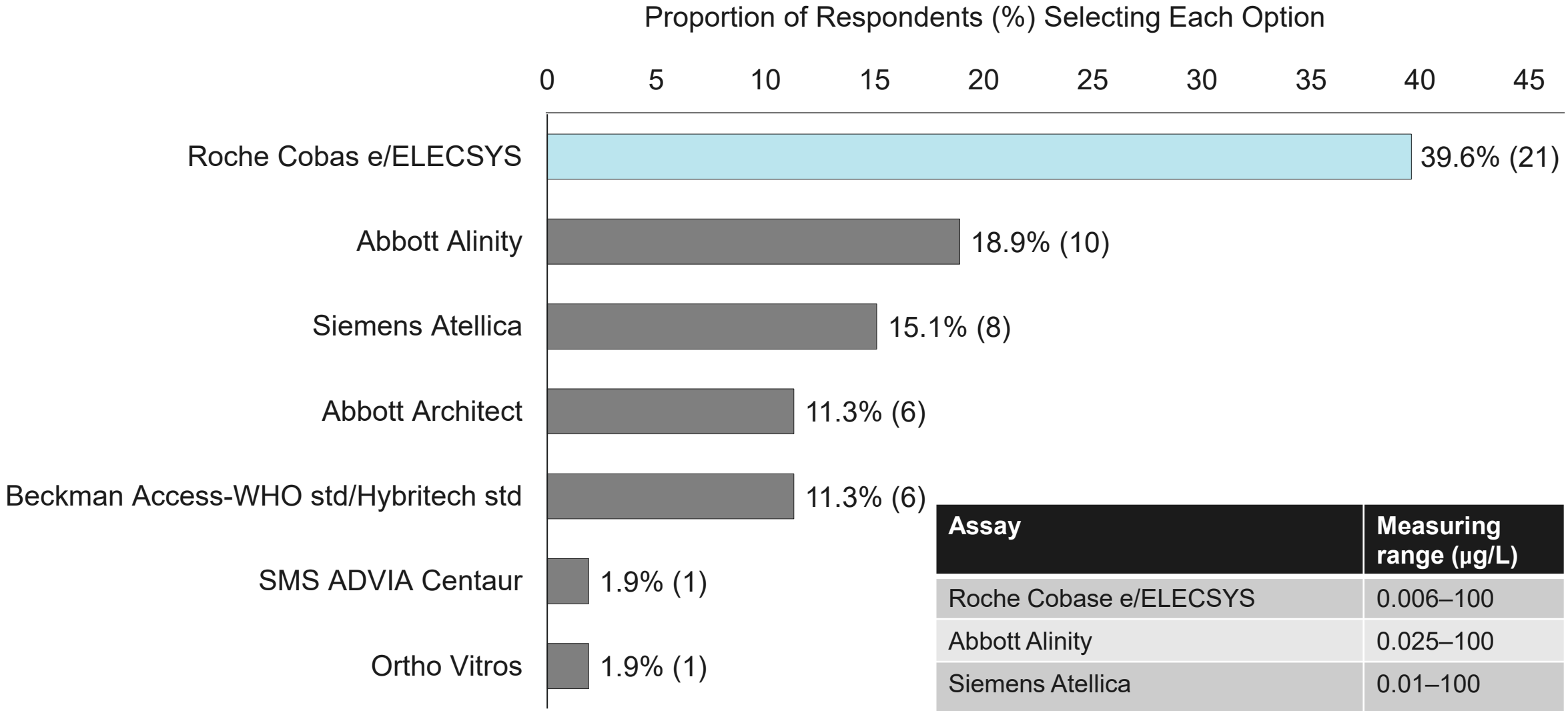
Association for Laboratory Medicine

UK LABORATORY PRACTICE: ASSAY AND QUALITY CONTROL

Sample Receipt and Testing

Assay and Quality Control

VARIATION IN PSA ASSAYS AND INSTRUMENTATION USED BY UK LABORATORIES (TOTAL PSA)



Assay	Measuring range (µg/L)
Roche Cobase e/ELECSYS	0.006–100
Abbott Alinity	0.025–100
Siemens Atellica	0.01–100

