Laboratory Haematology and Genomics:

The UK HMDS Network

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BSH Laboratory Specialist Interest Group Committee

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Overview

- BSH Lab SIG summary
- Lab SIG HMDS survey
- SIHMDS principles and progress
- Current SIHMDS challenges
- What is happening? SIHMDS survey results
- Genomics
- IT issues
- Other issues
- What next? An HMDS network

BSH ASM Audience Slido responses to questions now included

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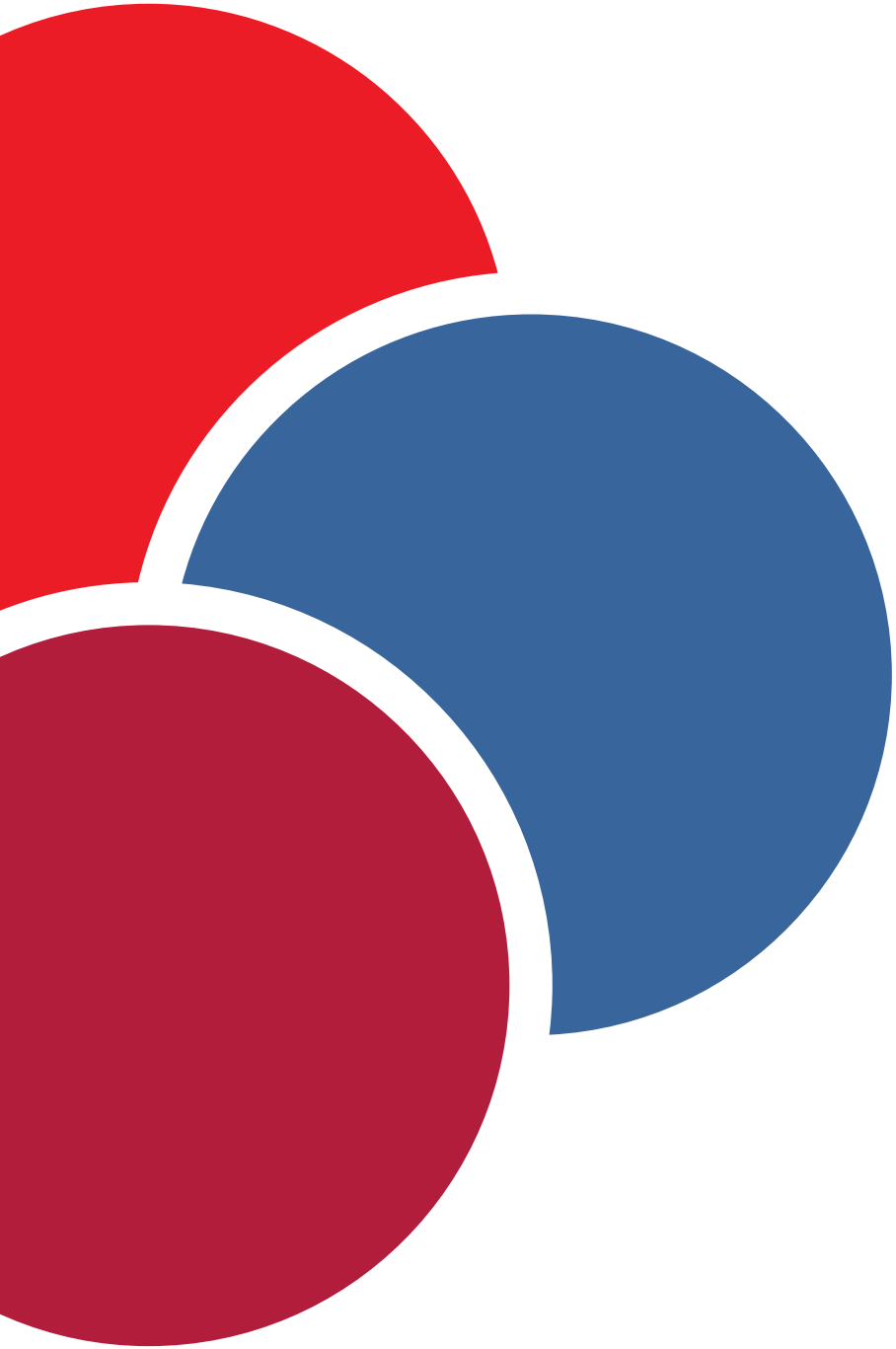

BSH Lab SIG Summary

BSH Lab Specialist Interest Group

The Board has established the SIG to further the practice and development of laboratory haematology, particularly in the areas not already represented by national bodies in the UK, haematological malignancy diagnosis, genomics and general haematology laboratory, particularly red cell diagnosis.

"To enhance multiprofessional, multidisciplinary collaboration and increase multiprofessional membership of the BSH. To encourage other professionals, such as clinical and biomedical scientists (involved in cytogenetics, genomic medicine, immunophenotyping, general laboratory haematology) as well as medical professionals (histopathologists interested in haematopathology) to participate and join the BSH, ensuring that the society provides a voice for all those who work in laboratory haematology"

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SIG functions

National leadership for laboratory haematology

- Education & training
- Advocacy
- Liaison
- Working with guidelines committee

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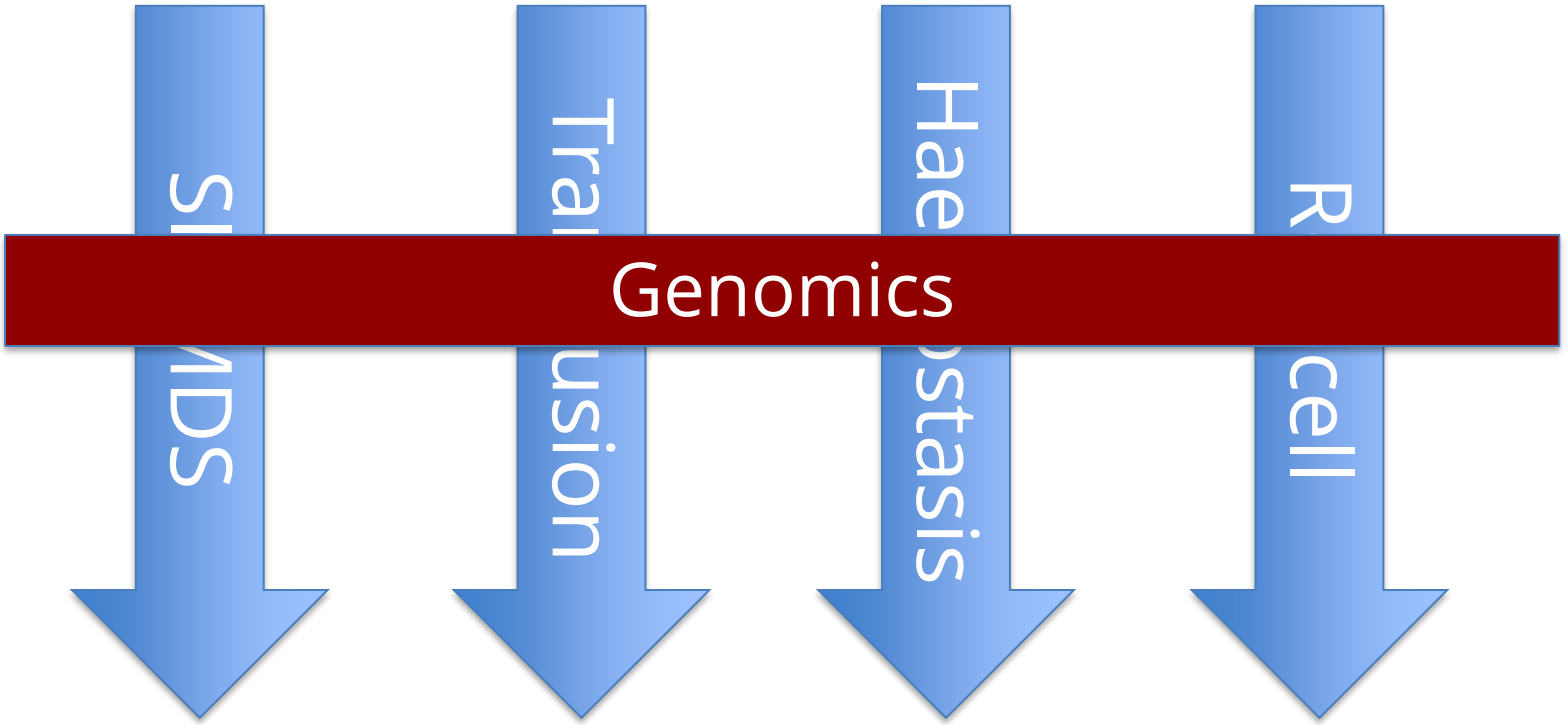
Genomics as a cross-cutting theme

SIG Organising Committee



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Laboratory SIG committee

- Tom Butler (Chair)
- Andrew Wilson (Vice Chair)
- Fergus Jack (Trustee link)
- Robert Baker
- Rachel Brown
- Emma Das-Gupta
- Timothy Farren
- Shireen Kassam
- Nagumantry Kumar
- Andrew McGregor
- Melanie Percy
- Noemi Roy
- April Sellors

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Current SIG Goals and Projects

- ICC/WHO issue: working with RCPath & BLPG:
  - Sir John Dacie Plenary Lecture with Catherine Cargo
  - *Which diagnosis shall we give? Two new international haematological malignancy diagnostic classifications*
  - Tuesday 25th 1.30-2.15
- ASM morphology session
  - Alesia Khan & Tom Butler
  - Tuesday 25th 8.30-10.15
- BSH Education committee: training days, website
- Red cell, rare disease genomics
- NEQAS, NQAAP, NHSE
- Haematological Malignancy Diagnostic Services: SIHMDS/HMDS
- Lab SIG survey on HMDS
  - Understand extent of issues
  - Determine what issues are shared nationally vs locally
  - Identify areas for improvement
- HMDS network

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Question 1

- Are you aware of the NICE IOG/NG47 standards for haematopathology diagnostics?

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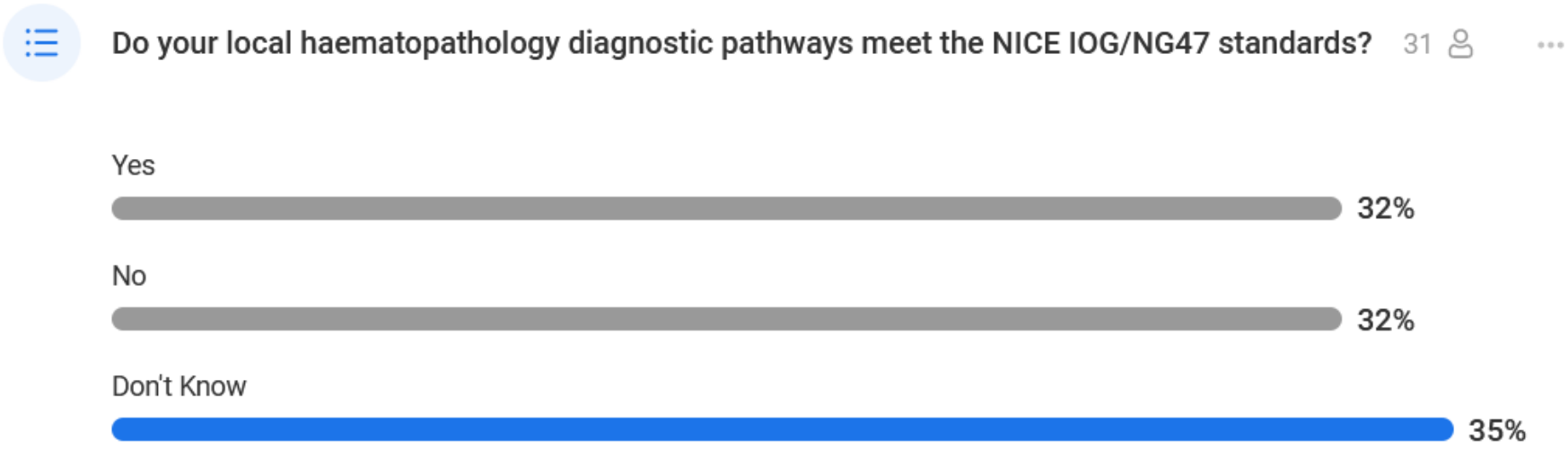
Question 2

- Do your local haematopathology diagnostic pathways meet the NICE IOG/NG47 standards?



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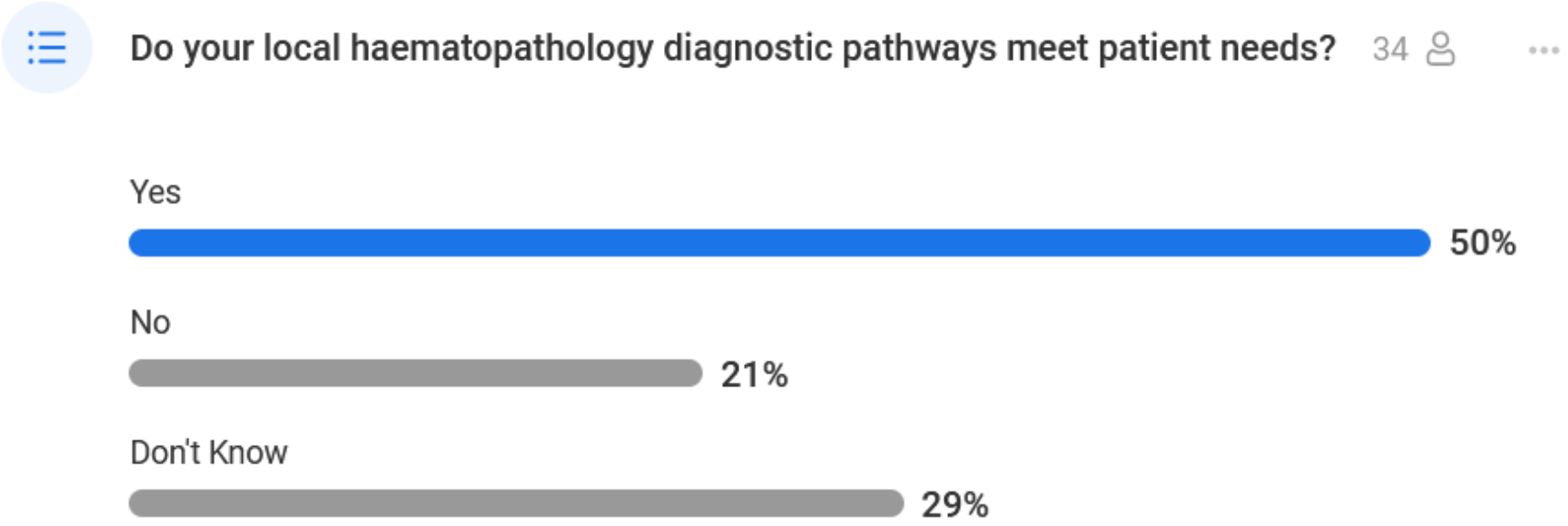
Question 3

- Do your local haematopathology diagnostic pathways meet patient needs?



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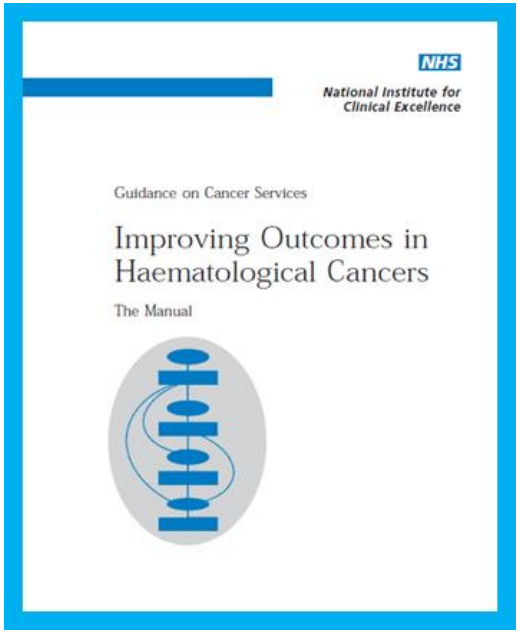
SIHMDS Principles

- Concept conceived in the 1990s
- Formally defined in 2003 NICE Improving Outcomes in Haematological Cancers
  - Outlined information relating to organisation of the specialist haemato-oncology laboratory service, along with treatment recommendations and continued management
  - Specifically related to adult haem-onc services
  - Updated 2016 (NG47)
- National Peer Review standards for haematological cancers
  - National cancer Peer Review programme in 2013-2016



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SIHMDS Principles

- "Improving the consistency and accuracy of diagnosis is probably the single most important aspect of improving outcomes in haematological cancer"[2]
- Key concept is integration: no single modality answers the diagnostic question[3]
- Studies suggest that 5–15% of lymphomas are misdiagnosed outside an SIHMDS setting
- A relatively small investment in pathology at the beginning of the pathway: greater effect on the patient and on the NHS than high-cost drugs.

