SIHMDS 2022 Survey Results

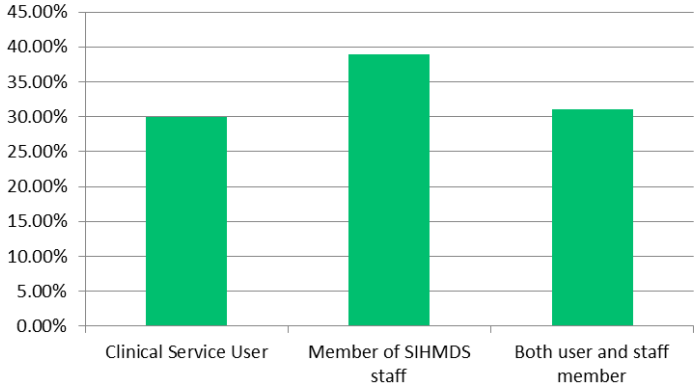
Thanks to April Sellors, Emma Das-Gupta, Tom Butler (Lab SIG committee) for designing and analysing the survey; Maxwell McCreton (BSH) for helping design and sending out.

SIHMDS Survey: BSH and BLPG

- SIHMDS survey sent out by BSH and BLPG
- Confirm the number of labs that offer an SIHMDS service in the UK, outline issues affecting HMDS labs in preparation for UK HMDS network
- BSH member bulletins July and August 2022 and via BLPG email
- Collate the findings from surveys and workshops, to outline the future shape of the SIHMDS network and the issues it needs to tackle
- Key themes in following initial slides, followed by full results

90 respondents, from across UK

What is your involvement with your local SIHMDS?



Clinical Service User	30.00%	27
Member of SIHMDS staff	38.89%	35
Both user and staff member	31.11%	28

- 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)

What region is your GLH in?

Central and South GLH	12.50%	11
East GLH	11.36%	10
North West GLH	11.36%	10
North Thames GLH	22.73%	20
South East GLH	9.09%	8
South West GLH	5.68%	5
North East and Yorkshire GLH	18.18%	16
Wales	1.14%	1
Northern Ireland	2.27%	2
Scotland	1.14%	1
Don't know	4.55%	4

Which services does your SIHMDS offer locally?

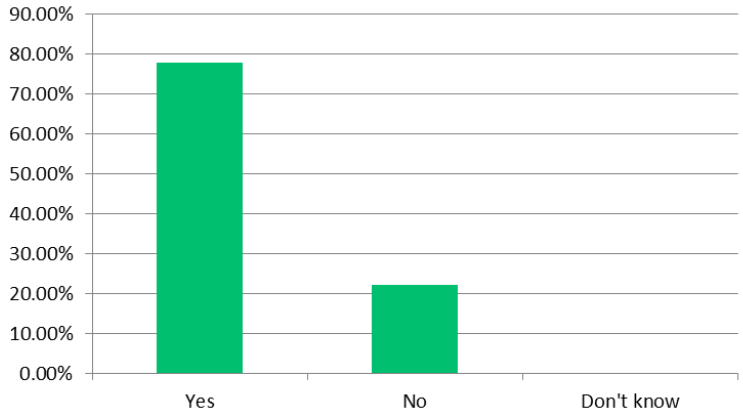
BMA reporting (adult)	86.67%	78
BMA (paediatric)	46.67%	42
Trephine reporting (adult)	92.22%	83
Trephine reporting (paediatric)	47.78%	43
Other histology reporting in relation to haematopathology including lymph nodes/immunohistochemistry (adult)	90.00%	81
Other histology reporting in relation to haematopathology 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**

Do you get an integrated report from your SIHMDS service?



All diagnostic modalities are undertaken locally at the SIHMDS and we receive a fully integrated report	26.25%	21
All diagnostic modalities are undertaken at the SIHMDS but are not all returned in a single integrated report	6.25%	5
We only send some elements of the sample to our SIHMDS (please specify)	8.75%	7
All diagnostic modalities are undertaken 'in house' at the SIHMDS and we receive a fully integrated report	8.75%	7
Not all diagnostic modalities are undertaken 'in house' at the SIHMDS, but we receive a fully integrated report	12.50%	10
All diagnostic modalities are undertaken via a combination of local SIHMDS and reference centre testing, and we receive a fully integrated report	15.00%	12
Don't know	2.50%	2
Other (please specify)	20.00%	16

- 22% don't receive an integrated SIHMDS report
- 50% update integrated reports as more results become available, 23.6% only authorise once all results available
- Clinicians routinely informed of updated report in 42.5% of cases (slightly higher in urgent scenarios, 18.4% are not alerted of updated results)