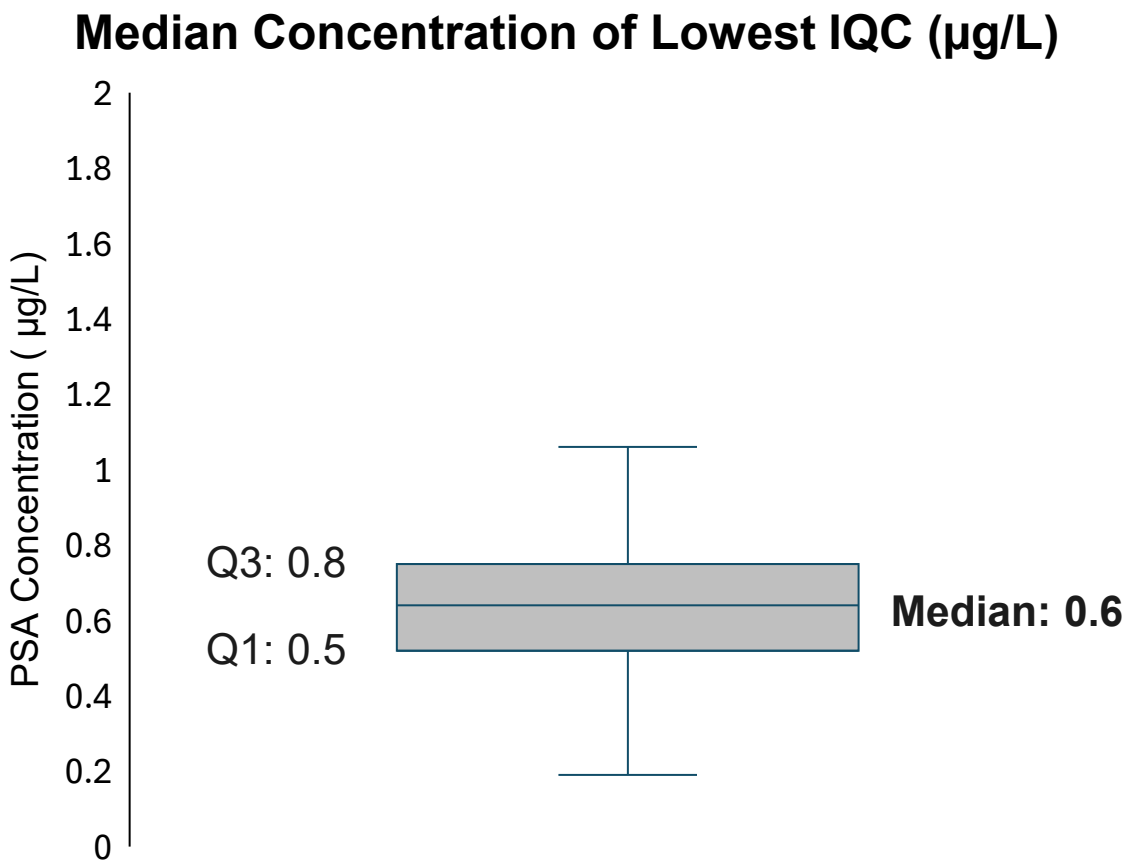
N=53 responders

PRACTICE AROUND LOWER REPORTING LIMIT DIFFERS ACROSS THE UK

- Definition of Lower Reporting Limit: the lowest concentration that can be reliably reported by a laboratory
- Most Laboratories (66.0%; 33/50) use manufacturer recommendations to determine Lower Reporting Limit for PSA assay.
- Most laboratories (82.0%; 41/50) do not have a programme to determine whether lower reporting limit remains valid after initial PSA validation
- Most laboratories (86.3%; 44/51) do not intervene when PSA results are below reporting limit

Roche Cobase e/ELECSYS	Example values (µg/L)
Limit of Blank	0.006
Limit of Detection; concentration at which concentration of compound is too low to distinguish from background	0.014
Limit of Quantification: concentration you can accurately quantify	0.03
Measuring range	0.006–100
Clinically important value for biochemical recurrence	2 consecutive rises with PSA ≥0.1µg/L OR 3 consecutive rises. International guidelines stipulate 0.2µg/L threshold

THE MEDIAN CONCENTRATION FOR LOWEST INTERNAL QUALITY CONTROL (IQC) IS HIGHER THAN REPORTING THRESHOLD FOR BIOCHEMICAL RECURRENCE



Definition; IQC is used to ensure ongoing accuracy, precision and reliability of test results within the laboratory. Lowest IQC is at low end of the assay's reportable range.

Consideration; median lowest IQC levels should ideally encompass PSA values as low as 0.1µg/L, as this value can prompt referral due to biochemical recurrence. However, lowest IQC may be subject to technical constraints.

Assay	Measuring range (µg/L)
Roche Cobase e/ELECSYS	0.006–100
Abbott Allinity	0.025–100
Siemens Atellica	0.01–100

N= 45 responders

SUMMARY OF UK LABORATORY PRACTICE: ASSAY AND QUALITY CONTROL

Association for Laboratory Medicine

Practice around Lower Reporting Limits/use of IQC may impact robust reporting of low levels of PSA due to:

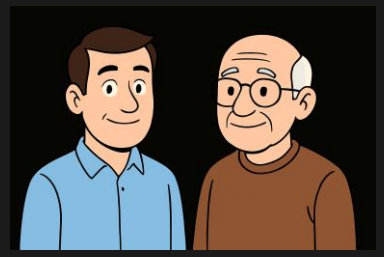
i. Differences in how reporting limits are determined
ii. Lack of a programme to determine whether lower reporting limit remains valid after initial PSA validation
iii. Median concentration for lowest IQC used (0.6µg/L) being greater than reporting threshold for biochemical recurrence, which can be as low as 0.1µg/L