2. Ireland R. Haematological malignancies: the rationale for integrated haematopathology services, key elements of organization and wider contribution to patient care. *Histopathology* 2011;58:145–154

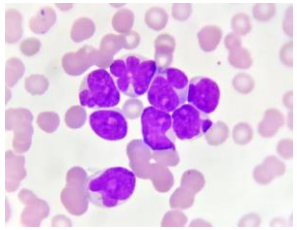
3. NICE. *Haematological Cancers: Improving Outcomes*. *NICE Guideline NG47*. www.nice.org.uk/guidance/ng47

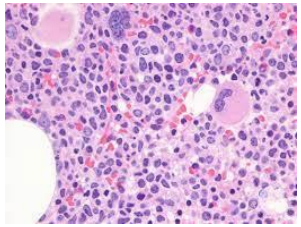
SIHMDS Principles

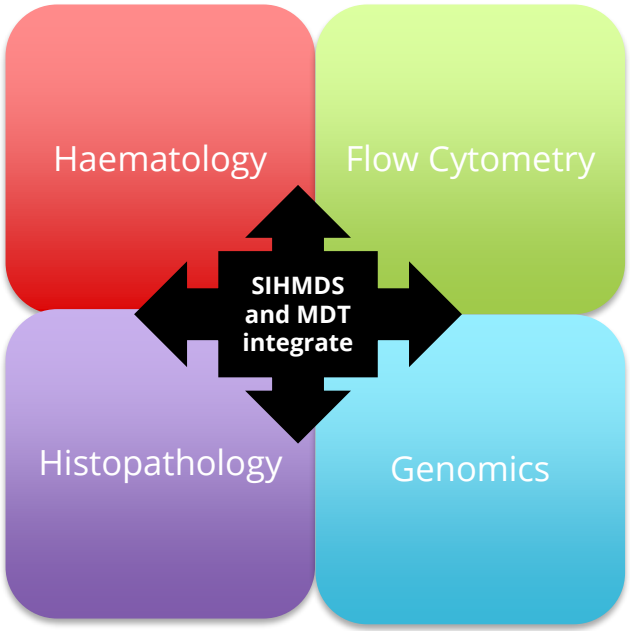
- Single specimen reception and collocated laboratories at a single site
- Multiprofessional staff work within a single quality management system
- Predefined diagnostic pathways to analyse specimens using a variety of diagnostic modalities
- Validate and correlate the results in a single IT system to produce an integrated diagnostic report
- The model for blood cancers has also informed integrated reporting in solid tumours[1]

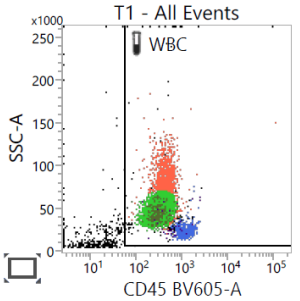
1. Royal College of Pathologists. *Standards for Integrated Reporting in Cellular Pathology*: www.rcpath.org/uploads/assets/442fcdc1-af22-401f-8fcd1b4b65603810/G155-StandardsIntegratedReportingCellPath-Jan17.pdf

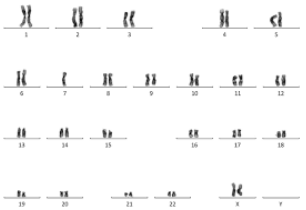
SIHMDS NICE Ideal

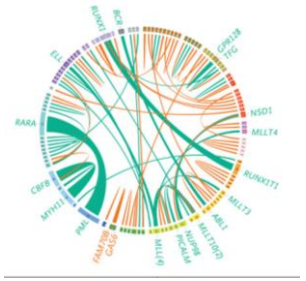












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SIHMDS Progress

- Progress was slow towards establishing fully integrated SIHMDS labs
- Challenges included
  - Investment in expert staff and technology
  - The need for overarching quality systems
  - The need for IT integration
  - Education
  - Cultural changes
- The National Cancer Peer Review Programme (2013-2016) Supported the development of SIHMDS laboratories within cancer networks by assessing against NG47 standards
- Beyond 2016, labs were established, there was a feeling that progress had been made and urgency for service development abated
- Yet challenges remained around achieving full NG47 compliance and no definitive national picture of SIHMDS operation

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UK NEQAS Leucocyte Immunophenotyping Survey

- Aimed to assess implementation of specific NG47 guidelines relating to the logistical and technical configurations of the laboratory and multidisciplinary team meetings
- Survey issued to UK NEQAS LI participants from England enrolled in molecular and flow cytometry programmes
- Completed questionnaires returned from **10** out of a 'potential' **17** laboratories

UK NEQAS
Leucocyte Immunophenotyping

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Cartwright A, et al. J Clin Pathol 2022;0:1–6. doi:10.1136/jclinpath-2021-208075

Results of UK NEQAS LI Survey

Implementation of 32 NG47 recommendations:
NG47 Compliance across laboratories ranged from 46.9-84.4%

Average 73.1%

- 3/10 responses stated they operated as a single entity (collocated, single accreditation), with the remaining 7 operating as a networked model
- Single entity SIHMDS had higher rates of compliance with measures
- Lowest rates of compliance for laboratory configuration recommendations related to SIHMDS management and IT system communications with other healthcare professionals
- Several networked SIHMDS not issuing final integrated reports containing all disease management information
- **Definition of Networked SIHMDS?**

UK NEQAS
Leucocyte Immunophenotyping

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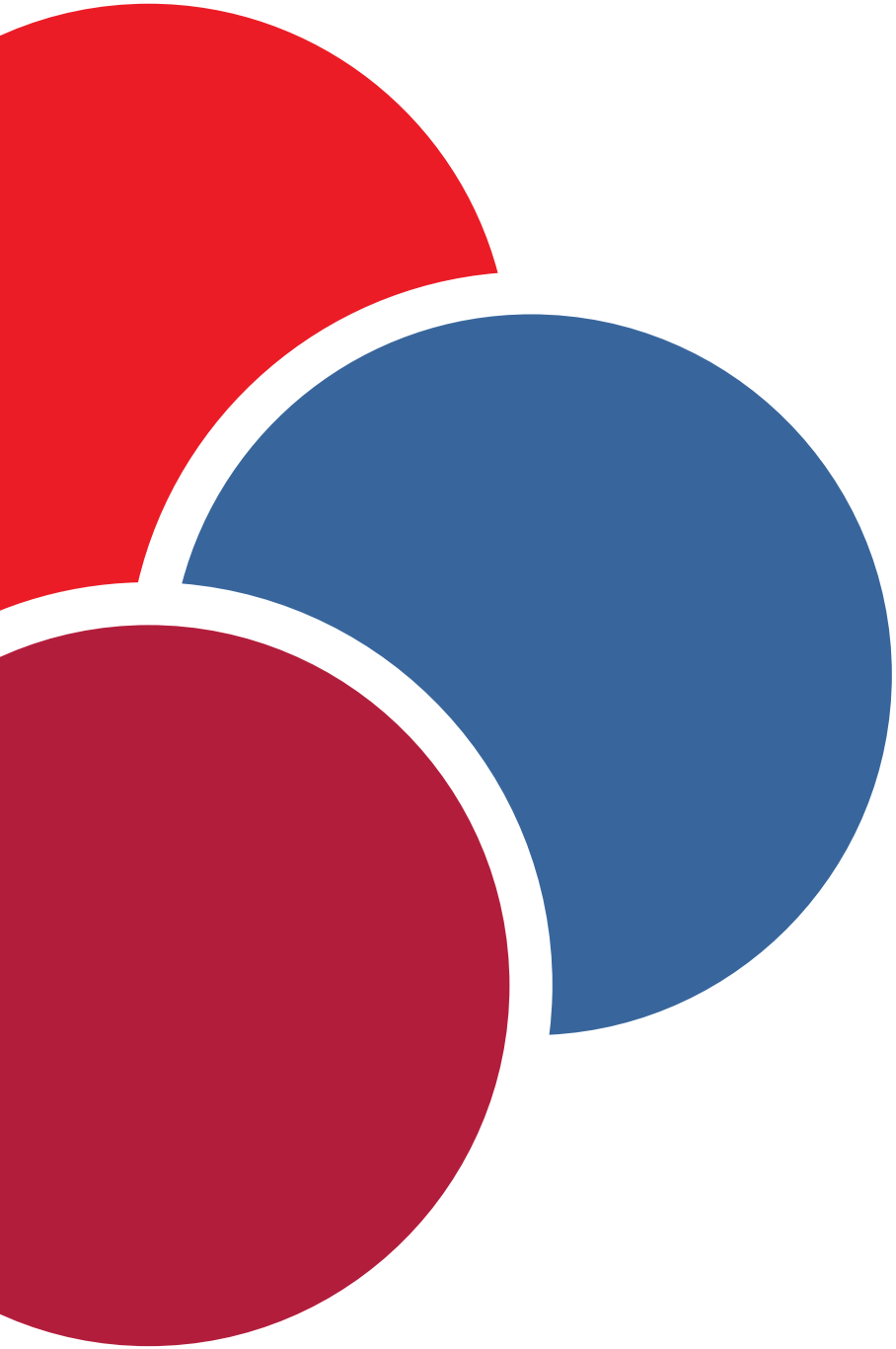
LI Survey Conclusions

- Complete NG47 guideline implementation in this study has not been achieved by any SIHMDS
- Variable implementation of guidelines across individual SIHMDS
- Equitable delivery of high-quality diagnostics has not been assured, may be at least inconsistent and possibly not adequately provided in some regions
- Implementation across single-entity or 'collocated' SIHMDS is more achievable than 'networked' SIHMDS
- **Concurrent major service delivery model changes such as NG47 and the redesignation of genomic services have inevitably led to conflicting priorities and ultimately compromised complete implementation of either**
- **NEQAS are proposing the establishment of an EQA programme that can evaluate the integrative testing and analysis of samples by SIHMDS services across the range of pathology disciplines rather than a programme that tests every discipline separately**



Current SIHMDS Challenges

National Genomic Strategy

- April 2003 – the human genome was published
- Late 2012 – David Cameron announced the 100,000 Genomes Project
  - Genomics England was set up to deliver this flagship project
  - Sequence 100,000 whole genomes from NHS patients
- October 2018 – NHS (England) Genomic Medicine Service (GMS) launched
  - Ensure equitable access to genomic testing across the country
  - Embed advanced genomic technologies in mainstream care

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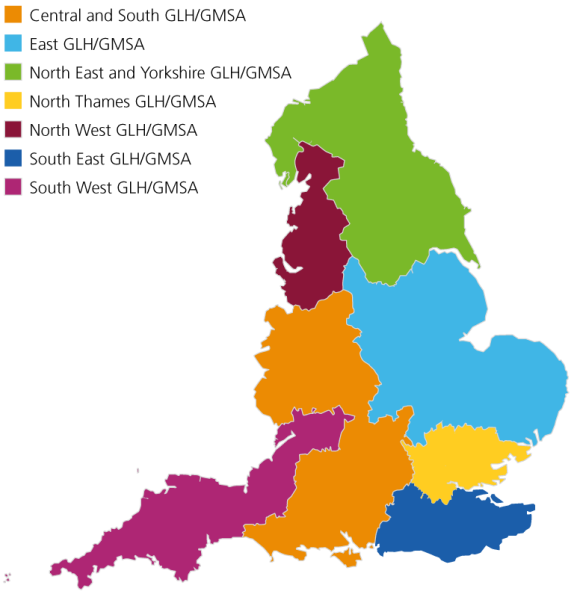
National (England) GMS *vs* NG47 Compatibility

- NHSE: Embed advanced genomic technologies in mainstream care
- Consolidation of genomic testing: 7 GLH regions, rare disease and cancer hubs
- GLHs focus on just the genomic testing elements of SIHMDS labs, not asked to consider the other modalities
- In many regions GLHs have led to a tension with the fundamental tenets of NICE guidance and integrated diagnostics
- First recommendation of the NICE guidance: 1.1.1: All SIHMDS testing modalities are best collocated on a single site
- SIHMDS laboratories pioneered introducing NGS techniques into standard care, but not all SIHMDS have been able to lever the investment in staff and equipment needed for NGS



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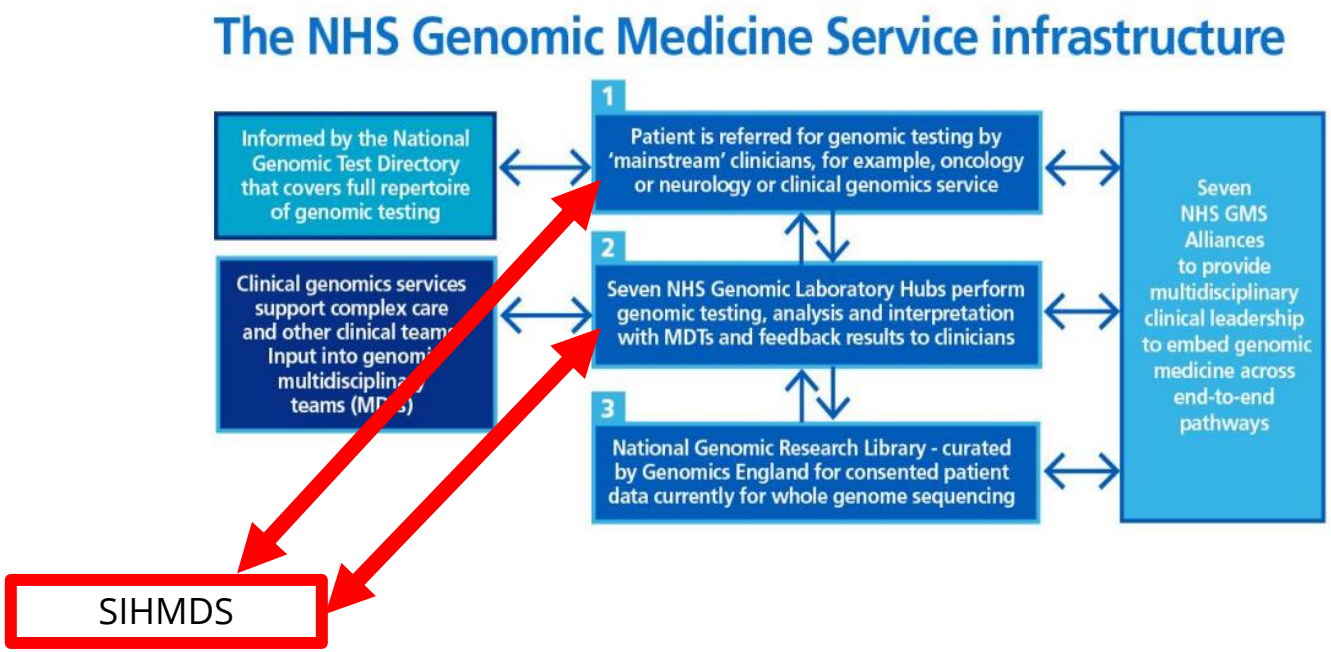
GMS Structure



Structure does not align to NG47 guidance that all SIHMDS testing modalities should be collocated on a single site

For the majority of SIHMDS practices, this requires establishment of a **networked model**

Role in haematopathology diagnostics in devolved nations?

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ICC/WHO: Collaboration with BLPG and BSH

- Publication of 2 new haematological malignancy classifications:
  - World Health Organisation 5th edition
  - International Consensus Classification
- Some differences in diagnostic entities/criteria
- BSH/BLPG asked to provide guidance, working with RCPath
- What about SNOMED coding?

- To be addressed at BSH ASM by Dr Catherine Cargo

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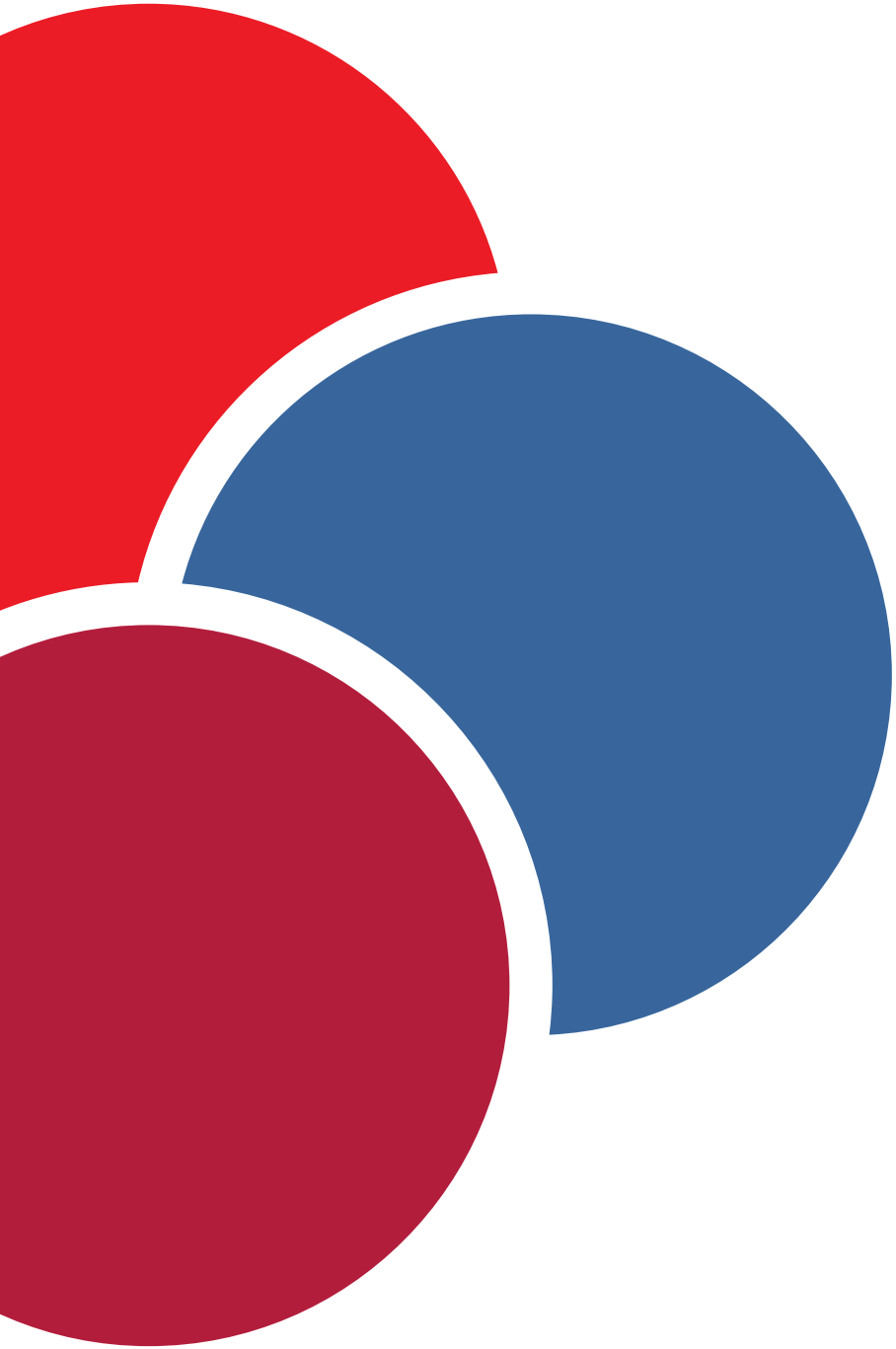

What is happening?