Key Themes: IT

IT section

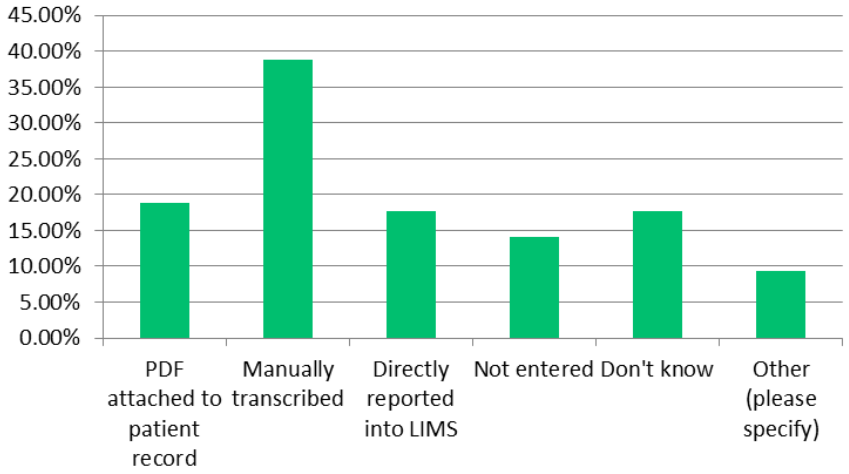
- Approximately 50% request SIHMD tests electronically, 38% said no electronic requesting available
- Concerns about results entry into LIMS, particularly transcription errors and lengthy input processes
- 79% think lack of integrated IT network has significant impact, citing risks of errors, delays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

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

IT

- LIMS integration / M-ware to allow results to go directly between systems Enhanced genomic testing locally Investment in cloud-based technology so that results can be reported remotely generate cloud based national bioinformatic support.
- Broadly IT is key to streamlining request and result from and to local systems which will inevitably vary
- IT networking to facilitate development of "factory style" processing wet lab/ and more local dry lab reporting/integration systems.
- Improved IT links between GLH Hub and SIHMDS LGL laboratories

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



Other:

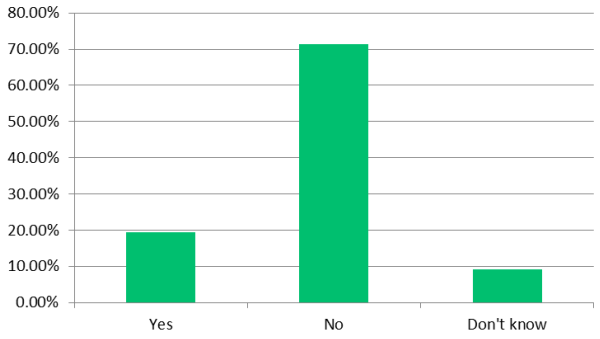
- Combination
  - "Entire reports are uploaded as pdf as well as summary being cut and paste directly into IR with reference to entire report."
  - "…Some uploads are automatic, some are more manual and more complex tests (NGS/WGS/Arrays) have a stand alone report as a pdf as well as a summarised result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

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

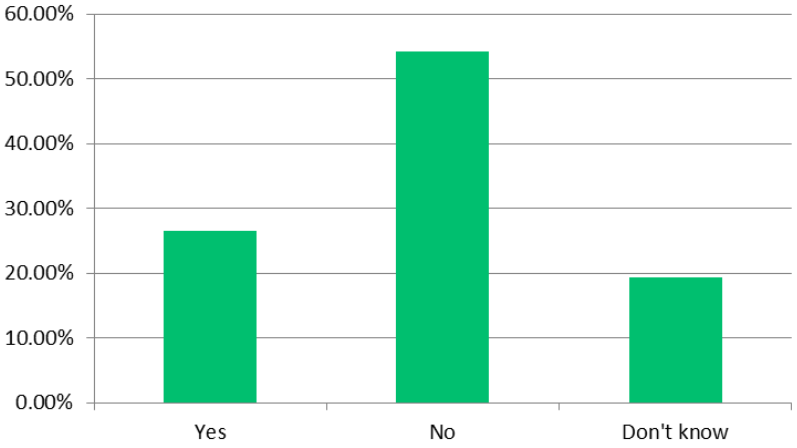
Significant (79.2%)

- "This is a major issue, patient safety (transcription errors), huge resource, delays reports, hinders integration."
- "…this needs addressing at a national level"
- "Timeliness and ability to interrogate primary data for quality assurance and clinical interpretation is the central role of any oncogenomics MDT"
- "Reports are not always sent to correct contacts. Results are hard to track down and not easy to locate. Any data received as a PDF is not useful for auditing or data mining…"
- "Risk of the loss/errors/delay of data when transferring data between IT systems. True TATs is difficult to capture & monitor"