UK LABORATORY PRACTICE: PSA CUT-OFFS/TARGETS

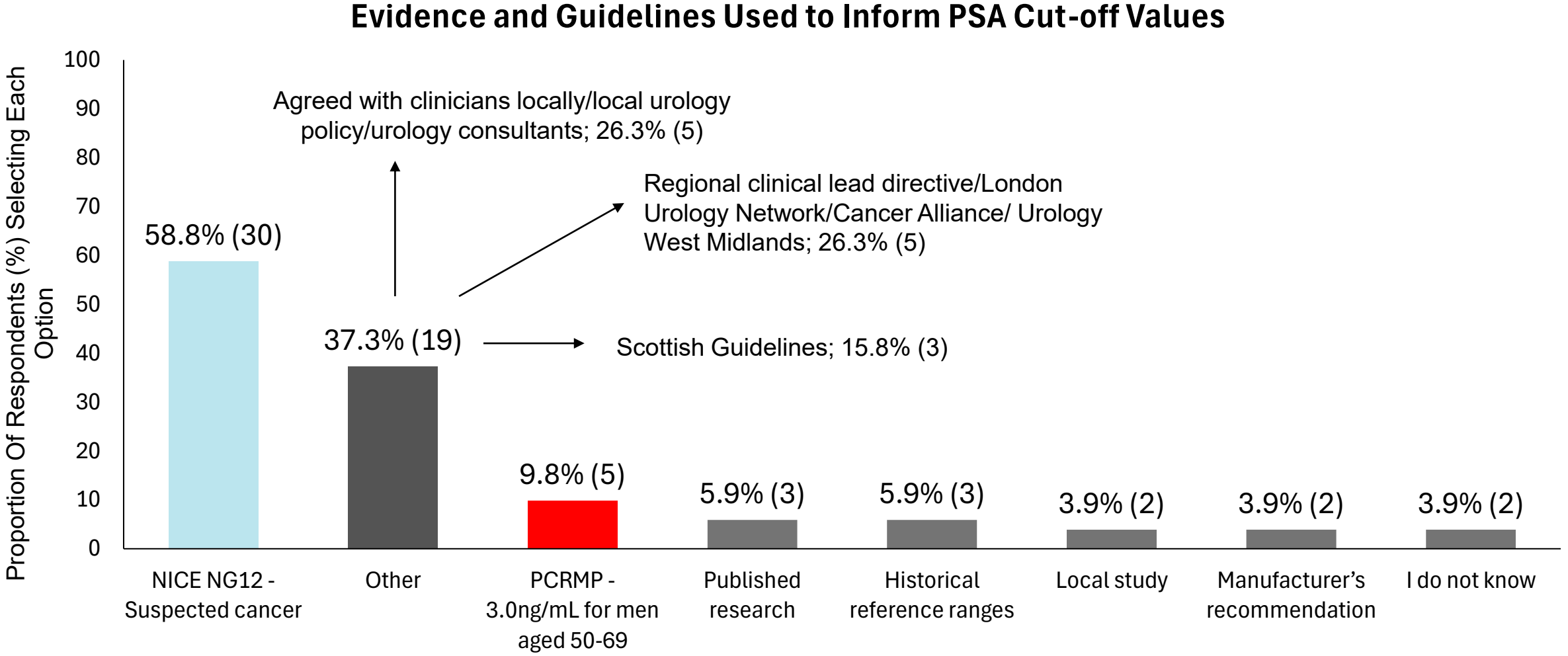
Sample Receipt and Testing

Assay and Quality Control

PSA Cut-offs/Targets

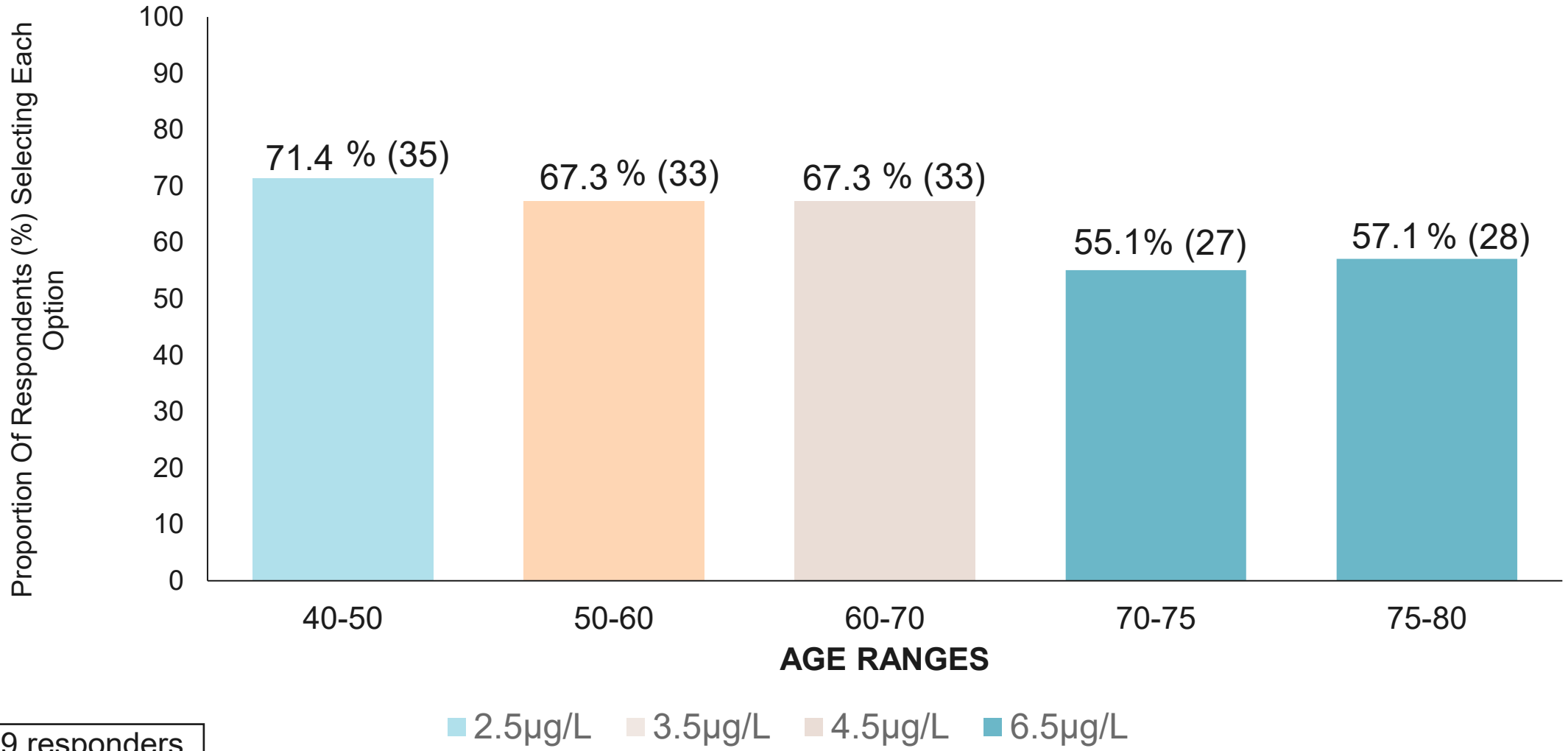


NICE NG12 AGE-BASED THRESHOLDS FOR REFERRAL IS THE MOST COMMON SOURCE FOR DETERMINING PSA CUT-OFFS IN LABORATORIES



N= 51 responders

THE MOST COMMONLY REPORTED PSA CUT-OFFS APPLIED WITHIN EACH AGE GROUP CORRESPOND WITH NICE NG12 AGE-BASED THRESHOLDS



N=49 responders

LABORATORIES INDICATED SPECIFIC CUT-OFFS AT AGE RANGES WHERE CLINICAL JUDGMENT SHOULD BE USED

Association for Laboratory Medicine

Proportion (%) of Respondents Selecting Options

PSA Cut-offs (µg/L)	<40	40-50	50-60	60-70	70-75	75-80	>80*
1	0	0	0	0	0	0	0
1.5	0	0	0	0	0	0	0
2	2	8.2	0	0	0	0	0
2.5	28.6	71.4	0	0	0	0	0
3	2	6.1	30.6	4.1	0	0	0
3.5	0	0	67.3	2	0	0	0
4	0	0	0	26.5	2	0	0
4.5	0	0	0	67.3	0	0	2
5	0	0	0	0	22.4	18.4	10.2
5.5	0	0	0	0	0	0	0
6	0	0	0	0	0	2	0
6.5	0	0	0	0	55.1	57.1	20.4
7	0	0	0	0	0	0	0

*NICE NG12 did not provide guidance for men >80 years of age at time of survey (December 2024-January 2025).

