



QC Lab Survey Feedback

NHS QA Committee

Key Points

(Draft July 2023)



Introduction

- Auditors conscious laboratory provision patchy
- Longstanding concerns over expertise of
 - In-house laboratories
 - Non-pharmaceutical laboratories
- Aware 1 or 2 larger labs had issues
- Loss of 2 or 3 laboratories nationally could lead to serious disruption
- NHS QA Committee wanted clearer picture...

Survey Design

- Online Survey Tool – SmartSurvey
- Short survey looking at
 - Who
 - Types and Number of Labs
 - Accreditation
 - Range and Scale of Activity
 - Oversight
 - Microbiology Advice
- Link to Survey Distributed via RQAs



Survey Response



106 respondents in total after data cleaning



Partial responses added for NW units taking numbers for some questions to n=124



Total number of units undetermined



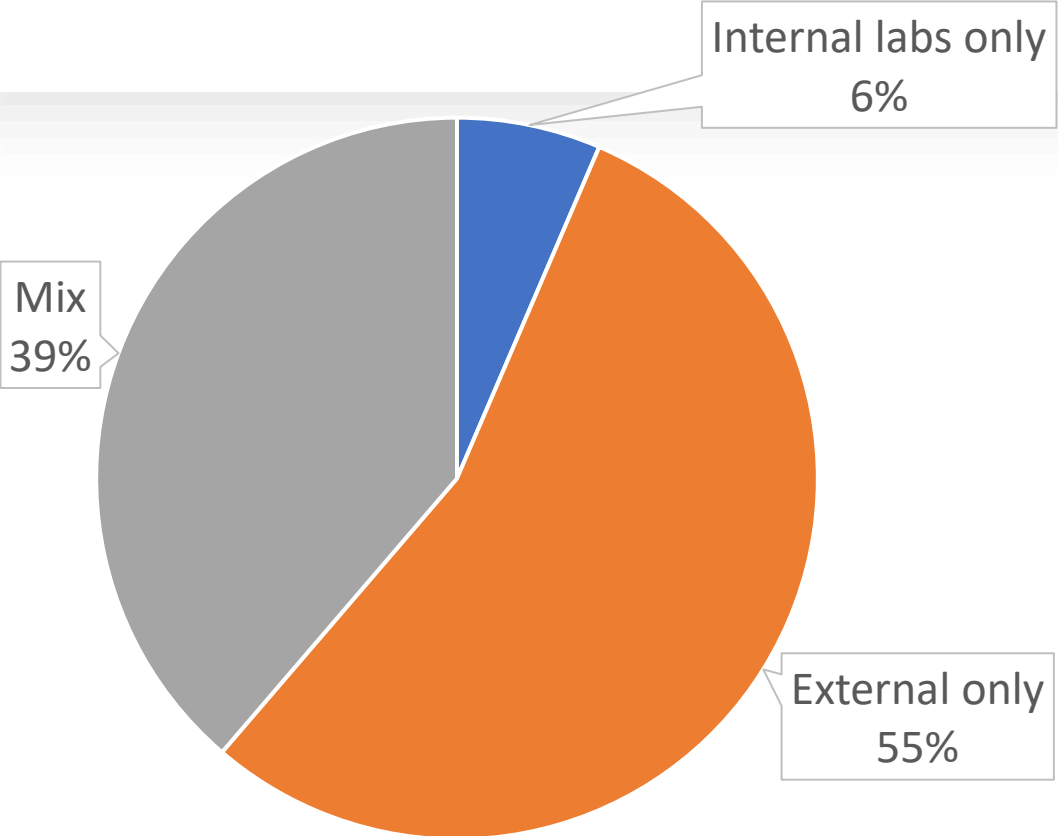
Devolved nations responses relatively complete



Patchy response from English regions



Internal or External Labs?