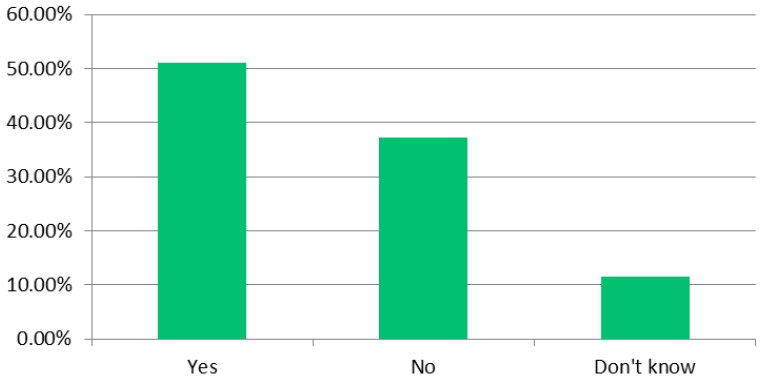
Is your SIHMDS service located at the same site as a GLH?



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



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



- 19.5% co-located with GLH
- 51.2 co-located with LGL

Key Themes

Genomics section

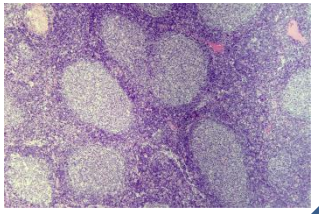
- Some (most?) genomic testing is occurring outside the GLH laboratories (58.7% have mutation sequencing capacity, 48% NGS sequencing, 45.3% molecular MRD)
- Most commonly requested GLH assays are myeloid NGS panels, MPN molecular testing and AML molecular (NPM1/FLT3)
- Only 27.4% of responders are sending all samples to local GLH for redistribution to other GLHs (41.7% send some samples directly to the specialist hubs)
- 52.3% of responders are not aware of turnaround times
- Only approximately 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
- Experience and perceptions of WGS highly variable 37% comfortable requesting, but many feel lacks clinical utility, has a detrimental impact on other investigations, or is not available/required
- Barriers to increased use of WGS include consenting, clinical utility, time/resource availability, requesting/testing pathways and germline sampling requirements

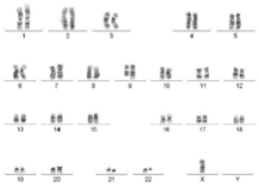
Key Themes

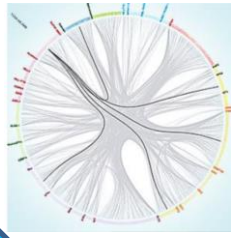
Genomic reconfiguration section

- 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

SIHMDS NG47
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?**

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

How do you feel developments in technology will change to model for how SIHMDS labs provide genomic testing?

- Rapid testing technologies, capable of running smaller batches of samples with a rapid TAT (overnight NGS, long read PCR) will allow the SIHMDS laboratories to provide much quicker TAT. The 24hr delay inevitable in sending samples to the GLH hub will become a much higher percentage of the time delay to a result as these technologies advance. The cost of the instrumentation and reagents will also reduce, meaning the financial impact of consolidation will be less

- At the moment we are in a phase of centralisation but with workload volumes and complexity increasing I think it is essential that we retain regional expertise and that imminent technological advances will lead to some devolution of testing again

- I'm sure over time new technologies, such as long read sequencing, NGS MRD, WGS, RNA fusion panels will change the technologies used for genomic testing and there will be reduction in G banding and FISH testing. These changes should be led by the clinicians and scientists of the SIHMDSs with specialist haem-onc knowledge.

- The need for rapid testing and more comprehensive testing will increase over time. Closer to patient testing, RNA testing and ct-DNA will increase. Delays due to transporting samples to a GLH hours from the bedside will not be possible as the samples will become too old. Consolidation into large factory-like laboratories does not always improve patient care

- …there is opportunity for funding and indeed more adventurous developments if managed in a consolidated, collaborative and innovative way.

- Virtual SIHMDS would be possible and co-location may not be necessary to achieve excellence

- 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 else could be done to ensure equity of access to genomic testing?

SIHMDS based Testing

- Scrap the GLH model and support local SIHMDS development
- More resources to local SIHMDS capacity
- Devolve and co-localise services
- Acknowledgement that some 'local' HMDS have very knowledgeable and skilled staff that are able to provide high standard of some 'specialist' tests. These should not be thrown out with the bathwater
- Let GLH concentrate on non-time critical tests like WGS but all rapid assays should be performed locally
- All haematological malignancies should be reported in SIHMDS. Still some areas where lymphomas are sometimes locally reported for historical reasons, despite all our efforts to centralise. All pathology departments should have ability to freeze fresh tissue samples, to allow WGS if indicated.
- Allow high quality, efficient testing to be performed within the SIHMDS if this improves patient care. If testing within SIHMDS meets the National test directory and can be performed within a nationally agreed tariff it should be permitted. Rare or complex tests that SIHMDS services choose not to perform can be performed by a GLH model if that is beneficial to the patient but not because of a forced agenda by NHSE.