SIHMDS Survey

SIHMDS Survey: BSH and BLPG

- SIHMDS survey sent out by BSH and BLPG
- BSH member bulletins July and August 2022 and via BPLG email
- Collate findings from surveys and workshops
  - Outline future shape of SIHMDS network and identify areas for development/improvement
  - Confirm the number of SIHMDS services in the UK
  - Outline issues affecting SIHMDS labs

Acknowledgement: Thanks to Maxwell McCreton (BSH) for helping design and distribute the survey

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Survey Aims and Purpose

- Identify all labs providing an HMDS service in the UK
- Understand extent of the challenges to service delivery
- Determine what issues are shared nationally vs locally
- Identify areas for improvement
  - Facilitate improved discussions between GLH and SIHMDS services
- Identify user and contributor baseline opinions

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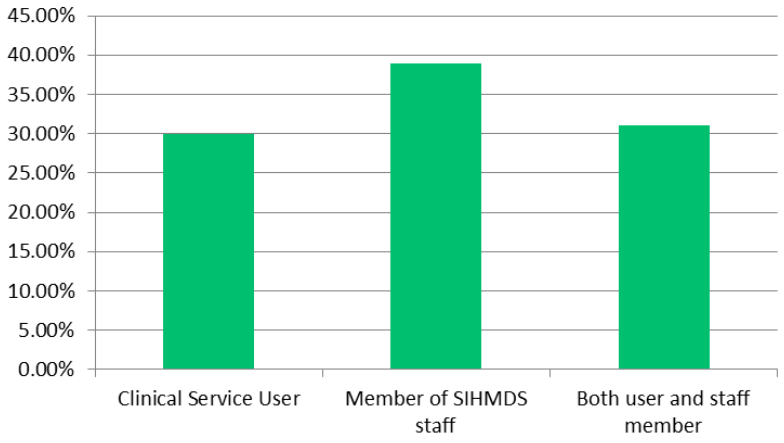
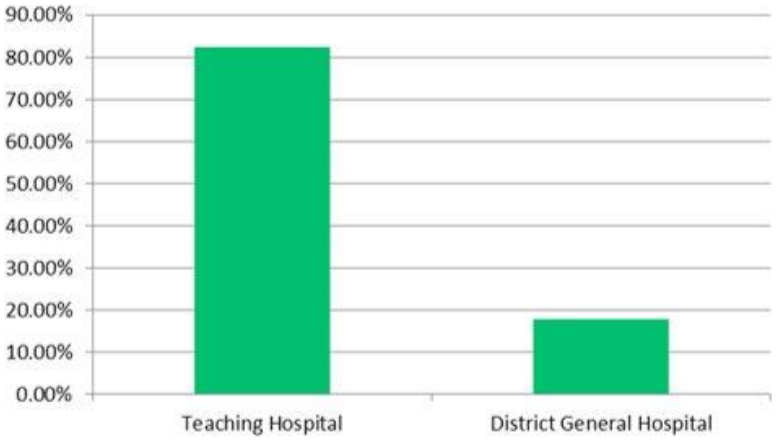
Survey Responses





- 90 responses received (78.9% doctors), mainly from teaching hospital sites (82.2%)
- 70% are members of SIHMDS staff (31.1% both user and staff member)
- 82.2% working in teaching hospitals
- From all regions of UK

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SIHMDS Landscape – Previous Data

- NEQAS: "... individuals working closely with NHS England suggesting there are **17 in England**"
- *Concerns on the impact of the genetics laboratories reconfiguration tender on functioning of SIHMDS and associated clinical pathways:* Letter sent to NHSE Dec 2017: **16 SIHMDS** signatories
- Haematopathologists in NICE guideline committee: **4**

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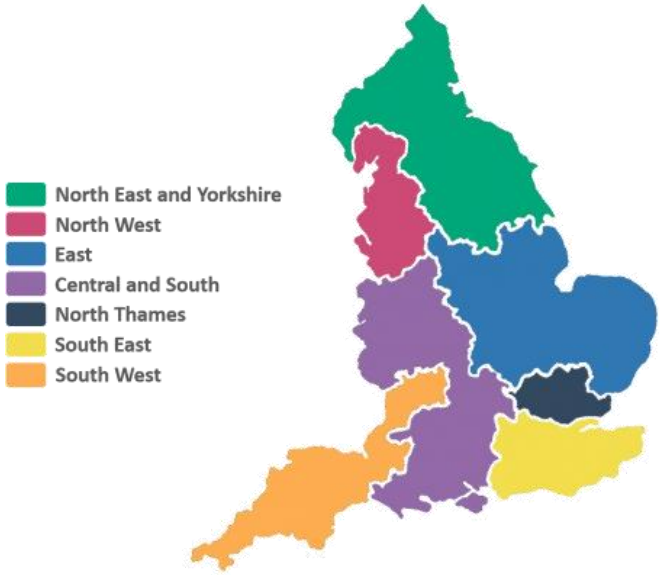
SIHMDS Landscape – Survey Data

GLH						Total
Central & South	Birmingham	Oxford	Southampton	Dorset		4
East	Cambridge	Leicester	Nottingham			3
North West	Liverpool	Manchester				2
North Thames	Barts Health	Great Ormond Street (Paediatric)	Imperial	Royal Marsden	University College London	5
South East	Guys & St Thomas'	Kings College Hospital				2
South West	Bristol	Plymouth				2
North East & Yorkshire	Leeds	Newcastle	Sheffield			3
Region						
Scotland	Edinburgh	Glasgow				2
Wales	Cardiff	Swansea				2
Northern Ireland	Belfast					1

SIHMDS by GLH/region:

- 21 SIHMDS in England
- 5 in Devolved Nations



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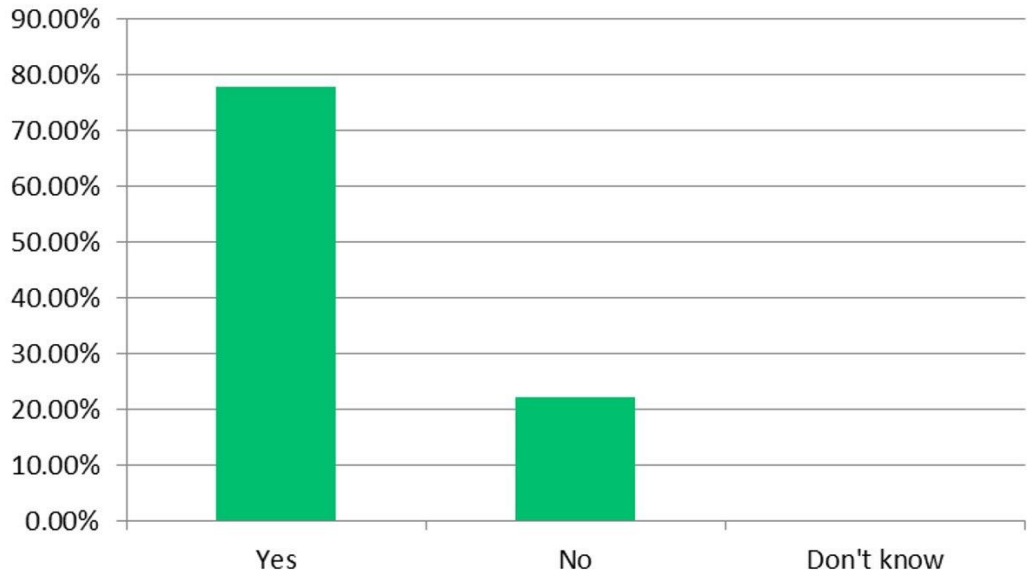
SIHMDS Integrated Reporting

Do you get an integrated report from your SIHMDS?



Yes	77.8%	70
No	22.2%	20
Don't know	0.0%	0

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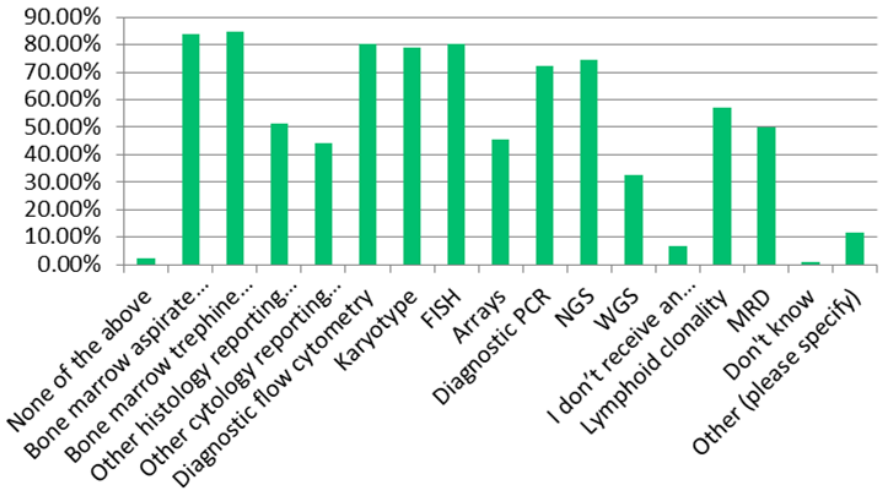
SIHMDS Integrated Reporting

What is included in your integrated report?

Modality	
Bone marrow aspirate reporting	83.7%
Bone marrow trephine reporting	84.8%
Other relevant histology reporting, including lymph nodes/ immunohistochemistry	51.1%
Other relevant cytology reporting, including CSF/fluid samples	44.2%
Diagnostic flow cytometry	80.3%
Karyotype	79.1%
FISH	80.2%
Arrays	45.4%
Diagnostic PCR	72.1%
NGS	74.4%
WGS	32.6%
Lymphoid clonality	57.0%
MRD	50.0%
None of the above	2.3%
Don't know	1.2%
I don't receive an integrated report	7.0%
Other (please specify)	11.6%



Other:

- "Occasional rarer specialist sendaway"
- "We report histology, with knowledge of flow cytometry. BM aspirate findings are not always available. Cytogenetics and molecular testing takes 4-12 weeks; so not really integrated report for the MDT"

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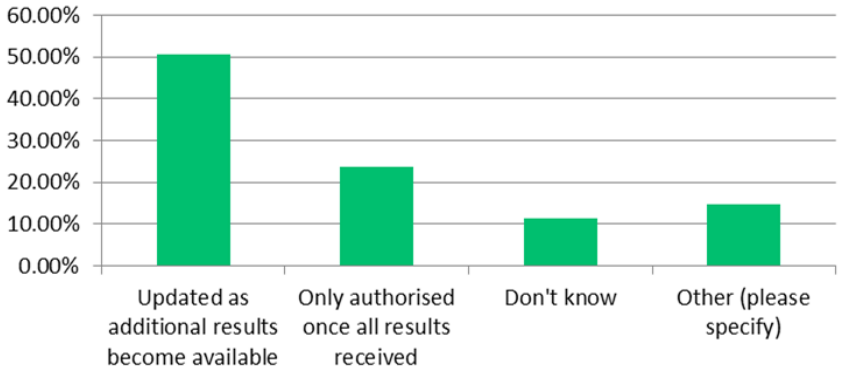
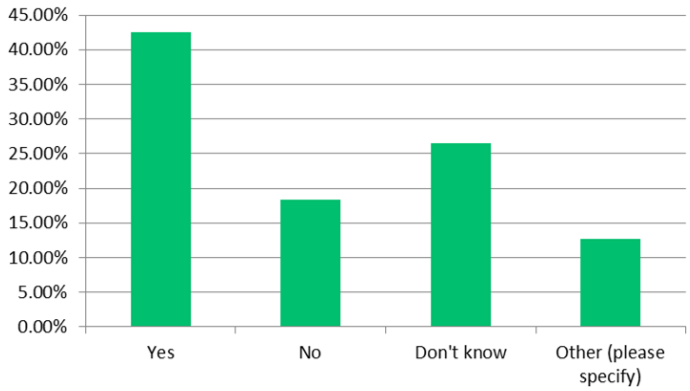
SIHMDS Report Updates

Are integrated reports updated as further results are received?



Are clinical staff alerted to updated reports?



"Urgent diagnosis as results become available"
"Cytogenetic and some molecular results are emailed to requestor (in addition to being added to integrated report)
"Not routinely but they are if the updated report changes diagnosis"

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Genomics

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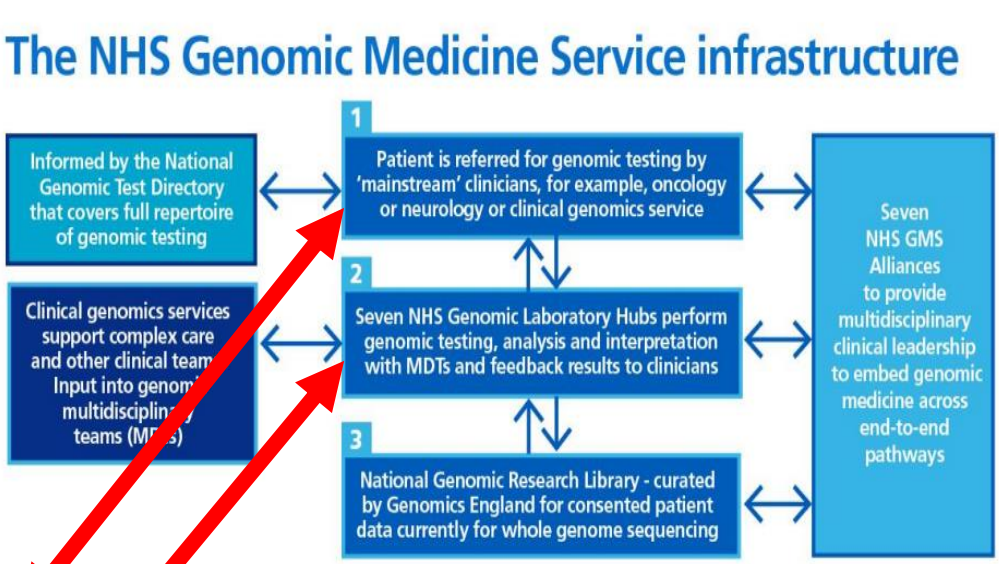
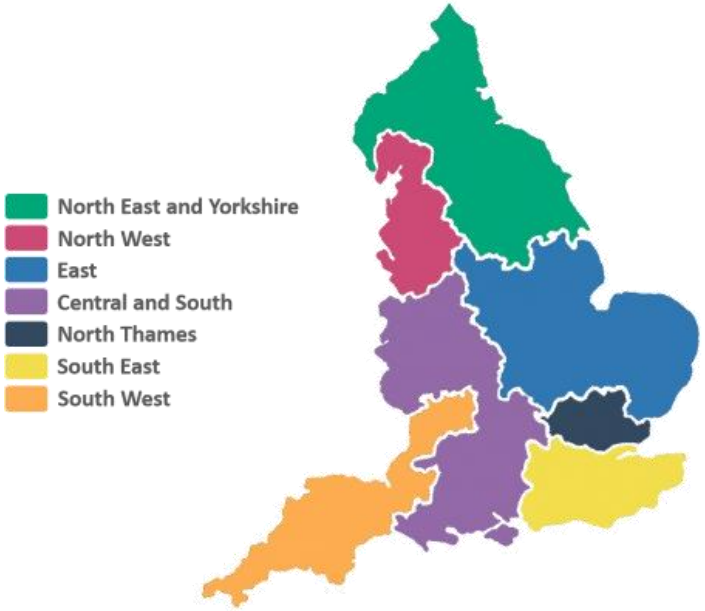
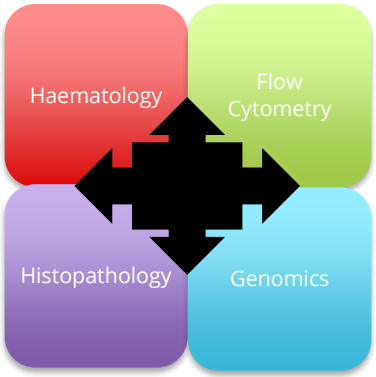
GMS – NG47 Alignment







First recommendation of the NICE guidance: 1.1.1: All SIHMDS testing modalities are best collocated on a single site

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Hub Model Drives Networked Working

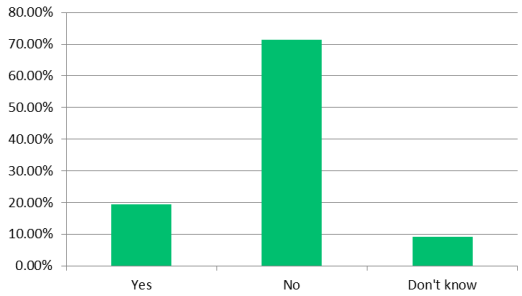
- Prior to the GLH model, SIHMDS services were split as to whether they had developed genomic testing in house or sent this to external labs (networked model)

- GLH model has encouraged consolidation of genomic testing into hubs
    - This has enabled some networked SIHMDS laboratories to access a wider range of tests.
    - It has also halted the development of these labs, particularly the introduction of local NGS capacity

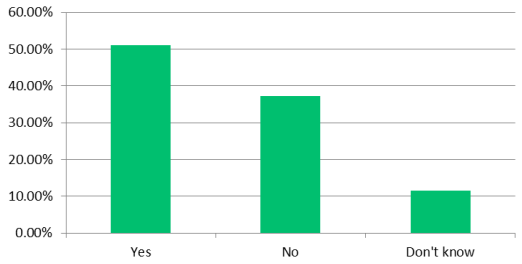
- For SIHMDS with established genomic testing, the clinical benefits of sending samples to a genomic hub are less clear: It is inherently inefficient, reduces integration and is antithetical to the gold standard described in NICE guidance

SIHMDS Location in Relation to Genomic Services

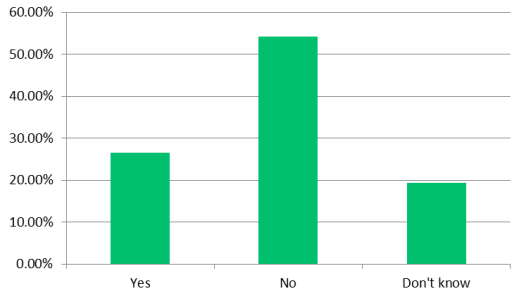
Is your SIHMDS service located at the same site as a GLH?