What Are Internal Labs Doing?- Chemistry

Finished Product Testing 40%

Water Testing 36%

Radiopharmacy QC 30%

Raw Material Testing 25%

Packaging Components 18%



What Are Internal Labs Doing? – Microbiology

Liquid Media Testing 89%

Plate Incubation/Reading 86%

Water Testing 36%

Sterility Testing 32%

Species Identification 29%



Internal Labs

Three types of internal laboratory evident

Large licensed centres

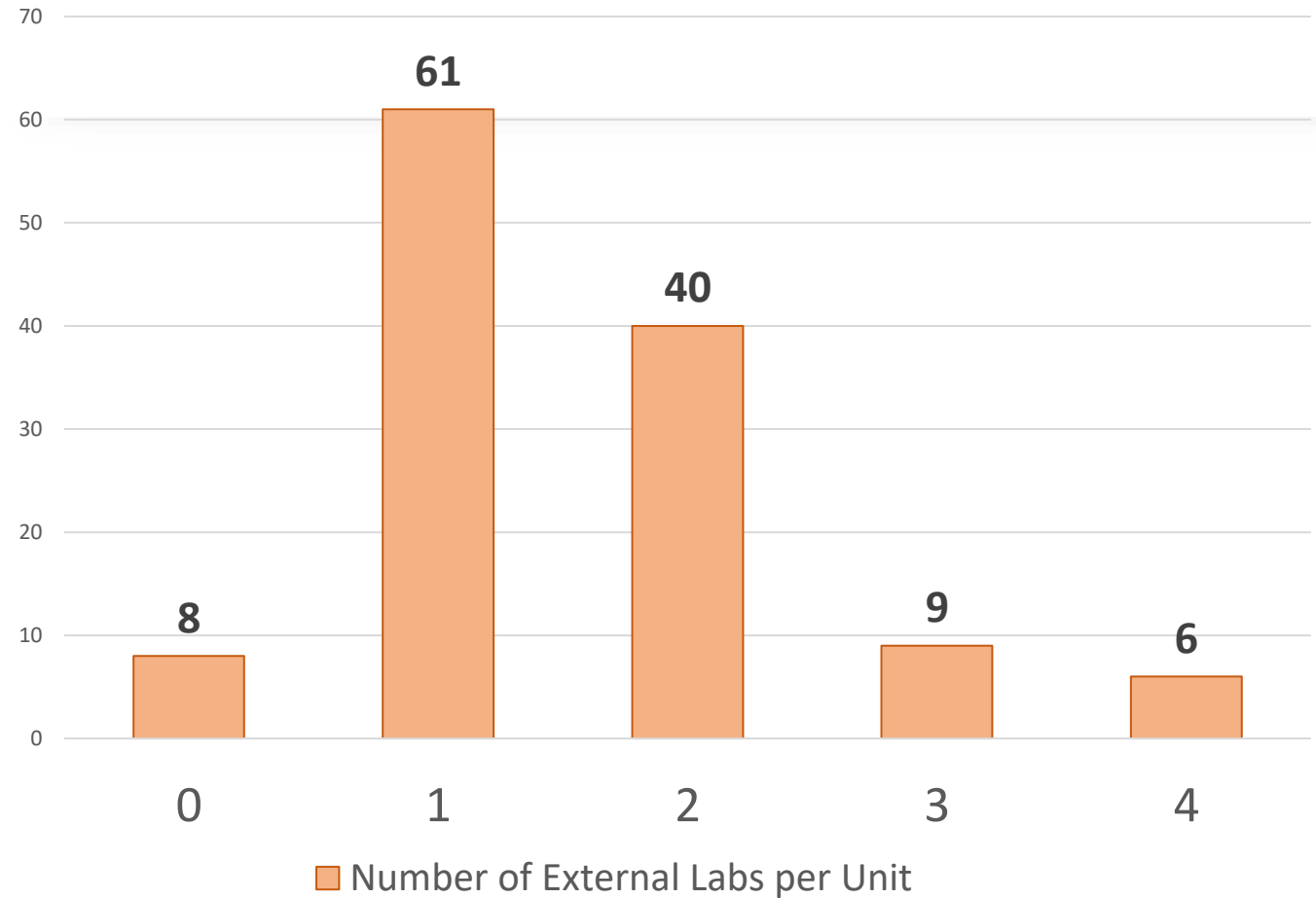
Smaller S10 units

Radiopharmacies

Range of activities very different



How Many External Labs?