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

Communication/Collaboration

- Align it to patient pathways not genomics hubs!
- Utilise the local hubs more efficiently rather than closing them
- More collaboration between GLH and LGLs, and an acceptance that LGLs provide a level of resilience and expertise, rather than just seeing them as inferior to GLHs
- 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

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

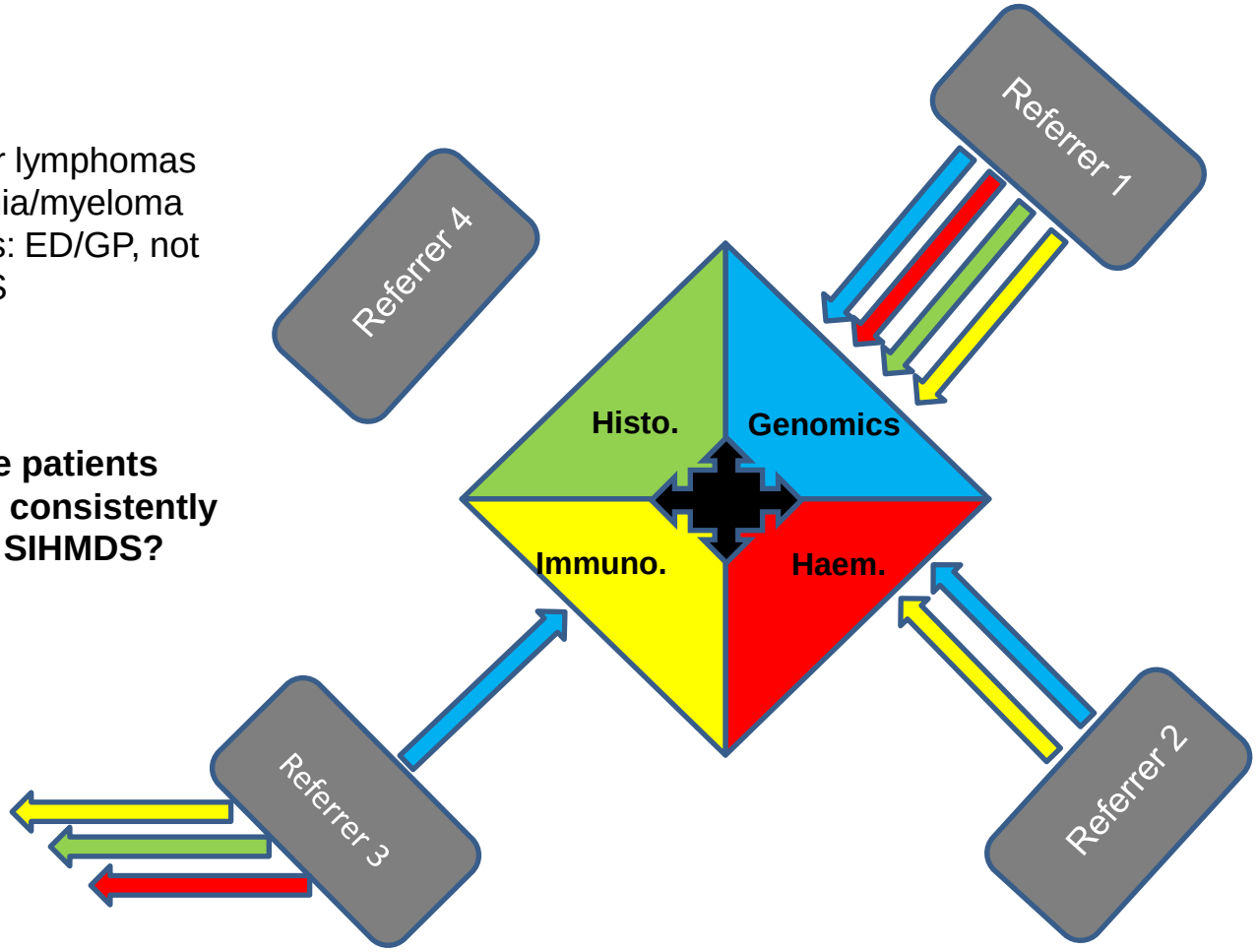
Other

- Paediatrics not really considered in the current model. Small number of centre geographically disparate. Tests offered locally only relevant to adults.
- Clinically informed, prioritised and led changes only from now on.
- The focus should be on ensuring all clinicians are accessing their local and NICE compliant SIHMDS. That will ensure equity of access to the correct genomic testing. Inappropriate focus on consolidation at cancer hubs deceases access. Scotland/Wales/N Ireland have been ignored by genomics commissioners and their patients deserve access to SIHMDS as well.
- Continual/ regular review of repertoire at GLH vs local testing taking into account new clinical requirements and the changes in technology. Continual horizon scanning needed.