Is your SIHMDS service located at the same site as an LGL?



Is your SIHMDS service on a separate site to both GLH and LGL?



- 19.5% co-located with GLH
- 51.2 co-located with LGL
- 26.5% separate to both

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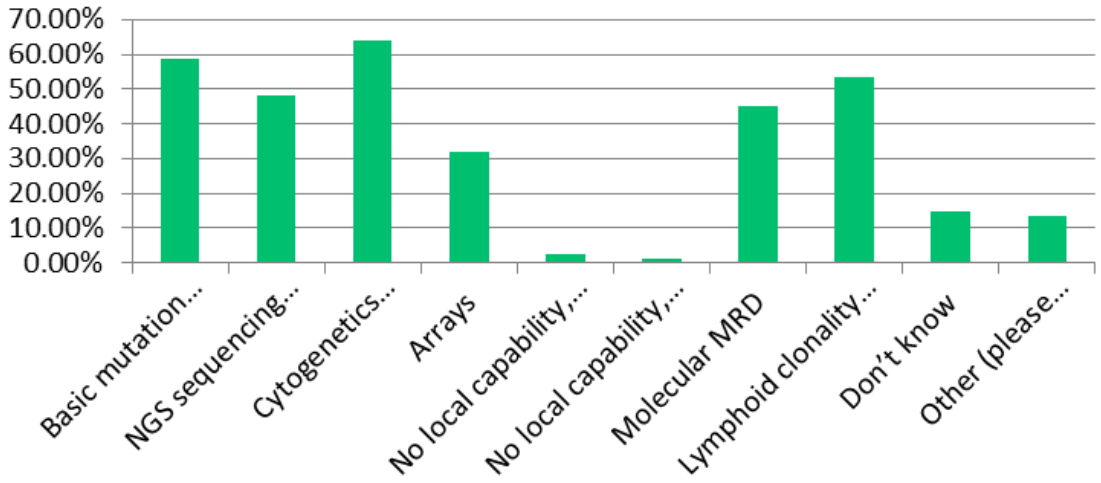
Does your SIHMDS have local molecular testing capabilities?



Basic mutation analysis	58.7%
NGS sequencing capacity	48.0%
Cytogenetics (karyotype/FISH)	64.0%
Arrays	32.0%
No local capability, all testing sent to GLH	2.7%
No local capability, testing sent to combination of GLH and other external centres	1.3%
Molecular MRD	45.3%
Lymphoid clonality assessment	53.3%
Don't know	14.7%
Other (please specify)	13.3%

Other:

- BCR::ABL1 RQ-PCR
- IGHV
- MYD88
- "NGS machines on site being validated"

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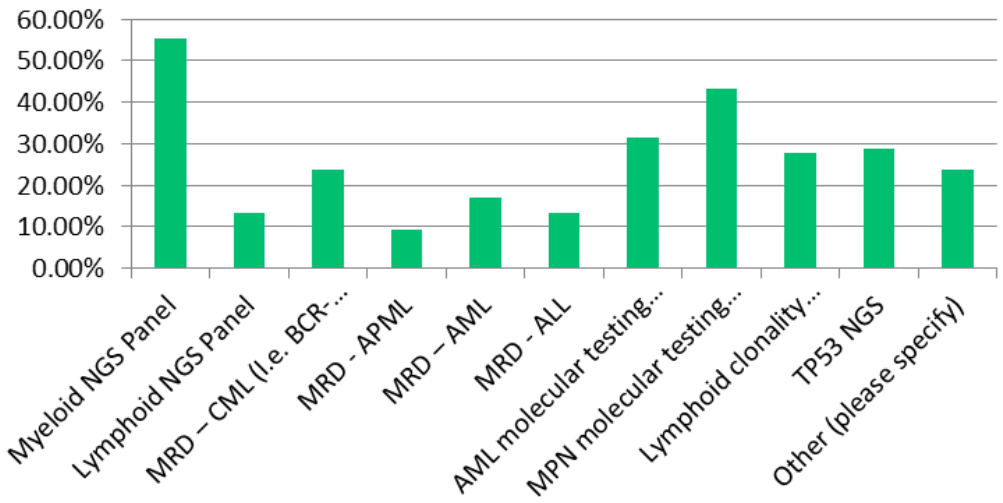
Which of the following do you most commonly request from your GLH?



Myeloid NGS Panel	55.3%	42
Lymphoid NGS Panel	13.2%	10
MRD – CML (I.e. BCR-ABL)	23.7%	18
MRD - APML	9.2%	7
MRD – AML	17.1%	13
MRD - ALL	13.2%	10
AML molecular testing (FLT3/NPM1)	31.6%	24
MPN molecular testing (JAK2/CAL-R/MPL)	43.4%	33
Lymphoid clonality assessment	27.6%	21
TP53 NGS	29.0%	22
Other (please specify)	23.7%	18

Other:

- FISH
- SNP Array
- Karyotyping
- MYD88
- Expert opinion
- Don't use GLH
  - "None, don't use GLH as all available in house"
  - "none, all performed at LGL SIHMDS (and APL/AML MRD sent to another GLH)"
- MRD
  - "Our GLH does not offer the full range of AML MRD so that is all sent to Guys. Clinical teams send directly and bypass the SIHMDS to reduce delays and maintain sample integrity"

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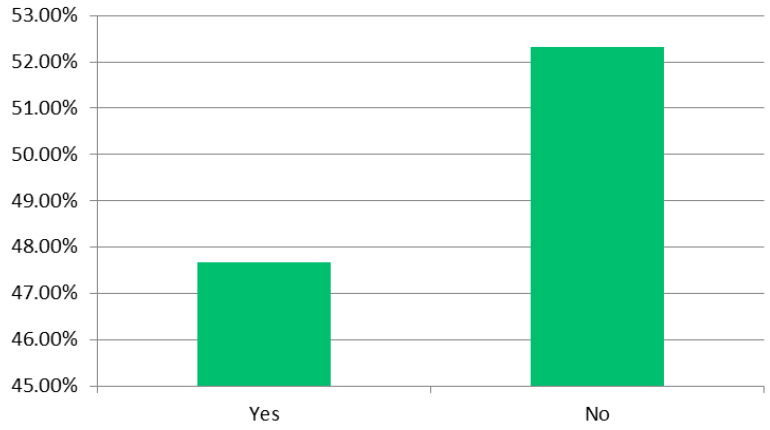
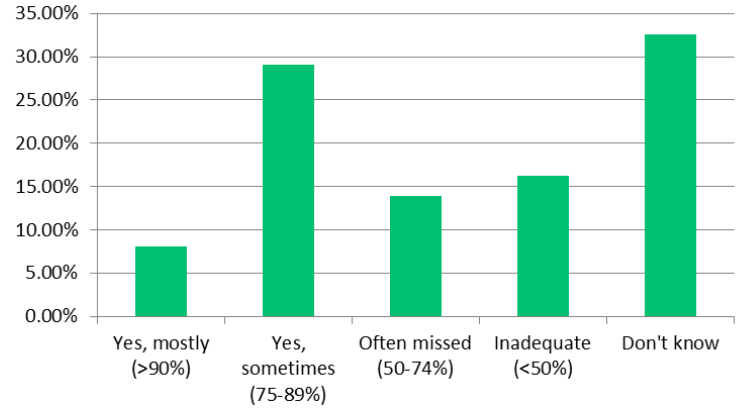
Genomic Turnaround Times

Are you aware of published GLH turnaround times?



Do you feel GLH turnaround times are met?



If you feel TATs are not met, which tests are most affected?

1. NGS Panels - 36%
2. Clonality – 27%
3. Cytogenetics/FISH - 21%
4. Single Gene (JAK2/MPL/CAL-R) – 21%
5. MRD (AML/ALL/BCR::ABL1) 15%

"The permissive turnaround times for some diagnostic categories are not clinically meaningful, even though the genomics hub perform them within the defined limit..."

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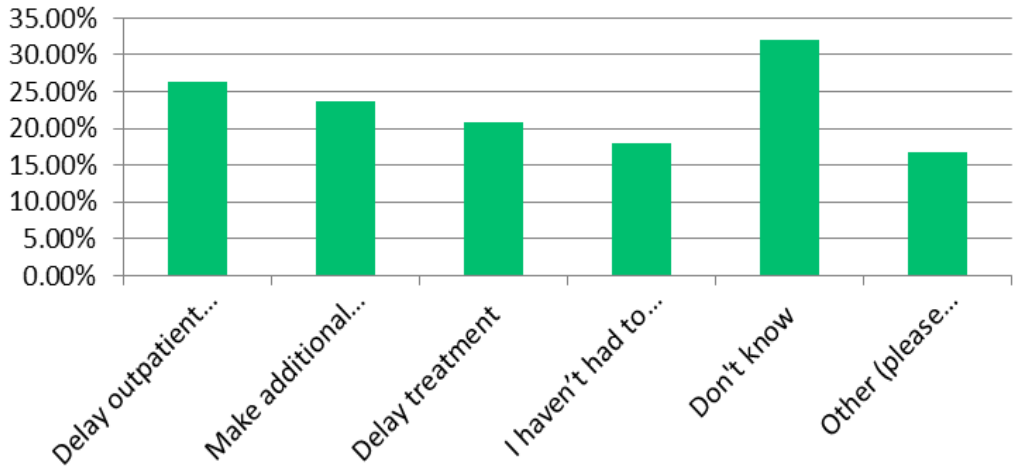
If TATs not sufficiently met, have you had to change practice?



Delay outpatient appointments	26.4%	19
Make additional outpatient appointments	23.6%	17
Delay treatment	20.8%	15
I haven't had to change practice	18.1%	13
Don't know	31.9%	23
Other (please specify)	16.7%	12

Other:

- Relist/delay MDT discussions
- Contribute to misdiagnosis
- Additional treatment
- "Usually have to send Lymphoid NGS (for TP53) earlier than otherwise clinically necessary if CLL treatment is anticipated in medium-term, to avoid delays."
- "do not send to GLH to prevent delays to patient care"

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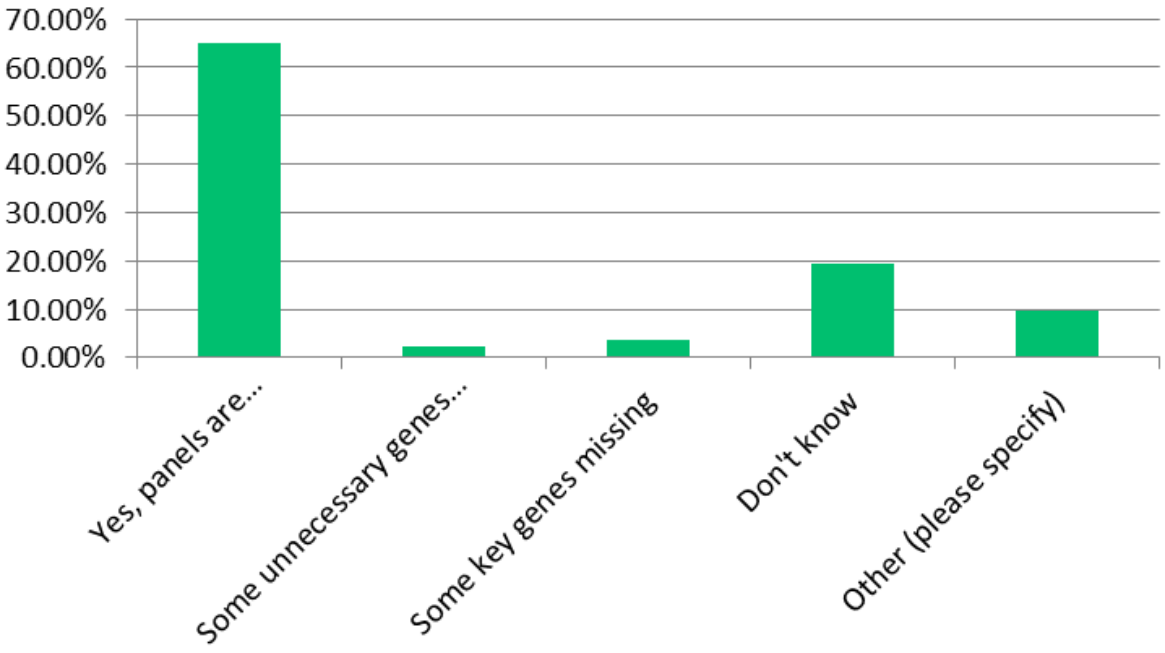
Are you happy with the contents of the NGS panels?



Yes, panels are comprehensive	65.1%	54
Some unnecessary genes included	2.4%	2
Some key genes missing	3.6%	3
Don't know	19.3%	16
Other (please specify)	9.6%	8

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Genomics Key Themes

- NG47 compliance is rarely met and there is no common networked model
- Some genomic testing is occurring outside GLHs
    - 58.7% have mutation sequencing capacity, 48% NGS sequencing, 45.3% molecular MRD
- The most requested GLH assays are myeloid NGS panels, MPN molecular testing and AML molecular (NPM1/FLT3)
- Only 37% think that turnaround times are met, particularly affecting NGS panels, clonality testing and FISH/karyotyping
- Delays in results availability is affecting clinical practice, including additional OPD patients delays in treatment, delayed MDT discussion

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Whole Genome Sequencing (WGS)

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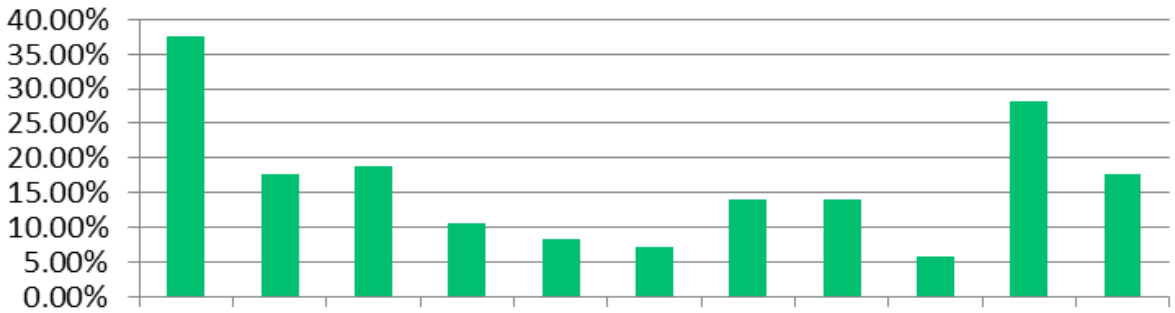
WGS

Extensive genomic profiling alongside standard of care diagnostics to potentially access novel therapies, clinical trials and contribute to research.[12]

12. Grantham M, Bartram J. Genomic testing for haematological malignancies: the next generation. *RCPath Bulletin* 2021;194:324–327.

What are your thoughts on WGS?



I'm comfortable requesting WGS	37.7%	32
I'm comfortable interpreting	17.7%	15
I'm comfortable clinically using results	18.8%	16
I'm unsure of when to request WGS	10.6%	9
I'm unsure of how to consent patients	8.2%	7
I'm unsure of how to request it	7.1%	6
I'm unsure of how to interpret the results	14.1%	12
I'm unsure how to clinically act on results	14.1%	12
I don't have time to organise WGS	5.9%	5
Not relevant to job role	28.2%	24
Other (please specify)	17.7%	15

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What are your thoughts on WGS?

- Limited clinical utility
  - –"In most cases, WGS results don't add much to standard-of-care testing and often arrive when patient is already well down their treatment pathway."
  - –"I think they deliver a huge amount of data with very little clinical guidance and utility. Very little actionable clinical information seems to be generated. It can be difficult to know if some germline findings need fu."
- Impacts on other investigations
  - –"… never do we find anything actionable that we had not found in the standard of testing. Shift has been put so much on the WGS that standard of testing TATs dangerously inappropriate"
- Not available/required
  - –"I understand the principals but for my clinical cohort it's not available so haven't done it directly."
  - –"WGS not currently offered in Scotland"

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Do you think there are barriers to WGS?