LIMITED AWARENESS OF THE EXISTENCE OF HOSPITAL CLINICAL PROTOCOL/GUIDELINES FOR PROSTATE CANCER PATIENTS

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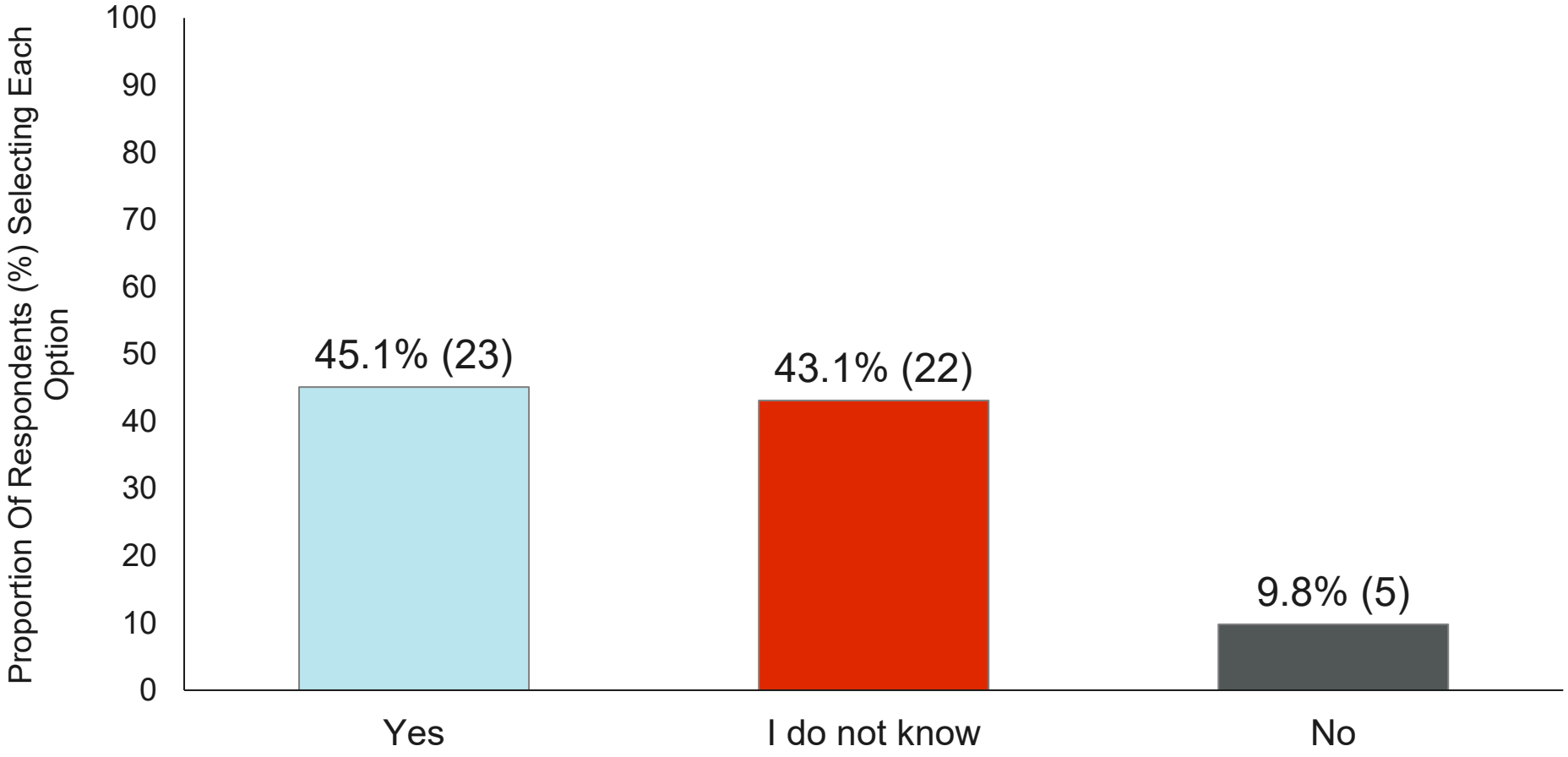
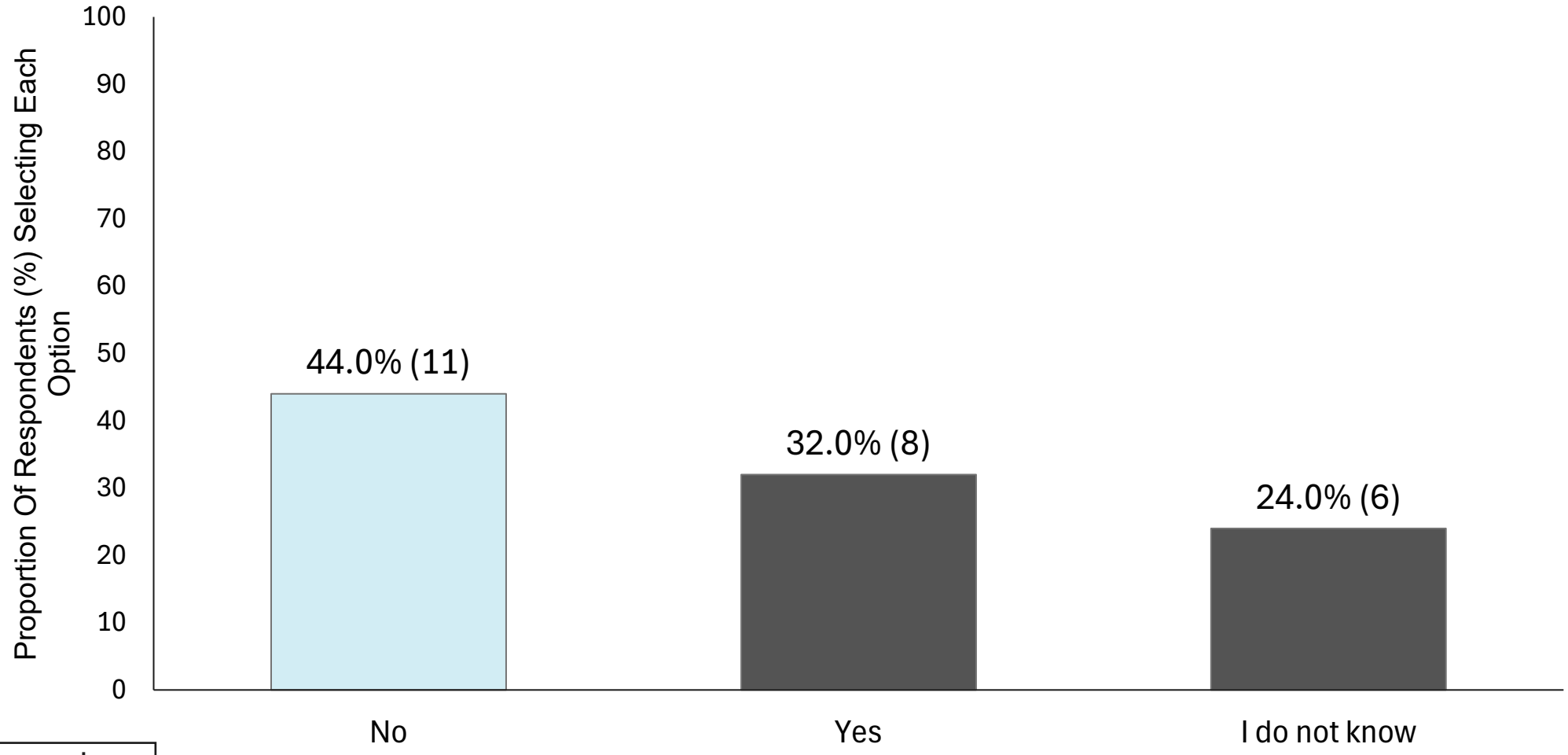
Does Your Hospital Have A Clinical Protocol/Guideline For Prostate Cancer Patients?