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

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

Accreditation/Standards

- Proper peer review with SIHMDS accreditation
- The main starting point is to ensure appropriate configuration and accreditation of SIHMDS services. There are probably very few in teh UK that come up to the required standard.
- The professional bodies including NICE, BSH, BLPG, Royal College of Pathologists and UKAS could mandate standards for Haemato-Oncology training and reporting through out UK.
- Establishing, monitoring and intervening on national standards for turnaround times for e.g. NGS.
- True accreditation / peer review of SIHMDSs would also help improve equity ensure adherence to the requirements / recommendations.
- all GLH need a good clinical governance structure

How is your SIHMDS laboratory ISO15189:2012 accredited?

As a stand-alone SIHMDS service	16.09%	14
Individual component laboratory accreditations	42.53%	37
Unknown	19.54%	17
pan-departmental accreditation, e.g. pathology, blood sciences (please specify)	21.84%	19

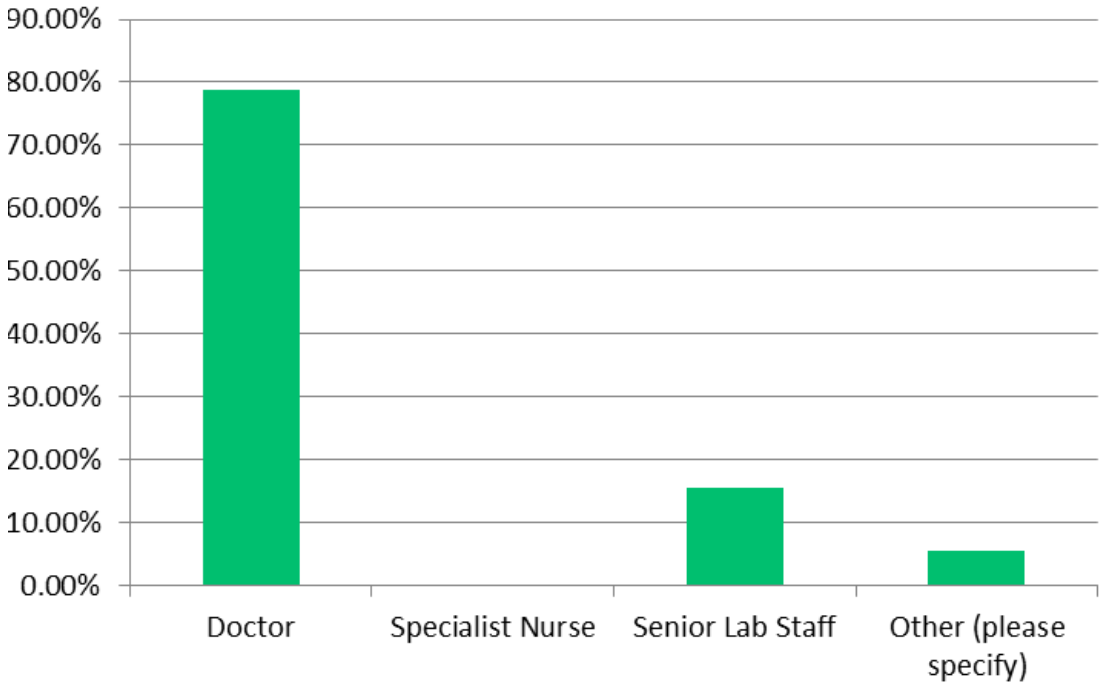
Do you think there should be specific UKAS standards for SIHMDS laboratories?

Yes – 69.5%

- "It would be useful yes as long as it was complimentary to other standards"
- "…assessors should assess against NICE guidance NG47 as well as ISO15189"
- **"…**this would help standardise and provide clear expectations of what an SIHMDS should provide (including governance and leadership)"
- "Yes, but our extension to scope changes too often and UKAS needs to be more flexible"
- "Yes, integration/integrated functioning of SIHMDS is key; not exactly standardised across the UK . SIHMDS are not directly comparable at present with respect to WHO diagnostic subtypes or patient outcomes; UKAS standards would be the 1st step."

Full survey results

Q1 – What is your role?