- Consenting
  - "Consenting process is difficult with patients dealing with a difficult diagnosis. Language barriers impact on consent. Difficult concept for patients to understand. Impact on family members causes concern for some patients…."
- Clinical Utility
  - "… the perception of lack of utility, in part driven by the long turn-around times and results which lack clinical actionability"
  - "Greater training of clinicians on how to interpret and act on the results"
- Time/resource availability
  - "No additional resource available to implement WGS. No additional scientific staff available to analysis and report."
  - "Clinician time and resources (needs coordination between IP and OP setting often)"
- Germline Sampling
  - "Germline (skin) samples to pair with leukaemia sample are often delayed in taking – not seen as priority. Record of discussion forms get lost or are incomplete, are not seen as priority"
  - "The germline sampling and ROD are probably reducing clinicians desire to send samples"

Do you think there are barriers to WGS?

"Feels like we are trying to run before we can walk with WGS given the developments required in myeloid/ lymphoid panels and other targeted tests, and most info it generates is not currently actionable, though I do think the direction of travel is interrogating more genes for diagnostic, prognostic and predictive info in the somatic setting as well as germline and pharmacogenetic info"

WGS Key Themes

- Experience and perceptions of WGS highly variable
  - 37% comfortable requesting
  - Many feel lacks clinical utility, has a detrimental impact on other investigations, or is not available/required
- Various, significant barriers to WGS that need to be rectified to facilitate widespread adoption
- Variable clinical genetics referral pathways for constitutional abnormalities
- SIHMDS has an important role in helping patients access WGS and the return of results, via genomic MDTs
- Much work needed to overcome scepticism to focus on patient recruitment, consent, results interpretation and turnaround times.
- WGS will no doubt find its place and bring benefits for many patients, but the results will need to be integrated with other SIHMDS modalities as the other genomics techniques have done.

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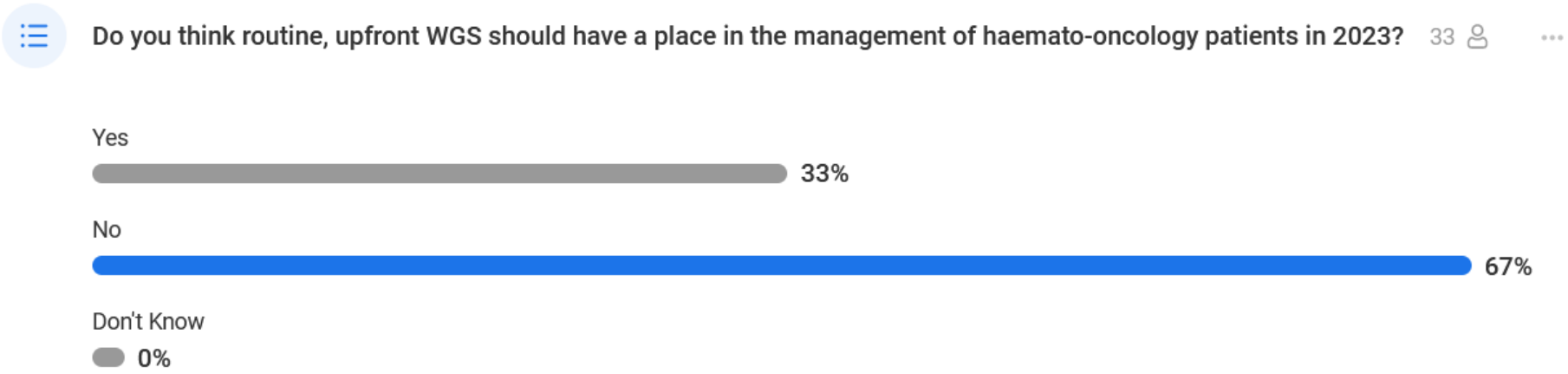
Question 4

- Do you think routine, upfront WGS should have a place in the management of haemato-oncology patients in 2023?



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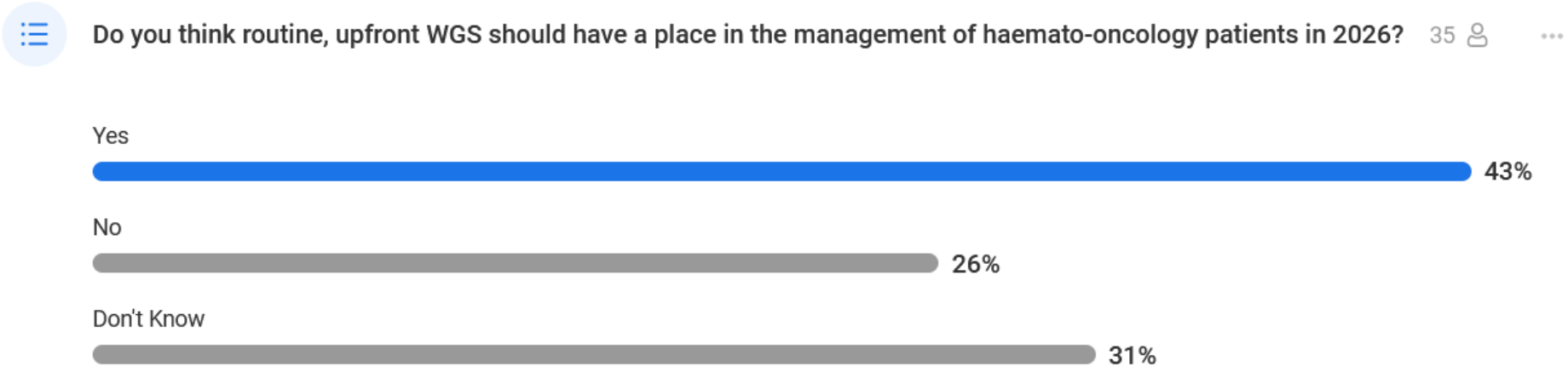
Question 5

- Do you think routine, upfront WGS should have a place in the management of haemato-oncology patients in 2026?



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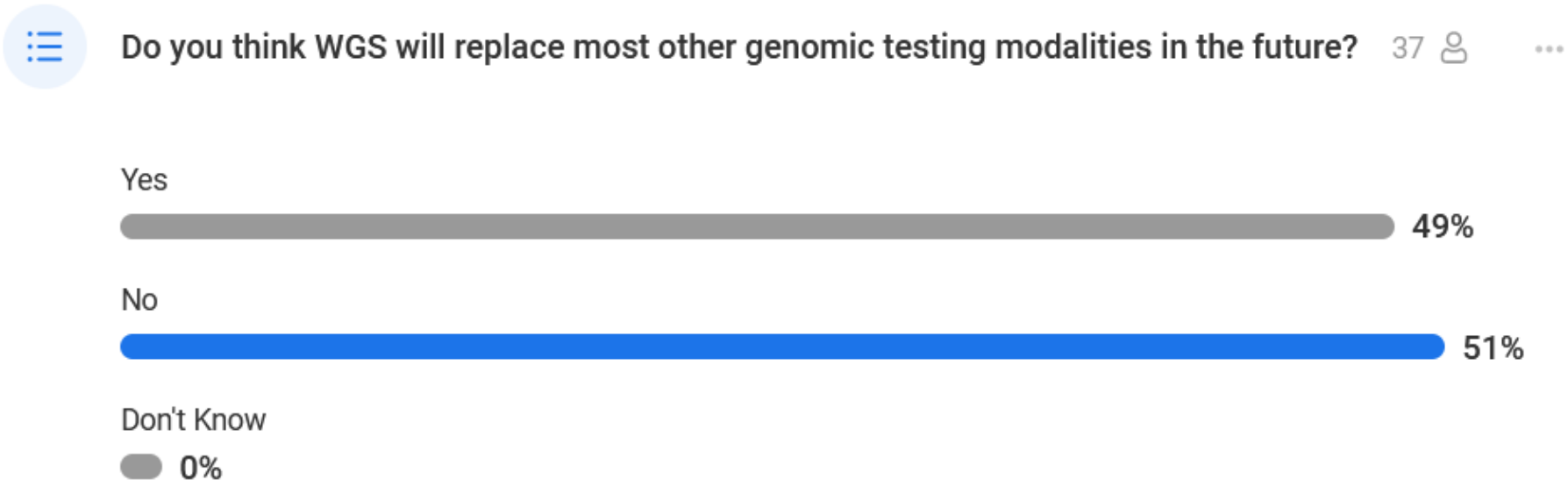
Question 6

- Do you think WGS will replace most other genomic testing modalities in the future?



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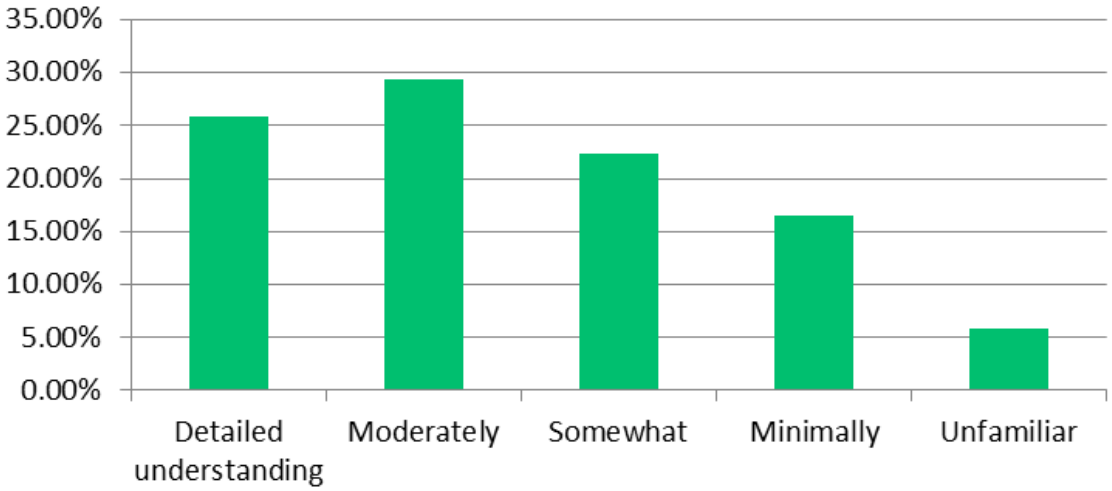
Genomic Reconfiguration

How familiar are you with the GLH reconfiguration?



Detailed understanding	25.9%	22
Moderately	29.4%	25
Somewhat	22.4%	19
Minimally	16.5%	14
Unfamiliar	5.9%	5

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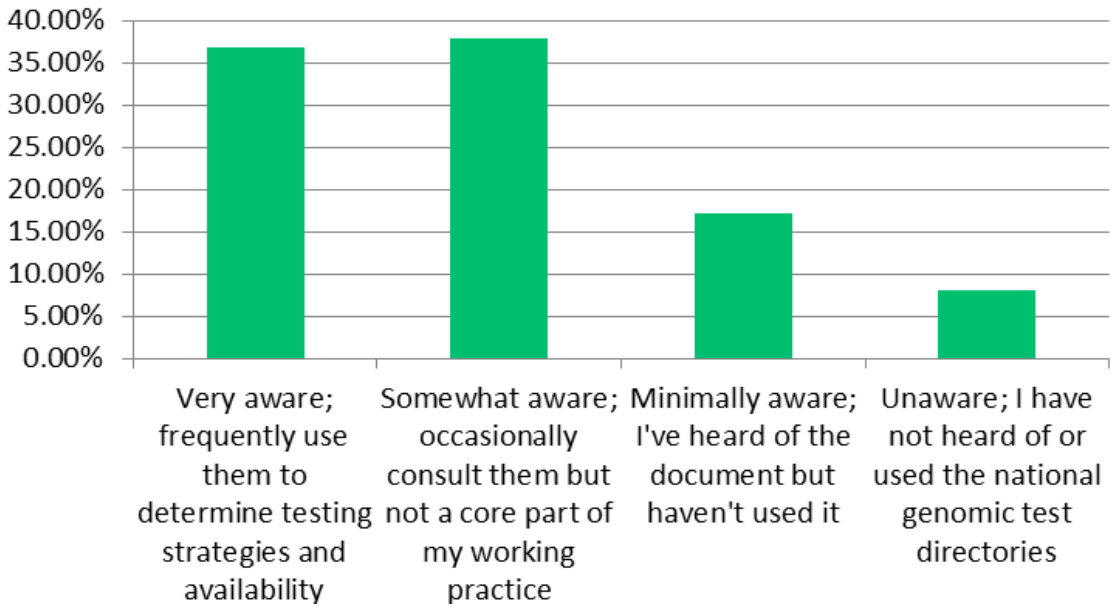
Are you aware of the national genomic test directories?



Very aware; frequently use them to determine testing strategies and availability	36.8%	32
Somewhat aware; occasionally consult them but not a core part of my working practice	37.9%	33
Minimally aware; I've heard of the document but haven't used it	17.2%	15
Unaware; I have not heard of or used the national genomic test directories	8.1%	7

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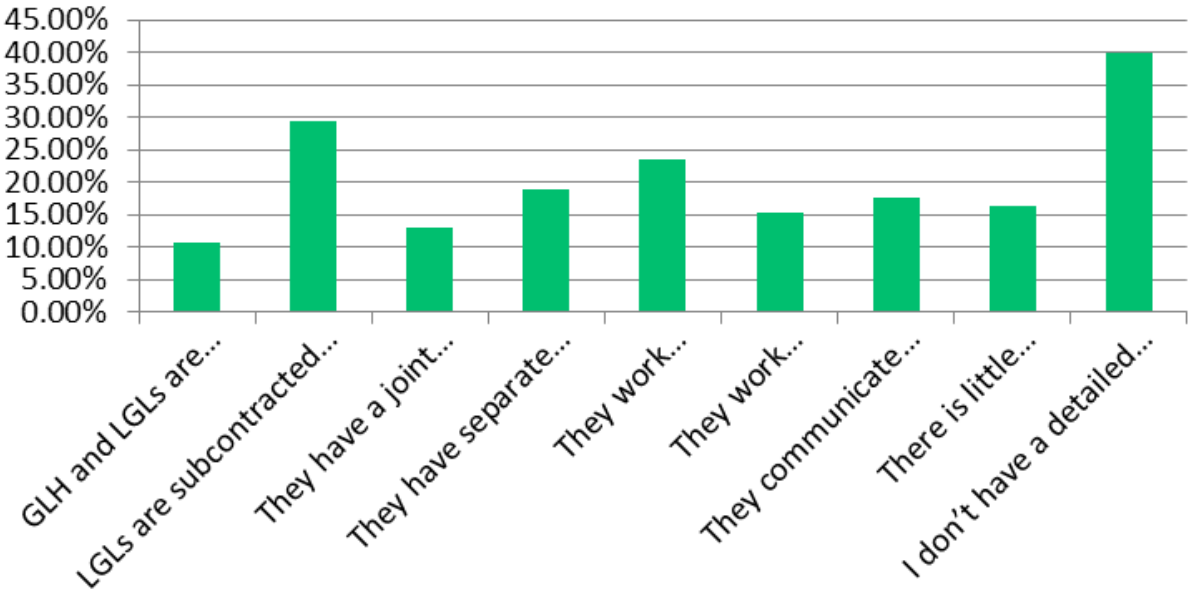
What do you understand to be the relationship between GLH and LGL?



GLH and LGLs are equal providers	10.6%	9
LGLs are subcontracted to GLH	29.4%	25
They have a joint governance structure	12.9%	11
They have separate governance	18.8%	16
They work collaboratively	23.5%	20
They work independently	15.3%	13
They communicate closely with each other	17.7%	15
There is little communication	16.5%	14
I don't have a detailed understanding of their relationship	40.0%	34

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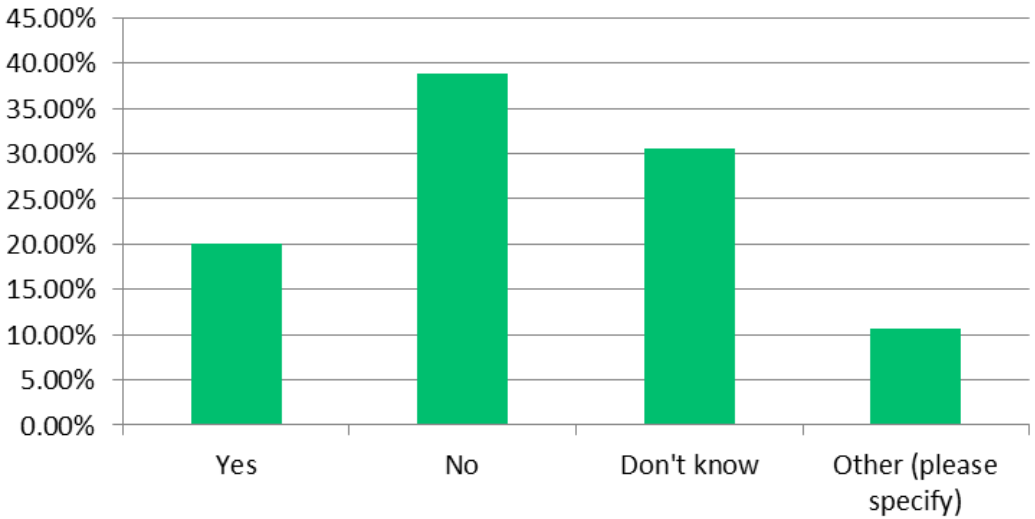
Do you feel access to genomic testing has been improved by the Genomic Reconfiguration?



Yes	20.0%	17
No	38.8%	33
Don't know	30.6%	26
Other (please specify)	10.6%	9

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Do you think NG47 is compatible with SIHMDS labs sending genetic testing to GLHs?