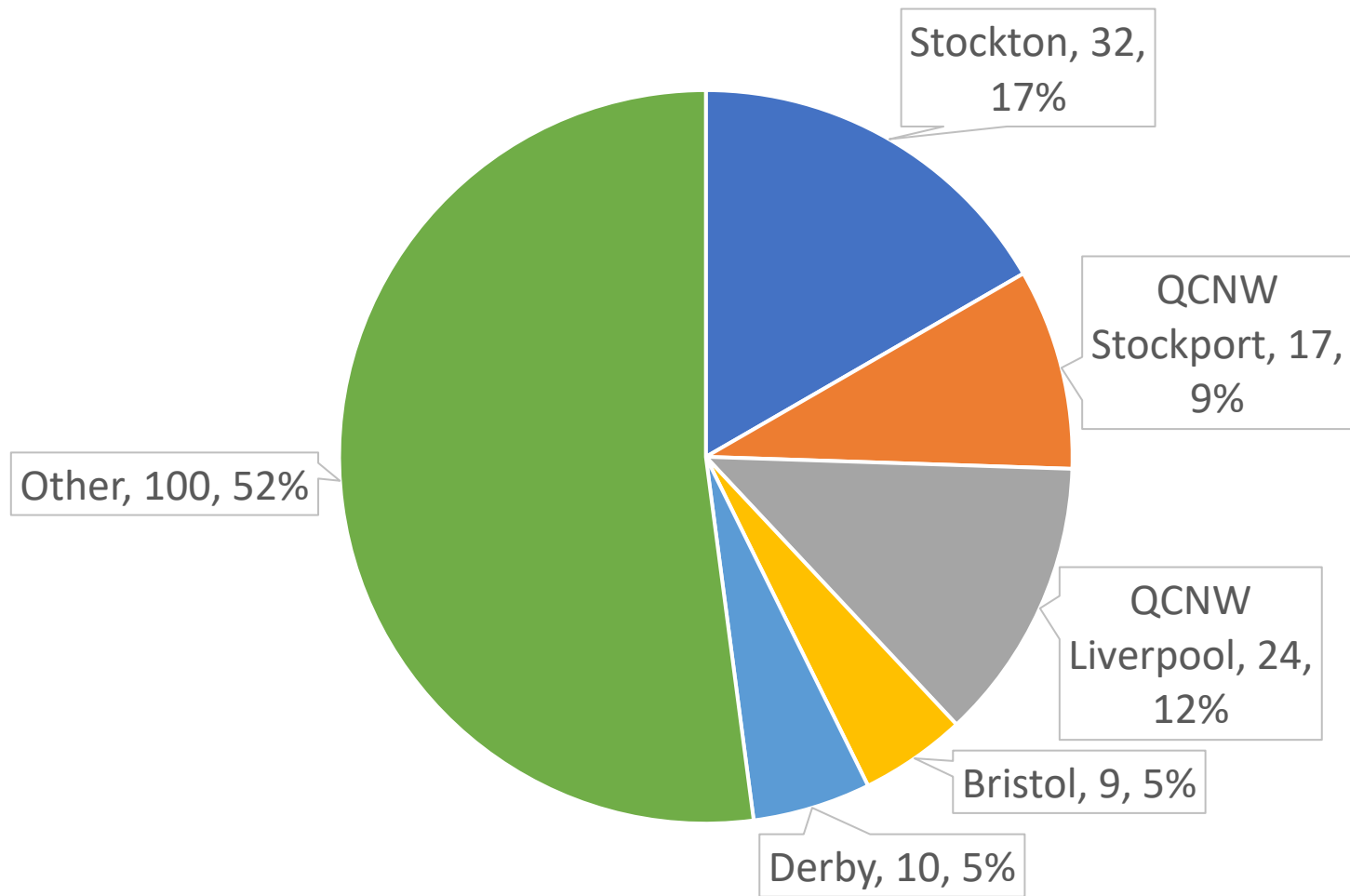
* Leads to web of 192 unit-lab relationships

This includes ALL laboratory services:

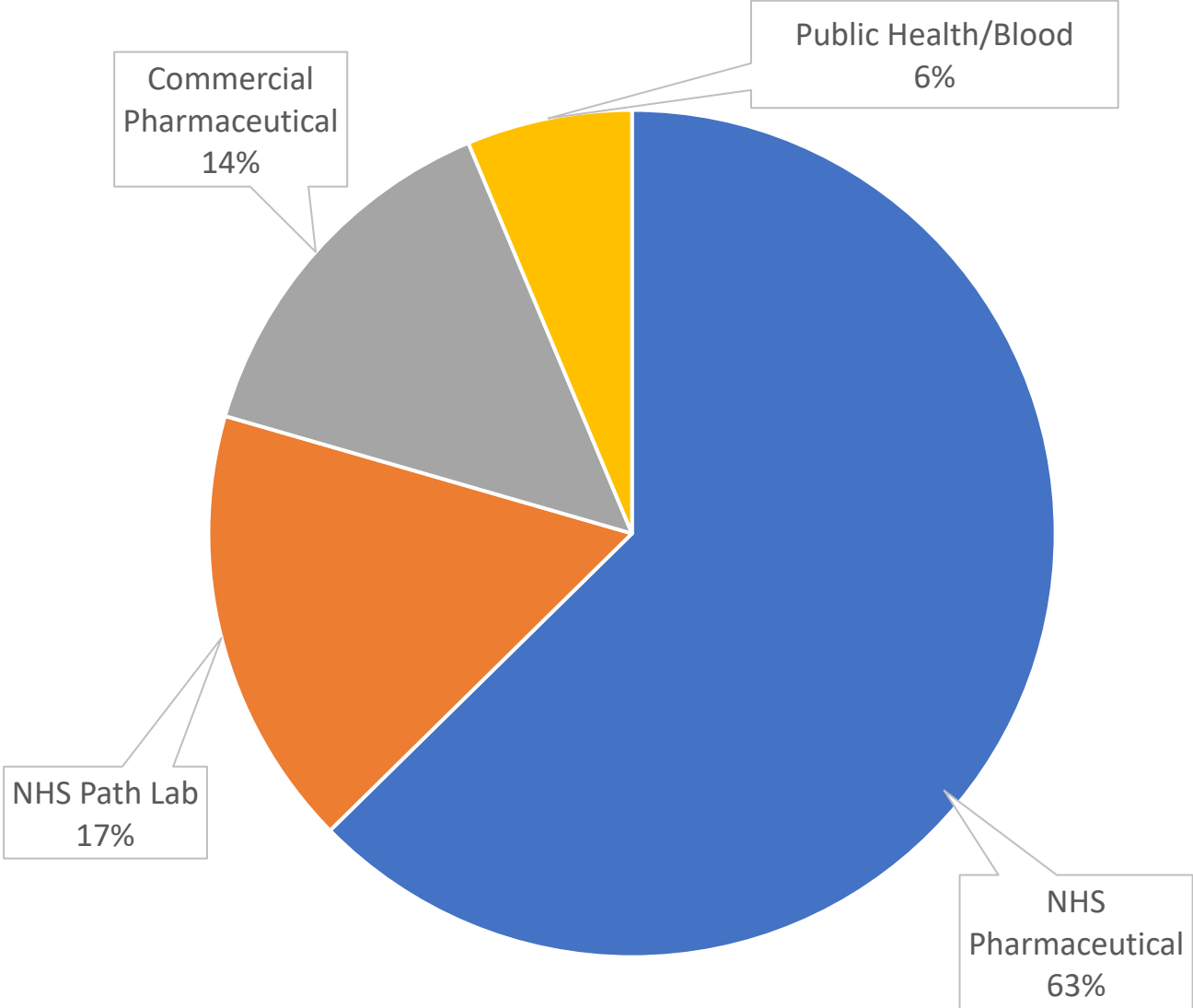
- Environmental testing
- Finished product testing
- Stability testing
- Organism identification

Who Are The External Labs?

Top 5 External Labs by Number of Relationships



External Labs Used By Sector?



- High Reliance on Non-Pharma
- Commercial sector small
- Large regional variation





Accreditation – Internal Labs



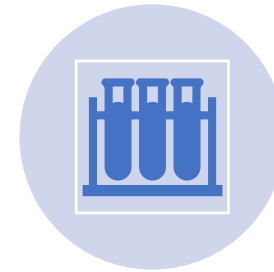
28 of 56 (50%)
Internal Labs Have
GMP Certification



6 Of 56 Internal Labs
Have ISO 9001
Accreditation



4 of 56 Internal Labs
Have UKAS ISO17025
Accreditation



10 Of 56 Respondents
Unaware Of Own
Lab's Status

Accreditation – External Labs

In 33% of the lab-unit relationships the lab (allegedly*) holds UKAS accreditation

In 49% of the lab-unit relationships the lab held a GMP certificate**

For 32% of lab-unit relationships the unit declared they were uncertain of the lab's accreditation status

*A number of labs referenced were public health/path labs

** Some respondents incorrectly claimed their lab did NOT hold a GMP certificate



Audit Checklist

- Audit Satisfactory
- Nonconformances Found
- Observations Made

Oversight – External Labs

37% of unit-lab relationships are underpinned by some kind of audit (including 3rd party)

79% of unit-lab relationships have a QTA in place

12.5% of unit-lab relationships have NO oversight at all



Access to Specialist Microbiology Advice

- 70/106 respondents were not able to get specialist microbiology advice from external laboratories.
- No similar question for internal laboratories

Conclusions

- 3 strands of concern
- Possible lab expertise gaps:
 - A number of small units do some QC (mainly micro)
 - Accreditation of 1 in 3 internal labs non-existent/unknown
 - Use of non-pharma labs is common in some areas
- Unit management expertise gaps:
 - Respondents unclear as to lab status was unexpectedly high
 - Oversight arrangements for external labs are not robust
 - Access to expert microbiology advice from labs is not universal
- Sector is not robust
 - Large proportion of units reliant on a very small number of NHS specialist laboratories
 - Commercial sector is not well-utilised generally



Next Steps – Missing Pieces?

More data to mine but main aims achieved

Survey the laboratories themselves

- Firm up picture as to relevant expertise/accreditation
- Look at system capacity/contingency capability?
- What do labs see as threats to continued service?

Can we work on providing better support?



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Can we work on providing better support?

- Dissemination of expertise/provision of laboratory training?
- Education on laboratory oversight?
- Capacity planning
- Approved Supplier programme?
- Better QTAs?
- Escalation