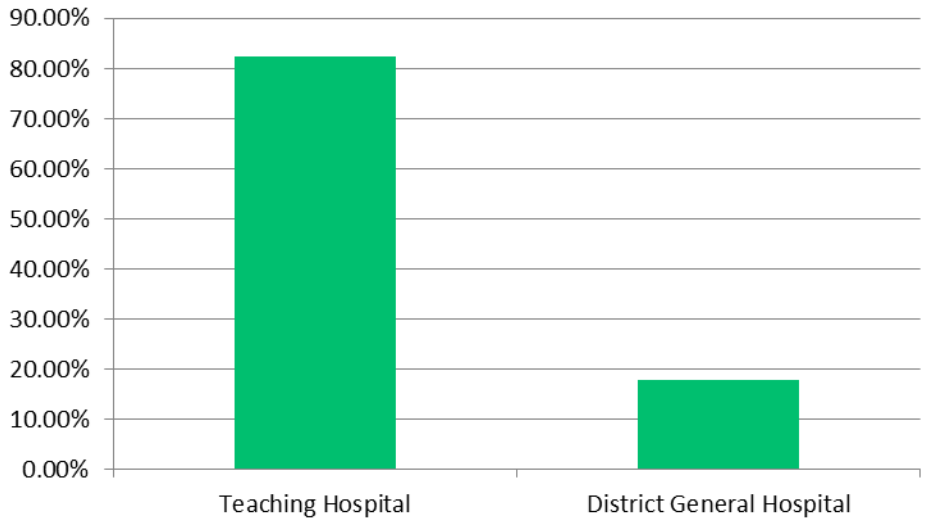


Doctor	78.9%	71
Specialist Nurse	0.0%	0
Senior Lab Staff	15.5%	14
Other (please specify)	5.6%	5

Other:

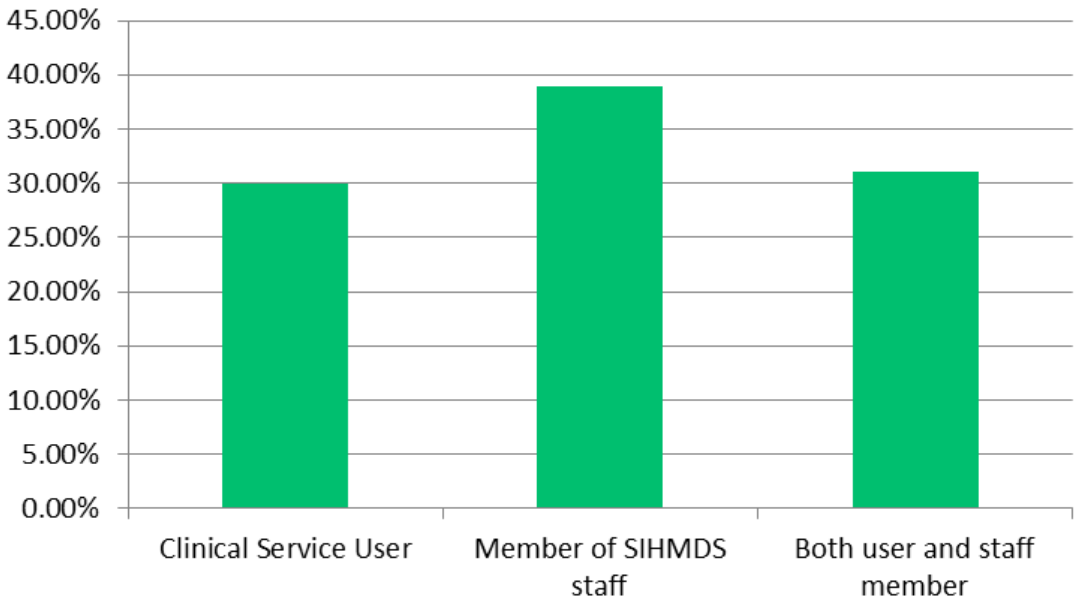
- Consultant Clinical Scientist x 2
- Band 6 NHS lab staff
- Trials Coordinator
- Quality Manager

Q2 – Which of the following best describes your hospital?