No: all SIHMDS should have the capacity to provide all genomic tests within the SIHMDS	16.47%	14
Partially: some rare haemato-oncology genomic tests can be performed outside the SIHMDS, but the majority should be provided within an SIHMDS	54.12%	46
Mostly: most genomic tests do not need to be performed within an SIHMDS	4.71%	4
Entirely: an SIHMDS does not need to provide any haemato-oncology genomic tests, if they are provided elsewhere in a cancer hub	5.88%	5
Don't know	11.76%	10
Other (please specify)	7.06%	6

- When asked about NG47 compatibility with the GLH hub model, only 5.9% said that all genomics could be provided in a cancer hub.
- 70.6% (87% if don't know/other excluded) said that SIHMDS should have the capacity to perform all/majority of genomic testing within an SIHMDS.
- 78.9% said that myeloid NGS panel testing should be provided within an SIHMDS

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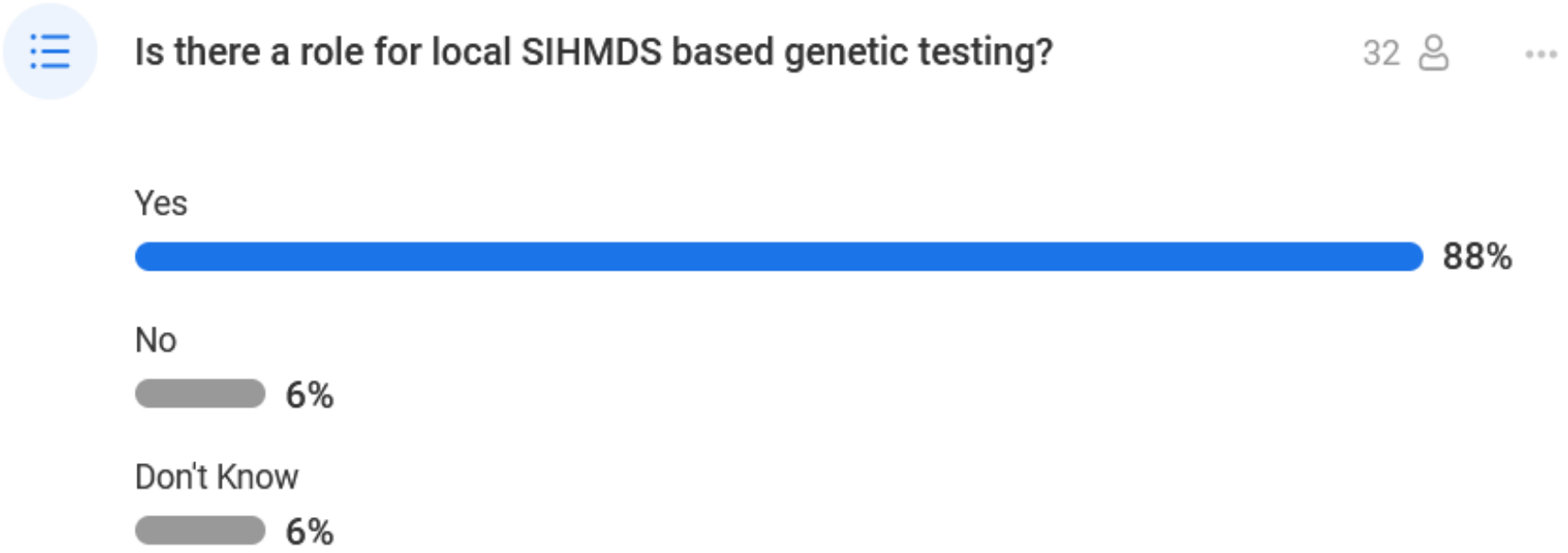
Question 7

- Is there a role for local SIHMDS based genetic testing?



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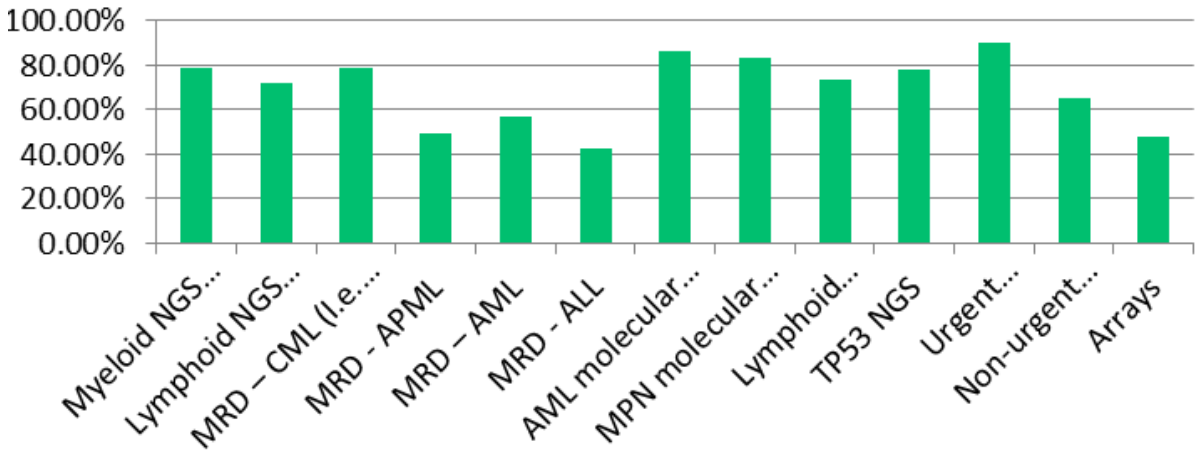
What tests would you like to see provided by local SIHMD services?



Myeloid NGS Panel	78.9%	56
Lymphoid NGS Panel	71.8%	51
MRD – CML (I.e. BCR-ABL)	78.9%	56
MRD - APML	49.3%	35
MRD – AML	56.3%	40
MRD - ALL	42.3%	30
AML molecular testing (FLT3/NPM1)	85.9%	61
MPN molecular testing (JAK2/CAL-R/MPL)	83.1%	59
Lymphoid clonality assessment	73.2%	52
TP53 NGS	77.5%	55
Urgent cytogenetics (urgent FISH/karyotype)	90.1%	64
Non-urgent cytogenetics	64.8%	46
Arrays	47.9%	34

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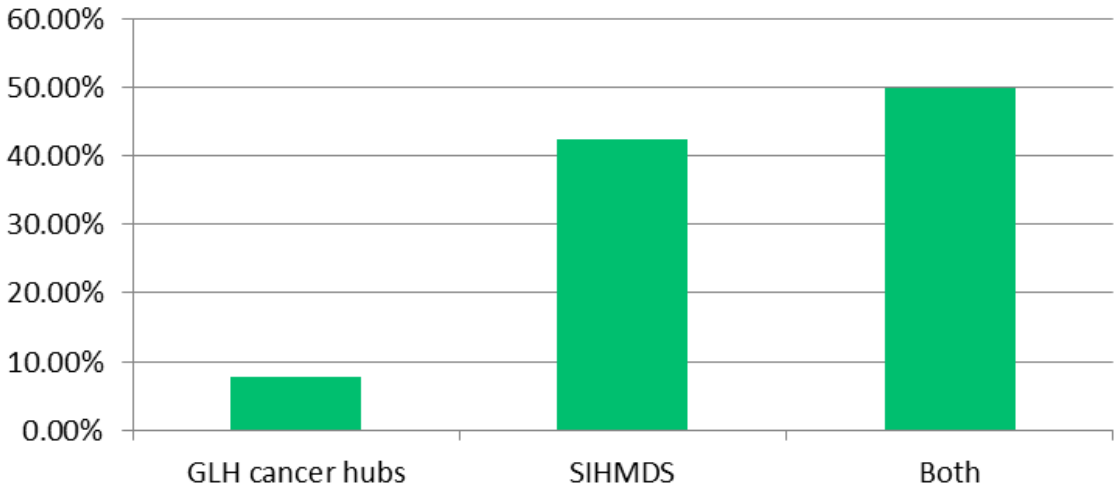
Should more resources be dedicated to improving genomic capacity in GLHs, SIHMDs, or both?



GLH cancer hubs	7.7%	6
SIHMDS	42.3%	33
Both	50.0%	39

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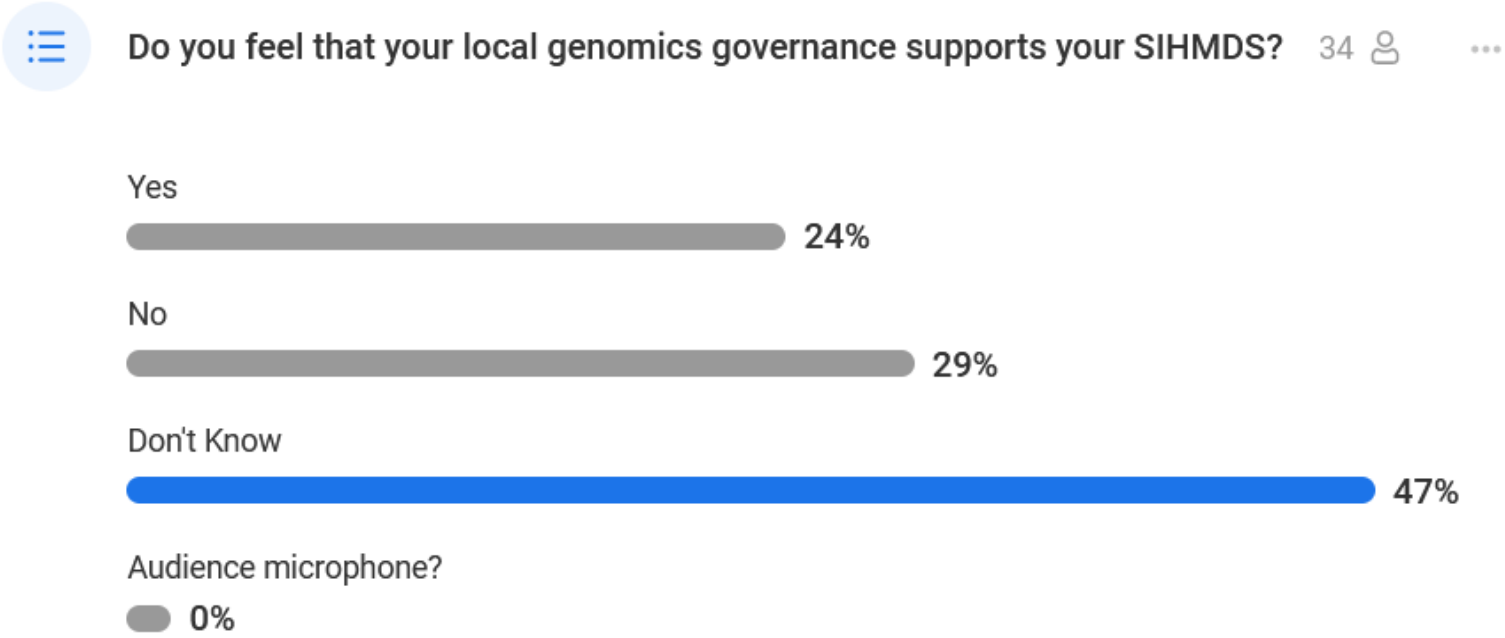
Genomic Reconfiguration Key Themes

- The majority of responders have a reasonable understanding of GLH reconfiguration and awareness of test directories
- There is poor understanding of GLH and LGL relationship – with a lot of contradicting (and sometimes slightly hostile) answers
- 38.8% feel that access to genomic testing has got worse under GLH reconfiguration plan. Only 20% think this has improved
- 50% would like to see resources being dedicated to improving genomic testing in both SIHMDS/LGLs and GLH hubs; 42% would like to see resources going to SIHMDS/LGLs only and 7.7% support more resources being dedicated to GLH hubs
- Many think genomic reconfiguration has had a detrimental impact on SIHMDS development, and would support a return to local testing as sequencing becomes more common place, cheaper and easier

Question 8

- Do you feel that your local genomics governance supports your SIHMDS?



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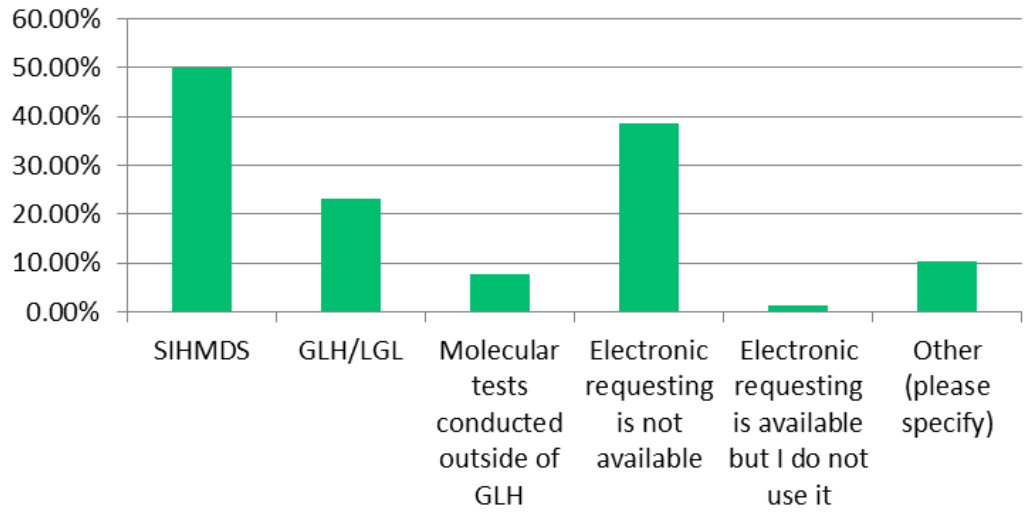
IT

Do you use electronic requesting for SIHMDS/GLH/LGL tests?



SIHMDS	50.0%	39
GLH/LGL	23.1%	18
Molecular tests conducted outside of GLH	7.7%	6
Electronic requesting is not available	38.5%	30
Electronic requesting is available but I do not use it	1.3%	1
Other (please specify)	10.3%	8

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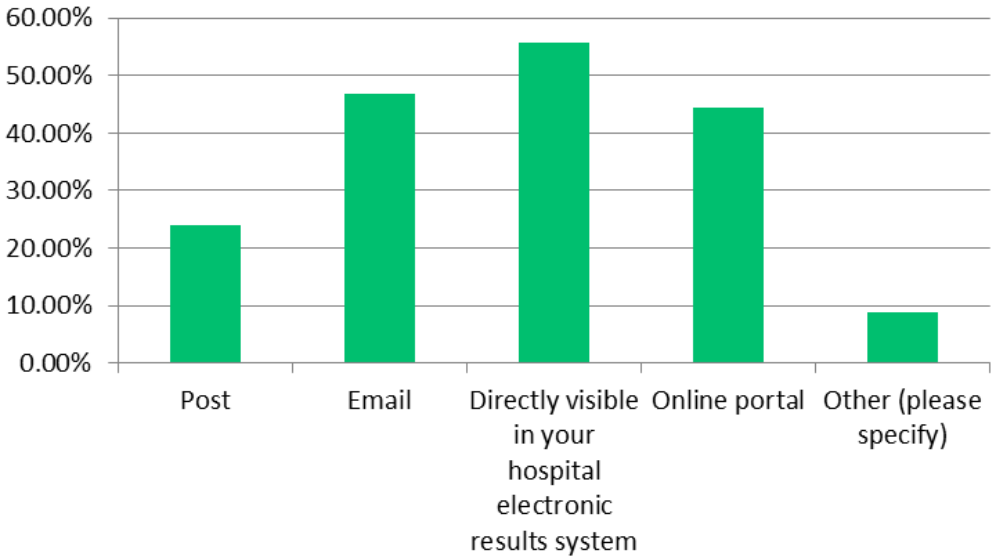
How do you receive results from your SIHMDS?



Post	24.1%	19
Email	46.8%	37
Directly visible in your hospital electronic results system	55.7%	44
Online portal	44.3%	35
Other (please specify)	8.9%	7

Other:

- PDFs
  - "… to be copied and pasted"
- Combination
  - "Molecular pathology department shares a LIMS with the rest of pathology and therefore results are viewable directly… All other molecular results are pdf that are emailed and then uploaded"

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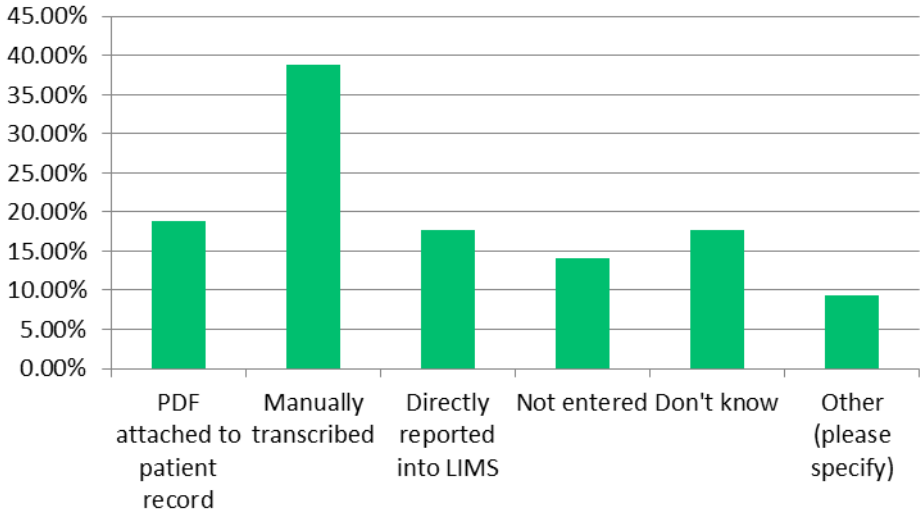
How are GLH results entered into a SIHMDS integrated report/LIMS?



PDF attached to patient record	18.8%	16
Manually transcribed	38.8%	33
Directly reported into LIMS	17.67%	15
Not entered	14.1%	12
Don't know	17.7%	15
Other (please specify)	9.4%	8

Other:

- Combination
  - "Entire reports are uploaded as pdf as well as summary being cut and paste directly into IR with reference to entire report."
  - "…Some uploads are automatic, some are more manual and more complex tests (NGS/WGS/Arrays) have a stand alone report as a pdf as well as a summarised result section."