N=51 responders

MOST PROSTATE CANCER PROTOCOL/GUIDELINES DO NOT SPECIFY POST TREATMENT PSA TARGETS

Does The Protocol Include A Target PSA Concentration Being Aimed For In Patients Being Treated For Prostate Cancer?



N=25 responders

SUMMARY OF UK LABORATORY PRACTICE: USE OF PSA CUT-OFFS/TARGETS

Association for Laboratory Medicine

1. Most laboratories use NICE NG12 to determine PSA cut-offs but there may be inappropriate use of PSA cut-off at <40 where NICE guidance suggests need for 'clinical judgment'

2. Since PSA survey was completed NICE have now (June 2025) included Academy of Medical Royal Colleges' PSA recommendations for men aged ≥80 (e.g. PSA >20 ng/mL or PSA >7.5 ng/mL and metastatic symptoms)

3. Differences in awareness of local prostate cancer protocols and PSA targets in those protocols.

4. Also, where local protocols exist, potentially more needs to be done to describe i) differences in PSA levels across various clinical scenarios and ii) limitations of PSA test

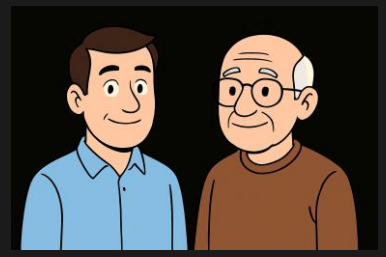
Association for Laboratory Medicine

UK LABORATORY PRACTICE: FOLLOW-UP INVESTIGATIONS

Sample Receipt and Testing

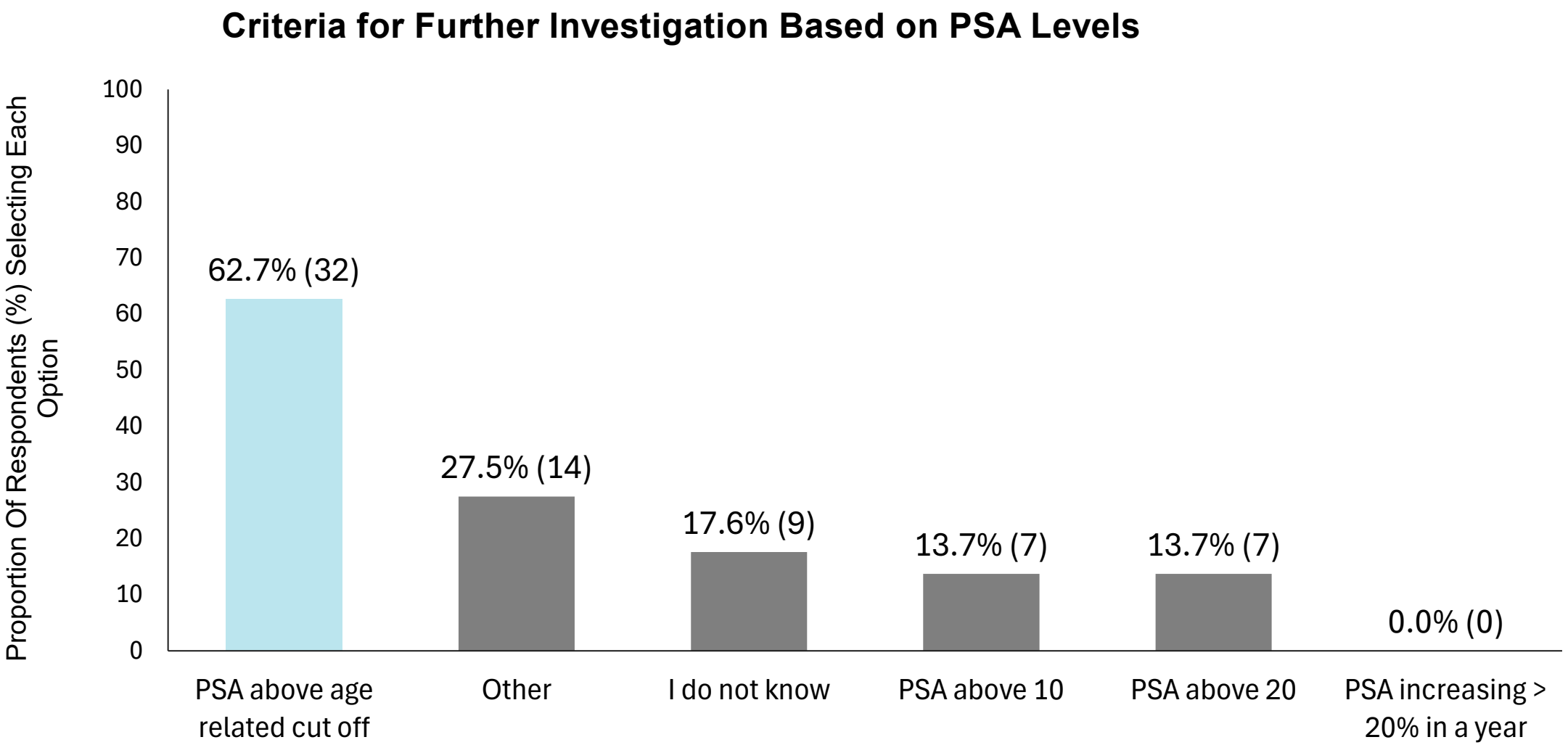
Assay and Quality Control

PSA Cut-offs/targets



Follow-up Investigations

‘PSA ABOVE AGE-RELATED CUT-OFF’ IS THE MAIN REASON FOR FURTHER INVESTIGATIONS INTO POSSIBLE PROSTATE CANCER



N=51 responders

MOST LABORATORIES DO NOT HAVE A MINIMUM PSA RETESTING INTERVAL ACROSS DIFFERENT CLINICAL SCENARIOS IN EITHER PRIMARY CARE OR SECONDARY CARE