Teaching Hospital	82.2%	74
District General Hospital	17.8%	16

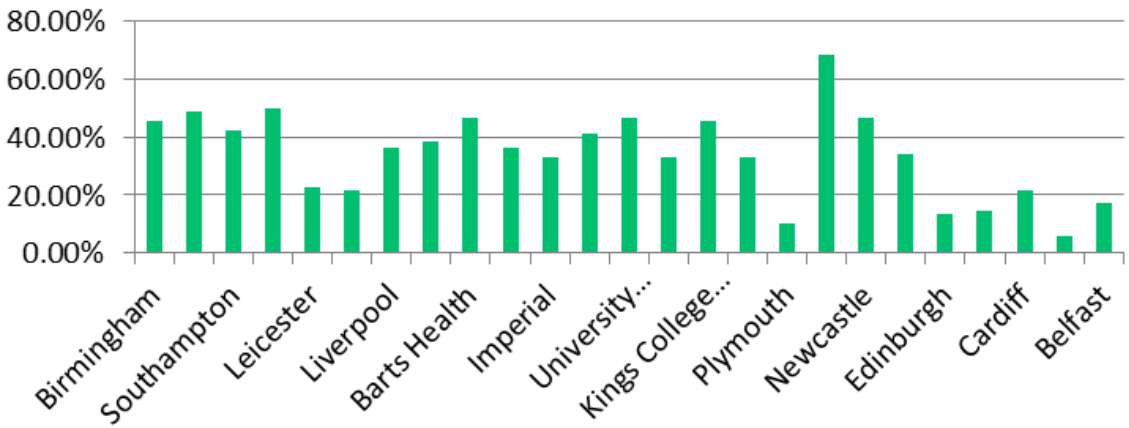
Q3 – What is your involvement with your local SIHMDS?



Clinical Service User	30.0%	27
Member of SIHMDS staff	38.9%	35
Both user and staff member	31.1%	28

Q4 – Which SIHMDS labs are you aware of?

Birmingham	45.5%	40
Oxford	48.9%	43
Southampton	42.1%	37
Cambridge	50.0%	44
Leicester	22.7%	20
Nottingham	21.6%	19
Liverpool	36.4%	32
Manchester	38.6%	34
Barts Health	46.6%	41
Great Ormond Street (Paediatric)	36.4%	32
Imperial	33.0%	29
Royal Marsden	40.9%	36
University College London	46.6%	41
Guys and St Thomas'	33.0%	29
Kings College Hospital	45.5%	40
Bristol	33.0%	29
Plymouth	10.2%	9
Leeds	68.2%	60
Newcastle	46.6%	41
Sheffield	34.1%	30
Edinburgh	13.6%	12
Glasgow	14.8%	13
Cardiff	21.6%	19
Swansea	5.7%	5
Belfast	17.0%	15



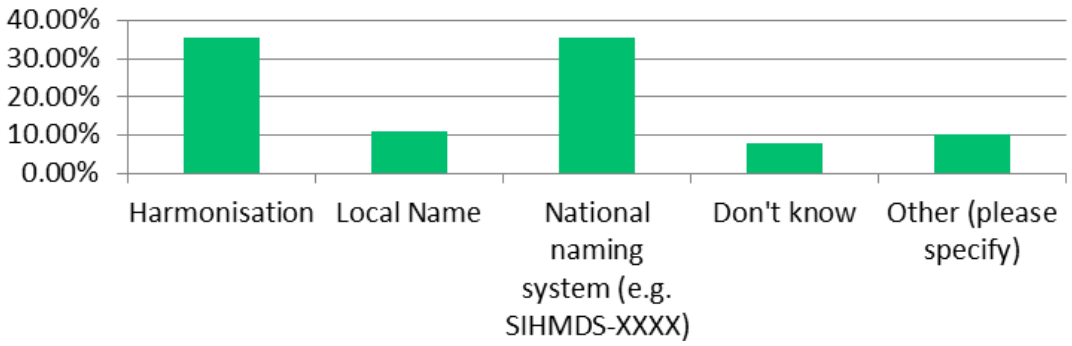
Q5 – Are there any SIHMDS labs listed you don't think should be?

- X
  - "only takes cases from 2 DGHs …"
  - "X and **[]** are ideally under one AHSC umbrella and should be one SIHMDS but guess they have service set ups at both sites"
  - "X does not have hmds structure. It does perform some tests but does not operate as an hmds".
  - "I am understanding X perform molecular MRD for AML as standalone tests for other hospitals / GLH's but are not a SIHMDS"
- Y
  - "not sure that at Y we are really functioning as a full HMDS"
  - "Y does not fulfil definition of SIHMDS in my view, there is no integrated reporting system as far as I am aware"
  - "I wasn't aware that Y had set up a full molecular service "
  - "Y Working towards this status but not currently meeting the NICE guidelines (multiple specimen receptions, >1 QMS system, no integrated reporting etc)"
- Z (Devolved Nations)
  - "I am not aware that there are formal SIHMDS labs outside of England."
  - "Z: not an SIHMDS. Conglomeration of laboratories; informal relationships between them. Haematology, Haemato-Oncology, Medical genetics and Cellular Pathology have different systems in place and put out independent reports."
  - "Z. Neither are constituted as a proper HMDS that would fulfill NICE criteria - no common reception, split department services, separate reporting of different parts of teh same specimen (especially BMAs and BMTs), no integrated final report."
  - "Z should be part of the **[]** with one centralised lab so wasn't aware of Z being a stand alone SIHMDS - what is the catchment population"
- General
  - "I dont know the other labs set up well enough to comment, but from recent Snowden publication would suggest many on this list are not NICE compliant SIHMDS's. "

Q6 – Are there any SIHMDS labs missing from the list?