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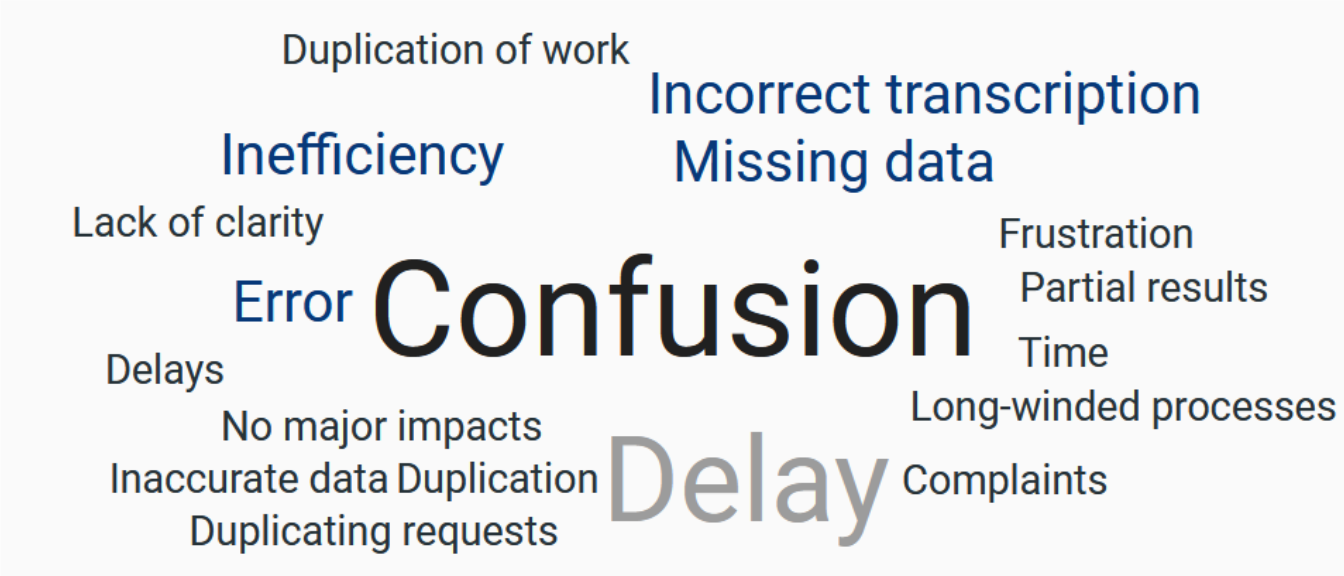
Question 9

What impacts do you experience locally as a result of a lack of integrated IT systems?

24



- Confusion
  Votes: 6
- Delay
  Votes: 5

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How significant is the impact of not having an integrated IT network between GLH and SIHMD/LIMS?

Significant (79.2%)

- Patient safety concerns
- Transcription errors
- Delays in result availability
- Lost results
- Incomplete reports with only headline data available
- Clinical time spent chasing results

Not Significant (20.8%)

- "…results are emailed quite efficiently"
- "Our local SIHMDS provides reporting that integrates this"
- "Not very due to lack of use of GLH - never been a problem. Will be if the volume ^^"

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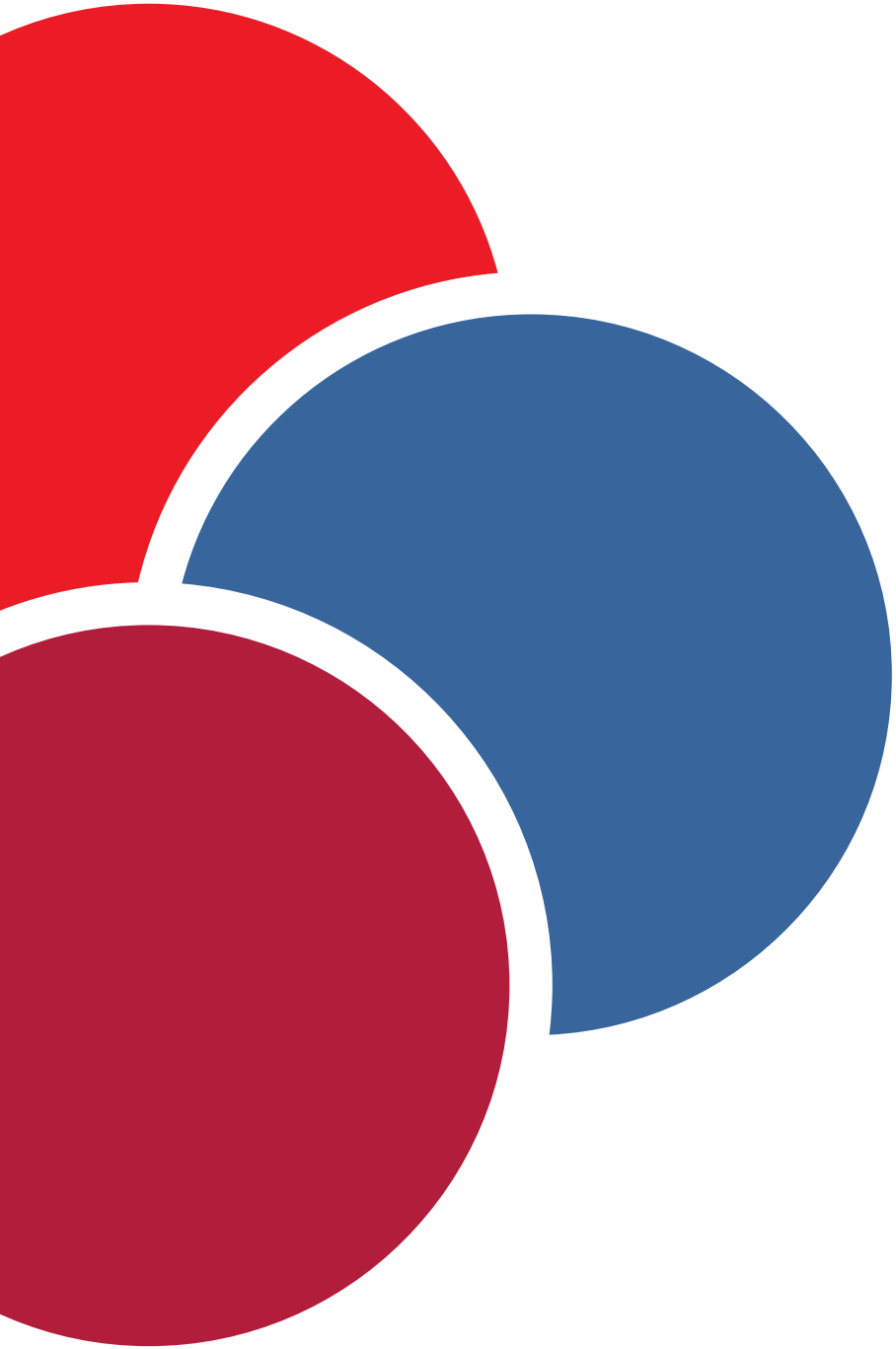
IT Key Themes

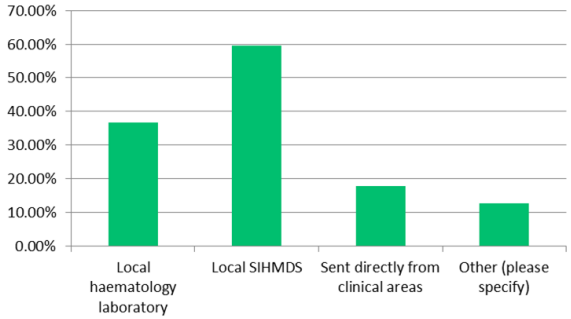
- Approximately 50% request SIHMD tests electronically, 38% said no electronic requesting available
- Concerns about results entry into LIMS, particularly transcription errors and lengthy input processes
- 79% think lack of integrated IT network has significant impact, citing risks of errors, delays to reports and impaired ability to interrogate for quality assurance/audit/data mining



Other issues?

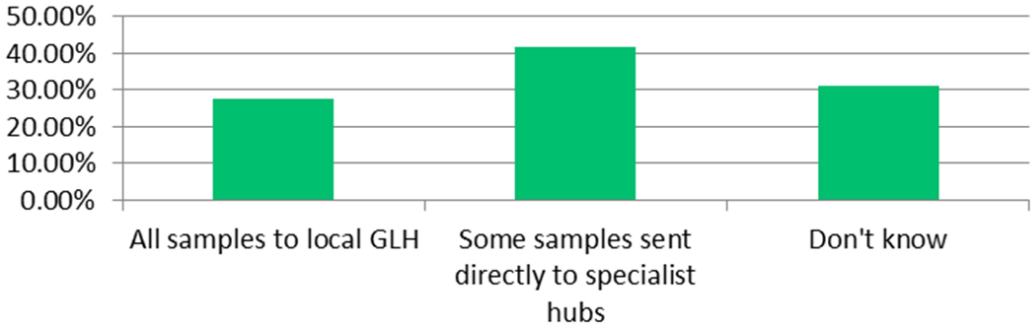
Variable Network Models

Who is responsible for sending samples to the GLH?



Local haematology laboratory	36.7%	29
Local SIHMDS	59.5%	47
Sent directly from clinical areas	17.7%	14
Other (please specify)	12.7%	10

Do you send all samples for GLH analysis to your local hub, or direct to specialist centres?



All samples to local GLH	27.4%	23
Some samples sent directly to specialist hubs	41.7%	35
Don't know	31.0%	26

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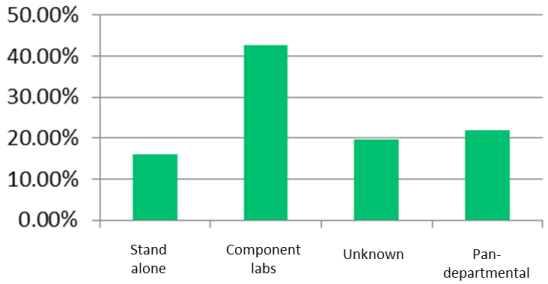
Service Accreditation Key Themes

How is your SIHMDS laboratory ISO15189:2012 accredited?



"…peer review for SIHMDS has fallen by the wayside, I would like to see some form of systematic accreditation for all SIHMDSs…"

Do you think there should be specific UKAS standards for SIHMDS labs?

No – 23.6%

"No, but UKAS could benefit from personnel/assessors who have a SIHMDS background, and the assessment could also take into consideration of NICE guidelines NG47 …"

Yes – 69.5%

"Yes, but our extension to scope changes too often and UKAS needs to be more flexible"

- Variation in current SIHMDS laboratory 15189:2012 accreditation strategies
- Significant support for specific UKAS standards for SIHMDS
- No clear vision of what these might look like (ranging from increased SIHMD experience of UKAS assessors, to full separate standards, to peer review accreditation)

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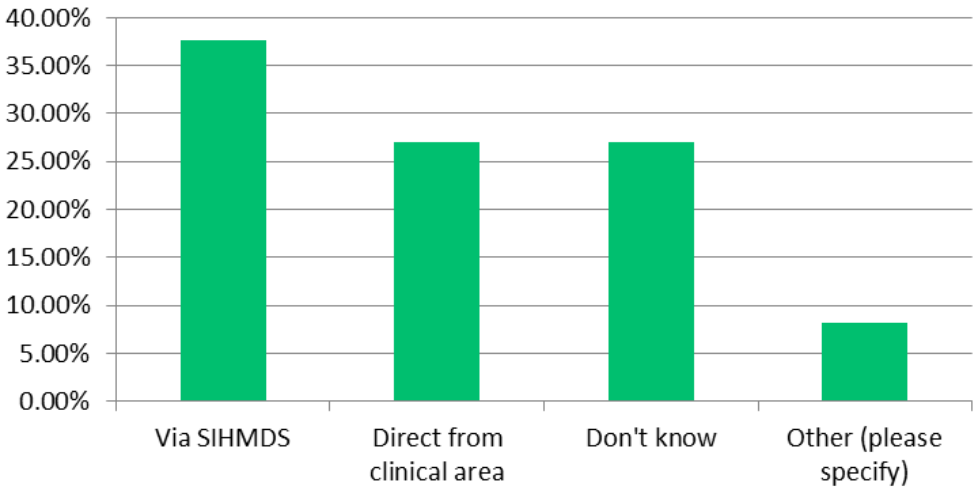
Do you have a pathway for sending bone marrow failure/non-malignant investigations?



Via SIHMDS	37.7%	32
Direct from clinical area	27.1%	23
Don't know	27.1%	23
Other (please specify)	8.2%	7

Other:

- In house testing
- Via local genomics
- Ad hoc arrangements
  - "...some from various labs, others direct from clinical areas"
- No pathway
  - "...Investigations requested as deemed necessary by individuals reporting aspirate or trephine"
  - "Not clear, it's a mess every single time. TATs from reference centres for Fanconi, telomere length and congenital BMF are ~6 months which is unacceptable"

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Paediatric SIHMDS?

Which services does your SIHMDS offer locally?

BMA reporting (adult)	86.67%	78
BMA (paediatric)	46.67%	42
Trephine reporting (adult)	92.22%	83
Trephine reporting (paediatric)	47.78%	43
Other histology reporting in relation to haematopathology including lymph nodes/immunohistochemistry (adult)	90.00%	81
Other histology reporting in relation to haematopathology including lymph nodes/immunohistochemistry (paediatric)	53.33%	48
Other cytology reporting in relation of haematopathology, including CSF/fluid samples (adult)	85.56%	77
Other cytology reporting in relation of haematopathology, including CSF/fluid samples (paediatric)	53.33%	48
Diagnostic flow cytometry	95.56%	86
Karyotype	81.11%	73
FISH	85.56%	77
Arrays	48.89%	44
Diagnostic PCR	83.33%	75
NGS	68.89%	62
WGS	36.67%	33
Molecular MRD	55.56%	50
Flow MRD	58.89%	53
Lymphoid clonality assessment	74.44%	67
Don't know	1.11%	1
Other (please specify)	17.78%	16

There is significant variability in what SIHMDS services offer: not all report aspirates (particularly paeds), but 95% provide flow cytometry

Other:

- Chimerism
- IGHV
- Fusion NGS panel
- Available but not integrated
  - "All of the above services are provided but in a disparate way, not in the form of an HMDS"
  - "…not part of an integrated service"
  - **Paediatric vs adult**
  - **Genomics**

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How might developments in technology change the model for how SIHMDS labs provide genomic testing?

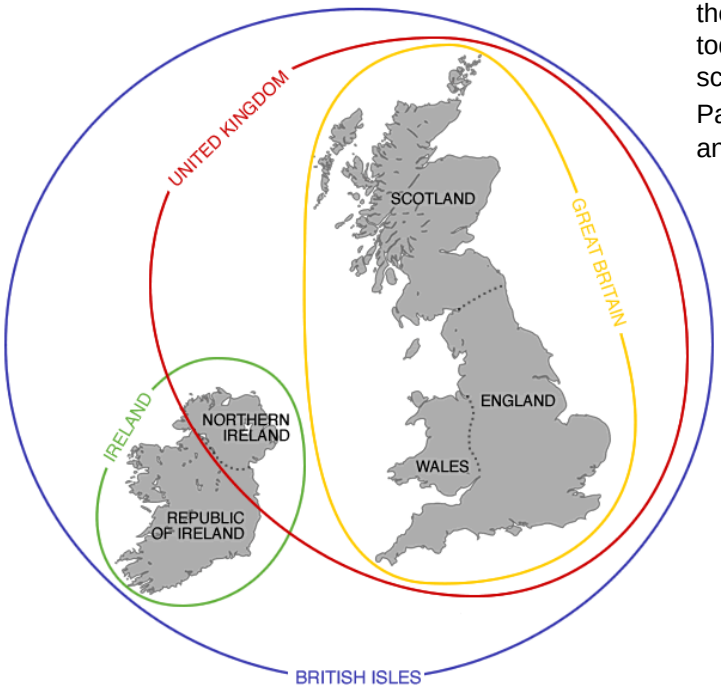
- Technology is constantly changing: NGS is getting cheaper and quicker, and the drive will be towards local SIHMDS rapid NGS testing as new treatments depend on results that may be needed in 24-72h.
- GLH cancer hubs will soon become inefficient and obsolete.
- Clinical scientific skills will be a limiting factor and investment in the genomic workforce will be important.
- The key relationship will be within SIHMDS/genomic MDTs. Local SIHMDS need the medical and scientific skills to discuss NGS panels within local MDTs. Cancer Hubs will never be able to do that. The same applies to WGS reporting, if it becomes applicable.
- The focus should still be on local SIHMDS NICE compliance for integrated reporting, not disrupting integration by forcing consolidation

What is a national society or guideline?

HMDS for patients in devolved nations

The **British Society for Haematology (BSH)** has been bringing haematology professionals together since 1960 to transform the care our members provide to patients. With over 2500 members worldwide, we are the largest UK haematology organisation and the only society to cover all aspects of the specialty.

The **Royal College of Pathologists** is a professional membership organisation with charitable status, concerned with all matters relating to the science and practice of pathology. It is a body of its Fellows, Affiliates and trainees, supported by the staff who are based at the College's London offices. The College is a charity with over 11,000 members worldwide. The majority of members are doctors and scientists working in hospitals and universities in the UK.



The British Lymphoma Pathology Group (BLPG) was established in 1974. It initially gathered a small group of Haematopathologists who have historically shaped some of the most important developments in the understanding and classification of lymphoma. The BLPG today gathers more than 200 members with practice in Haematopathology. It provides important scientific and practical diagnostic updates, advice and guidance to the Royal College of Pathologists and other bodies relevant to Haematopathology practice in the United Kingdom and runs the Haematopathology External Quality Assurance (EQA) scheme.