Question *(number of responders)*	**Most popular answer**
Do you have a minimum retesting interval for PSA? *(n=51)*	No (80.4%)
How frequently do you test PSA (minimum re-testing interval in the following scenarios for Primary care? *(n=20)*	No minimum retesting interval (45.0%)
How frequently do you test PSA minimum re-testing interval in the following scenarios for Secondary care? *(n=20)*	No minimum retesting interval (55.0%)

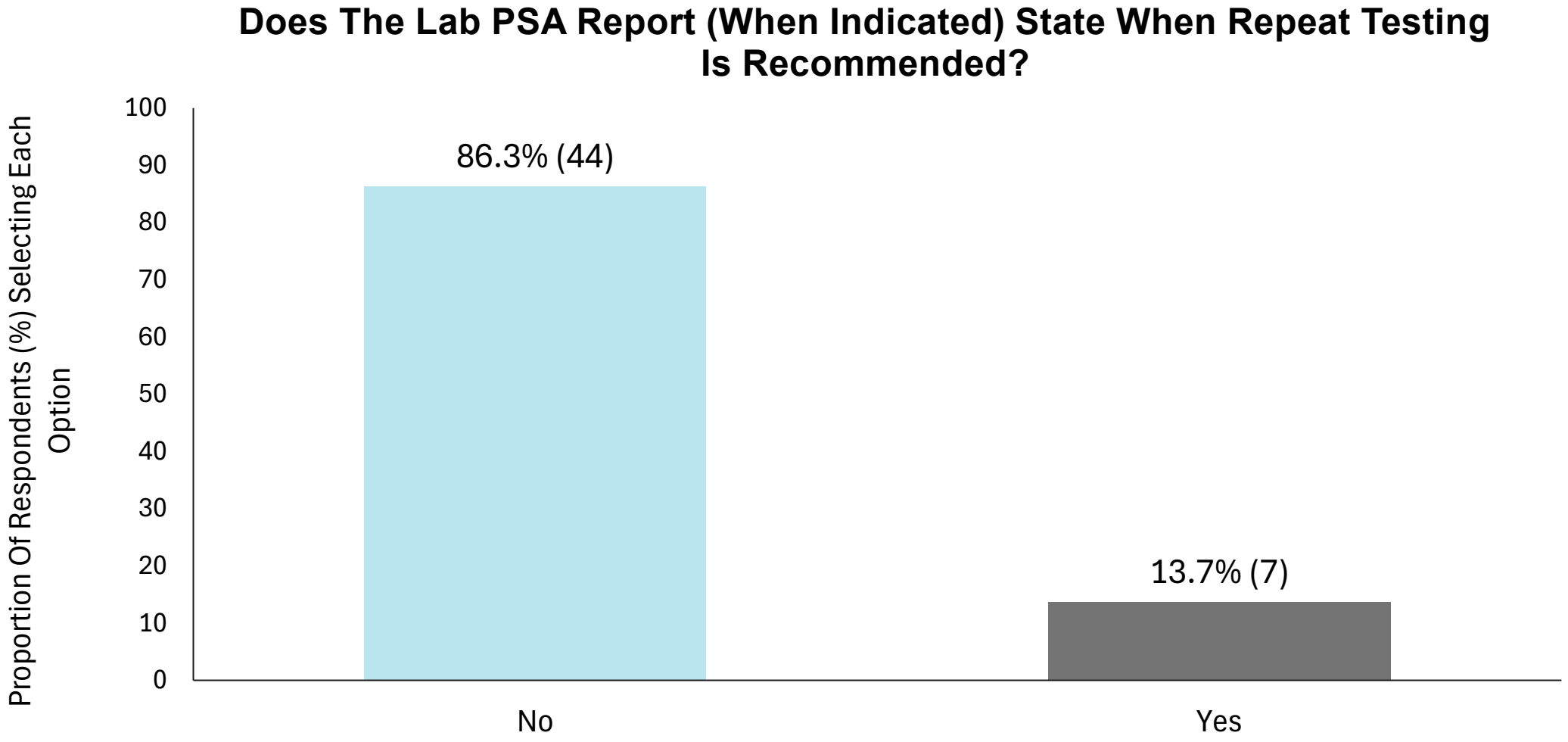
Frequency of PSA tests (3 weeks/8 weeks/3 months/6 months/other (free-text))

PSA status (raised/not raised)

Active surveillance

Radical treatment

VAST MAJORITY OF LABORATORIES DO NOT INDICATE IN REPORT WHEN REPEAT PSA TESTING IS RECOMMENDED



N= 51 responders

SUMMARY OF UK LABORATORY PRACTICE: FOLLOW-UP INVESTIGATIONS

1. Laboratories do not apply minimum retesting intervals and do not state when repeat PSA testing is recommended

2. If appropriate, laboratories could utilise sources to increase awareness of how frequently men should be tested across clinical scenarios:

Guidelines/recommendations	Reasons for use
NG12 age-based threshold (symptomatic)	To acknowledge lack of consensus on minimum retesting interval
Getting It Right First Time (GIRFT)	Provides re-testing interval for active surveillance
Royal College of Pathologists	Provides guidelines for monitoring disease
EAU follow-up criteria	General guidelines post treatment

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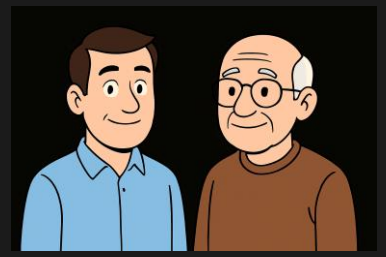
UK LABORATORY PRACTICE: REPORTING

Sample Receipt and Testing

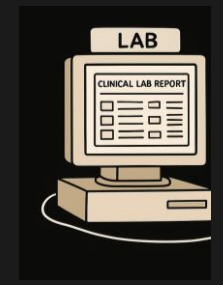
Assay and Quality Control

PSA Cut-offs/Targets

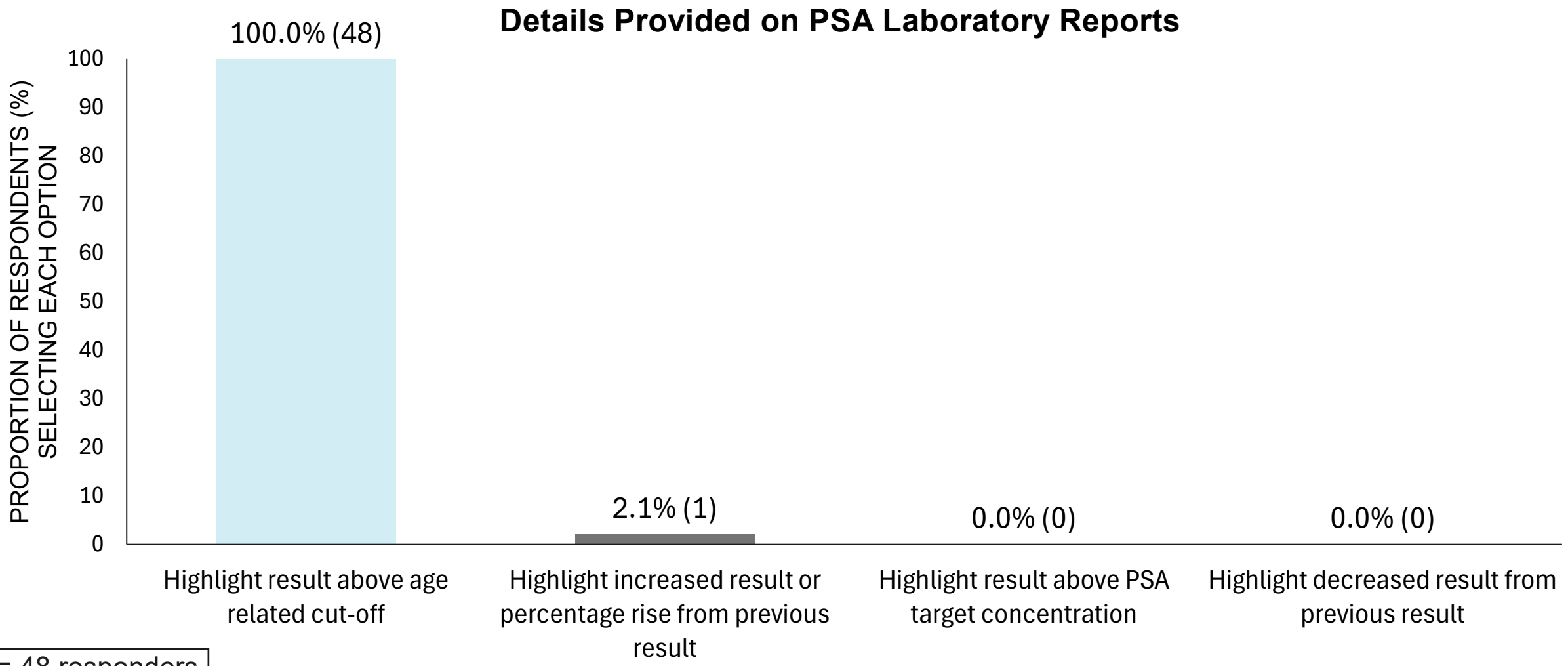


Follow-up Investigations

Reporting



MOST LABORATORIES HIGHLIGHT WHEN A RESULT IS ABOVE AGE-RELATED CUT-OFF IN PSA REPORTS

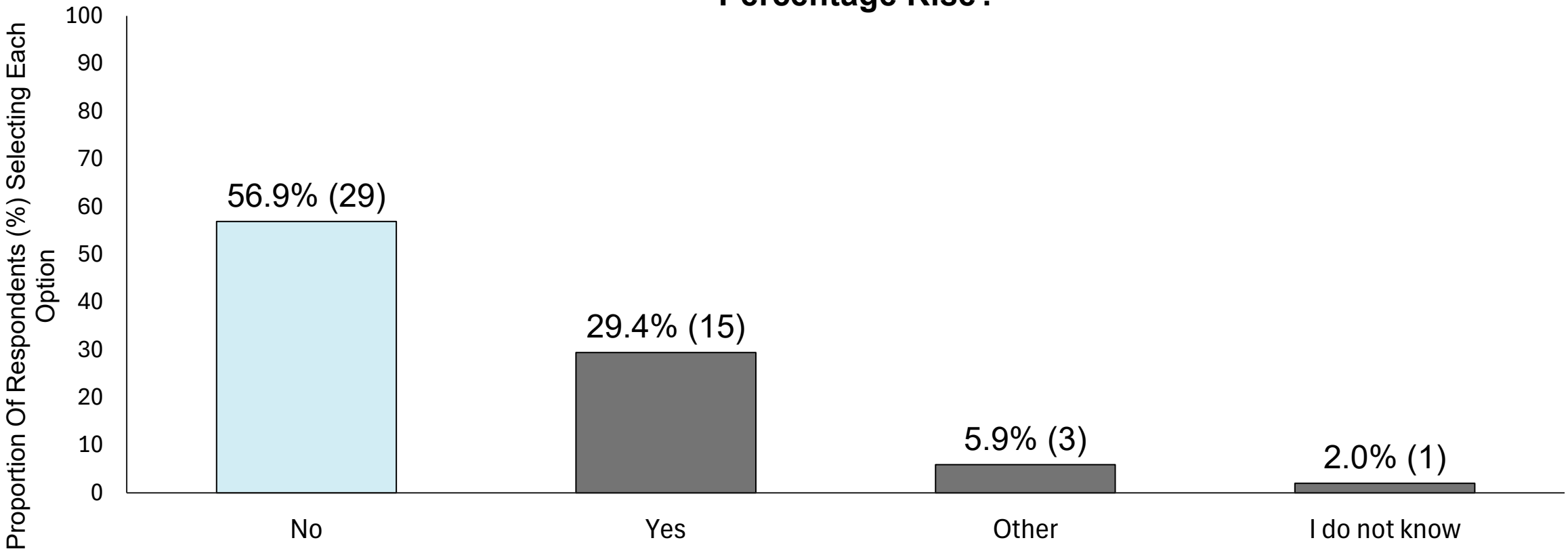


N= 48 responders

MOST LABORATORIES DO NOT HAVE A RED FLAG SYSTEM IN PLACE TO ALERT GPS/SECONDARY CARE CLINICIANS OF A RISE IN PSA > CUT-OFF

Association for Laboratory Medicine

Does The Laboratory Have A Red Flag System In Place Which Alerts The GP / Secondary Care Clinician Of A Rise In PSA Above The Defined Cut-off / Percentage Rise?



N= 51 responders

THE MOST COMMON APPROACH FOR COMMENTING ON PSA TEST RESULTS WAS THROUGH USE OF AUTOMATED SYSTEMS

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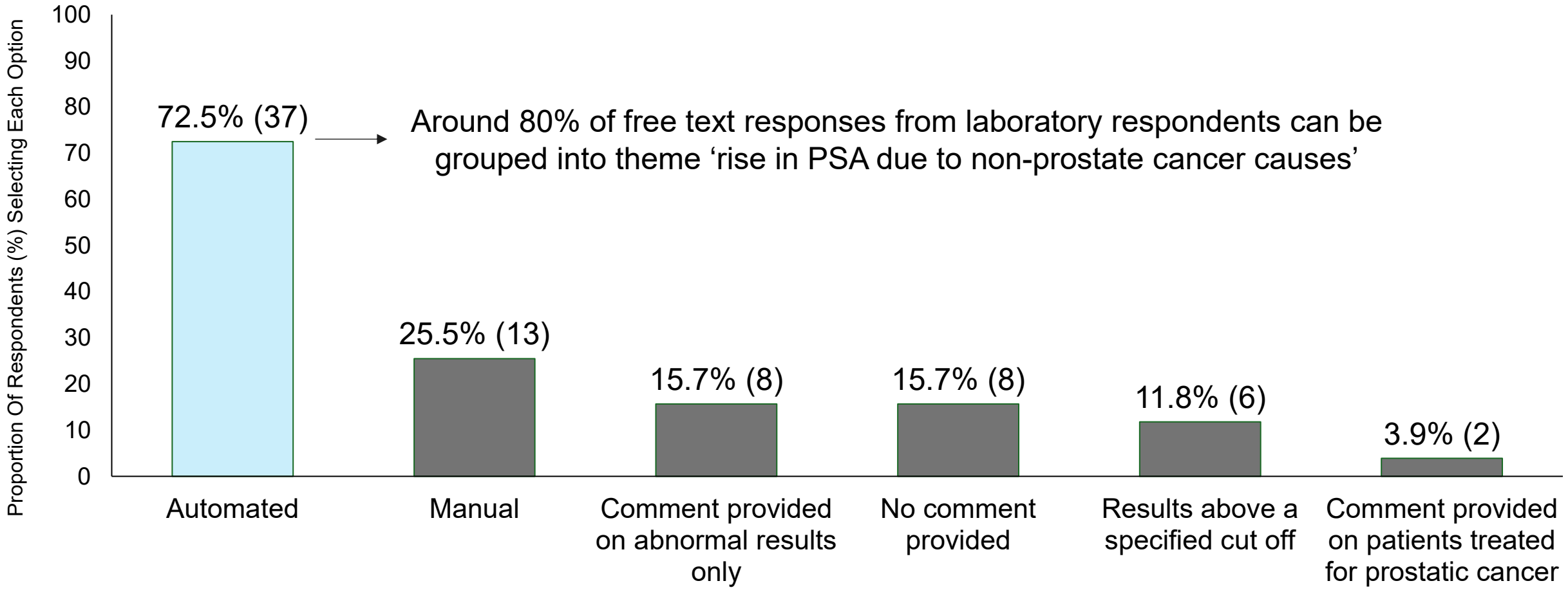
Commenting Approaches/Reasons for PSA Test Results Across Laboratories



N= 51 responders

SUMMARY OF UK LABORATORY PRACTICE: REPORTING

1. Automated comments and red flag systems should be in place to trigger treatment specific comments and action

2. Improvements in reporting require more detailed information being provided to laboratories across referral/diagnostic and post-treatment settings

CONCLUSION

Association for Laboratory Medicine