NHS Genomic Medicine Service for England

National Institute for Health and Care Excellence (NICE) clinical guidelines cover the NHS in England, Wales and Northern Ireland. (See www.sign.ac.uk for information about clinical guidelines in Scotland.) NHS organisations such as hospitals, clinical commissioning groups, local health boards and GP practices are expected to take into account the recommendations in NICE clinical guidelines when deciding what treatments to offer people.

NICE guidance: Applicable to all UK?

- NICE guidelines cover health and care in England.
- Decisions on how they apply in other UK countries are made by ministers in the Welsh Government, Scottish Government and Northern Ireland Executive.[8,9]

8. www.nice.org.uk/process/pmg20/chapter/introduction

9. www.nice.org.uk/guidance/ng47/history

- NICE clinical guidelines cover the NHS in England, Wales and Northern Ireland. (See www.sign.ac.uk for information about clinical guidelines in Scotland.) [10]

10. www.nice.org.uk/public-involvement factsheet

- NICE clinical guidelines are used internationally

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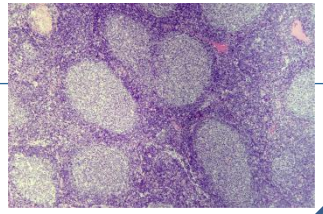
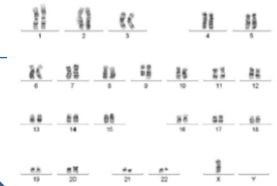
Legal implications of NICE guidance

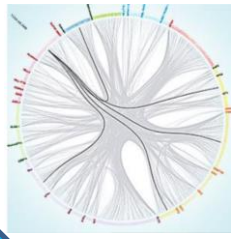
- “The essence of the judgement is that the CCG was wrong to refuse the patient access to the treatment that she needed because the CCG simply disagreed with the recommendation made by NICE.”[10]
- The recent court judgement does however mean that if organisations refuse to put NICE clinical guidelines in place because they disagree with them, this could leave them open to challenge.
- There are of course lots of other reasons for using the recommendations in NICE clinical guidelines:
  - Clinical guidelines help you know you are delivering clinically and cost effective services for patients
  - They enable you meet CQC standards and demonstrate good or outstanding care;
  - The NHS Litigation Authority encourages providers to follow NICE clinical guidelines;
  - Clinical guidelines enable those caring for patients to reassure them that they are following evidence based practice.

11. www.nice.org.uk/news/feature/court-judgement-what-it-means-for-commissioners-and-providers-and-using-nice-guidance-and-standards

SIHMDS NICE compliance







- Modalities co-located
- Integrated approach
- No single approach or platform, but unifying principles
- National Cancer Peer Review Programme 2013-16

- **Are all SIHMDS Labs NICE compliant?**

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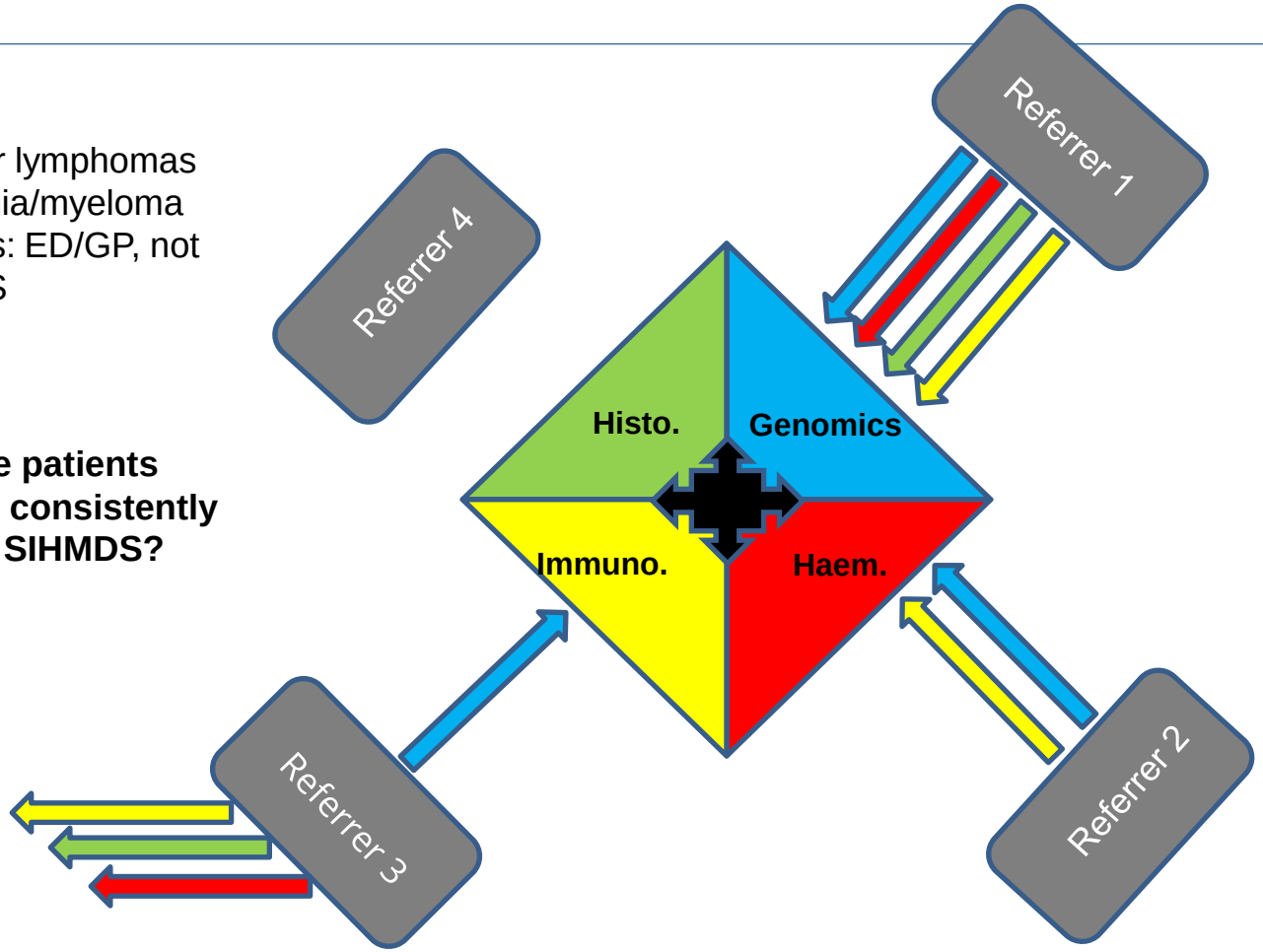
Access to SIHMDS labs

- Backdoor lymphomas
- Leukaemia/myeloma diagnosis: ED/GP, not 2ww/FDS

Are all eligible patients equitably and consistently accessing an SIHMDS?



Myeloid *vs* lymphoid neoplasms
Haematologists & Histopathologists & Scientists
Clinical Genetics

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BLPG roundtable June 2022: key themes

- Services: co-localised *vs* networked *vs* none
- Desire for co-localised labs, but recognition not always possible currently
- Testing modalities will change, changes will be easier if things are collocated
- Differences between devolved nation and England and their unique problems
- Effective communication with commissioners and policy makers
- The need for BSH and BLPG collaboration
- Need a co-ordinated voice on training, accreditation, organisation, influence external bodies.
- Standards set by the BLPG, BSH, RCPath

Need for data

- **To achieve parity between nations we need to measure outcomes.**
- **Following standards is a surrogate marker of harm is and whilst there are no recent studies/ publications that have quantified harm, NICE guidance and accreditation are used to imply that harm is mitigated or minimised.**
- **Should use epidemiology to capture harm, for example, incidence of a particular cancer being more or less in an area and ask the question why.**
- **Without data to back up our claims, things cannot be fixed.**
- **Audits needed to prove the point we are making or take us to a very different discussion.**

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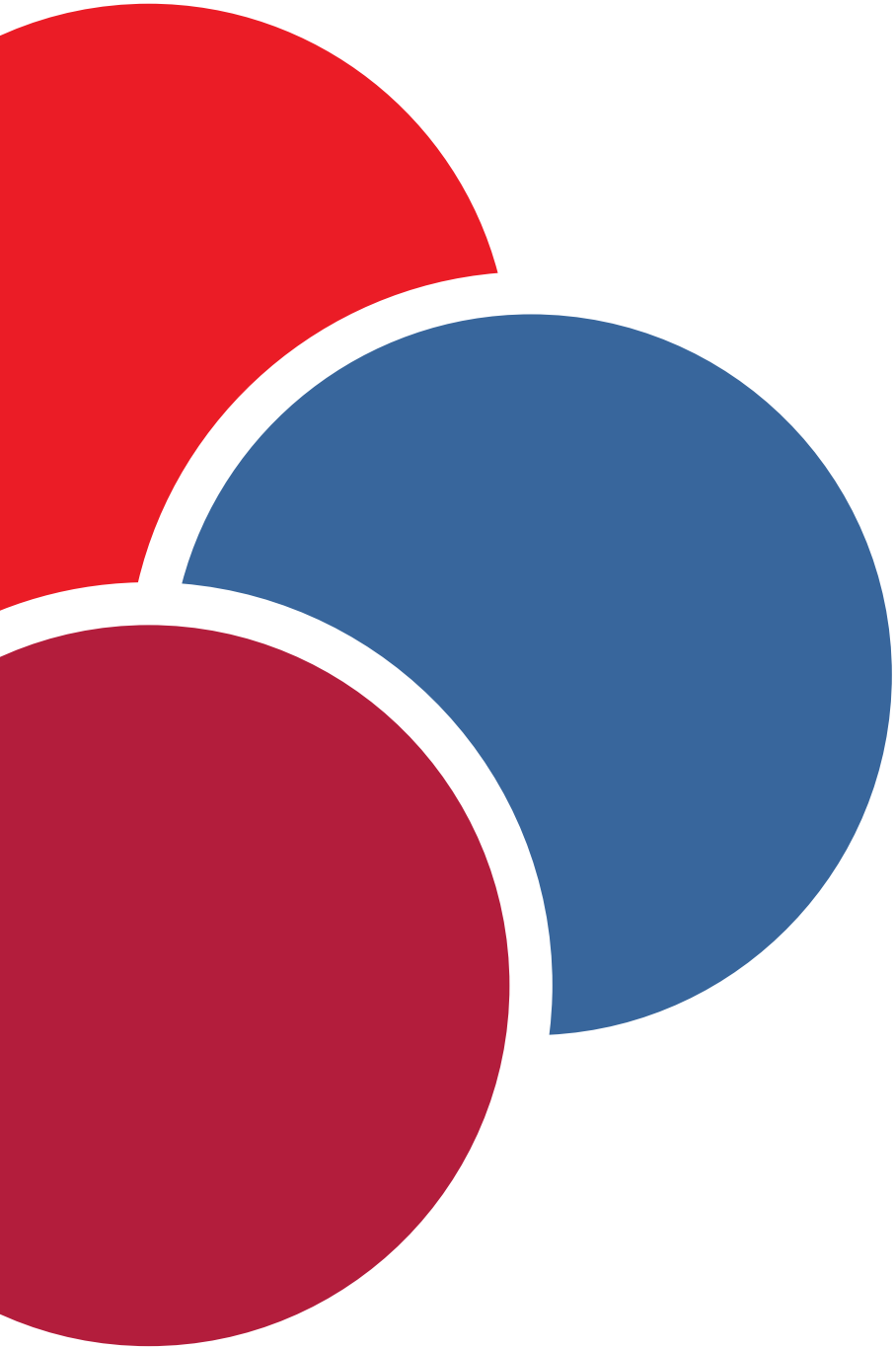

What next?

What could be done to ensure equity of access to genomic testing?

Communication/Collaboration between SIHMD Services

- "Less politics and more partnership working. Involves listening to local services and tapping into the considerable Existing experience of SIHMDS who have been at the forefront of service delivery for their local populations"

- "It would also be really excellent to see a working group including leads of all the UK SIHMDSs to ensure sharing of best practice and equity of process. The current groups are not all inclusive."

- "Better communication / collaboration between SIHMDS services to standardise test offerings and TATs."

- "The clinical expertise no doubt resides within the SIHMDSs, and so good communication and collaboration is crucial to guide the genomics developments within this area. Engagement with the TD update process is also crucial"

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UK SIHMDS Network:
Initial meeting 27th Feb 2023

- **Purpose:** bring together SIHMDS leads and other stakeholders to agree how to establish SIHMDS network
- Initially arranged with support from BSH/BLPG, but long-term plan to consider support by independent organisation?
- Agenda:
  - Welcome and introductions
  - Declaration of interests
  - Results of BSH Lab SIG survey
  - Results of UK NEQAS LI survey on SIHMDS
  - Summary of BLPG workshop
  - Genomics commissioning (NHSE and devolved nations)
  - ICC/WHO issues and RCPath datasets
  - Confirmation of SIHMDS leads list
  - Proposal for SIHMDS peer review process
  - Proposals for audits/education/research projects

- **SIHMDS:**
  - 21 SIHMDS in England
  - 5 in Devolved Nations
- **BSH**
- **BLPG**
- **NHSE (and genomics commissioners in devolved nations)**
- **NEQAS**
- **RCPath**
- **UKAS?**

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HMDS Network Meeting: Genomics Discussions

- There is a misconception that genomics can't happen in an SIHMDS or that it has to happen in a genomics hub. That isn't true. It can happen in either. What has to happen is the governance needs to be managed within the GLH.
- From a commissioning perspective and working within an HMDS, we have a structure in place and need to make that work. We've seen many excellent examples of that working in many different ways in lots of different GLHs.
- We have struggled with governance where our SIHMDS is not at the GLH, and there isn't a joined-up overarching governance structure.
- All systems don't have to be the same. There is a possibility of varying from a co-located HMDS to a fully-functioning networked HMDS that provides the same level of services irrespective of where patients are. There is flexibility.
- But it comes back to the definition of 'networked'
- There's no recommendation and no integrative governance step between various other laboratory aspects for haematological malignancies that largely sit in the one governance structure and genomic services on the other
- NHS England and the genomics medicine unit – they're always going through different transformations – but we'll see a lot of change over the next year or two as the finance and IT evolves.
- Genomics in Scotland is undergoing extensive review to develop a national strategy for provision. A 'Haematologic Malignancy Strategic Working Group' is part of this process.

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Main Issues

- Equity of access to testing
- Devolved nations
- Networked vs Collocated models
- Conflicts with GLH model, disconnect from NHSE
- Uncertain governance structures
- Lack of IT interoperability
- Lack of data
- What TATs do we want?
- Accreditation? EQA? SIHMDS Peer review?

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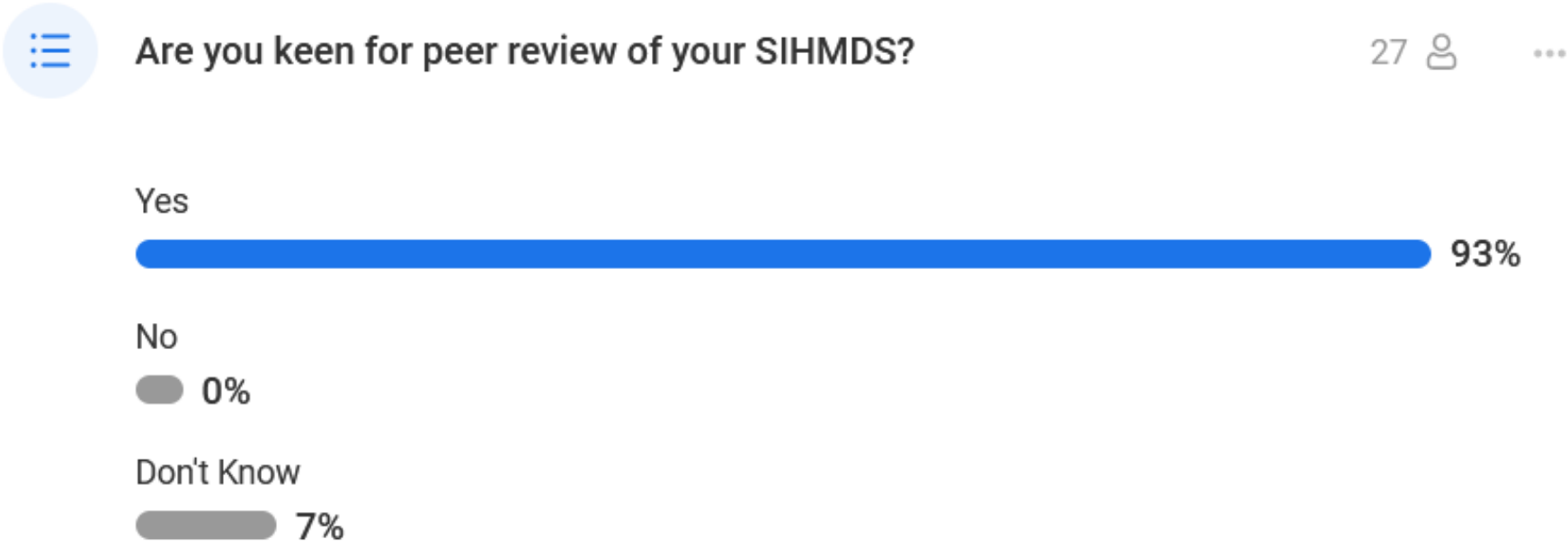
Question 10

- Are you keen for peer review of your SIHMDS?
- Yes
- No



Question 11: What would you like us to prioritise?

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