1. Are men experiencing variation in PSA testing depending on where they live in the UK?

Potentially, e.g. variations in number of PSA tests conducted by different laboratories, and awareness/interpretation of PSA cut-offs based on relevant national guidelines/hospital protocols

2. Could variation have an impact on clinical decision-making and subsequently the treatment men receive for prostate cancer?

Potentially, if results are generated and reported in a way which is not optimised for patients who have been treated, then referral/treatment may not be triggered in a timely manner by requestor

3. Which areas of practice require improvement?

- Detailed and standardised patient information on or alongside request forms – e.g. presence of symptom and gender reassignment history
- *On PSA cut-offs*: standardise practice plus acknowledge gaps in evidence to reduce heterogeneity in practice
- Optimise automated comments and install red flag systems so that requestor can act accordingly across different clinical scenarios and ultimately help improve patient care

THANK YOU

PROSTATE CANCER UK

Joseph Woollcott

Harris Wong

Association for Laboratory Medicine

Dr W S Wassif

Dr Louise Ward

Dr Neil Syme

ALM Audit Committee

UK NEQAS

Education I Quality I Global

Mrs Dina Patel

Patient Representative

Dr Neil MacLachlan

NHS Hull University Teaching Hospitals NHS Trust

Dr John Shepherd

All Survey Responders