- Dorset
  - "Dorset - Bournemouth, Poole and Dorset County Hospitals. We provide an IR and were assessed by Peer review"
- "Do Glasgow and Edinburgh serve all of Scotland Haematological malignancy diagnosis? If yes, then we can learn a lesson from them in England"

Q7 – Would you like standardisation of SIHMDS names?



Harmonisation	35.6%	32
Local Name	11.1%	10
National naming system (e.g. SIHMDS-XXXX)	35.6%	32
Don't know	7.7%	7
Other (please specify)	10.0%	9

Other:

- It doesn't matter
  - "…it is diagnostic quality that needs to be consistent"
- No preference
  - "I'm not sure what having the same title would really achieve but equally happy to go with the flow "
- Harmonisation
  - "If national naming this should follow development of formal accreditation"
  - "…but also a system that allows patients to recognise the function of the services"

Q8 – Which services does your SIHMDS offer locally?

BMA reporting (adult)	86.7%	78
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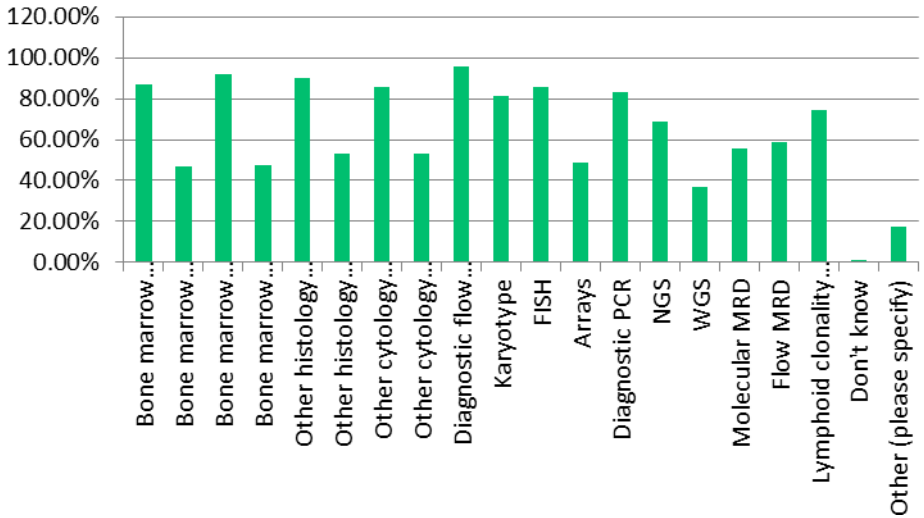

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- Available but not integrated
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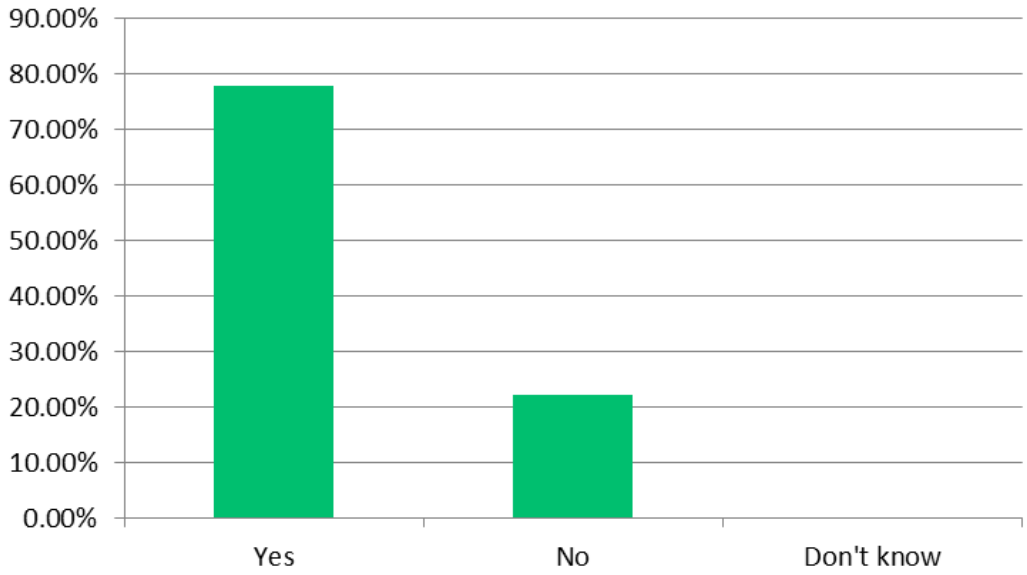
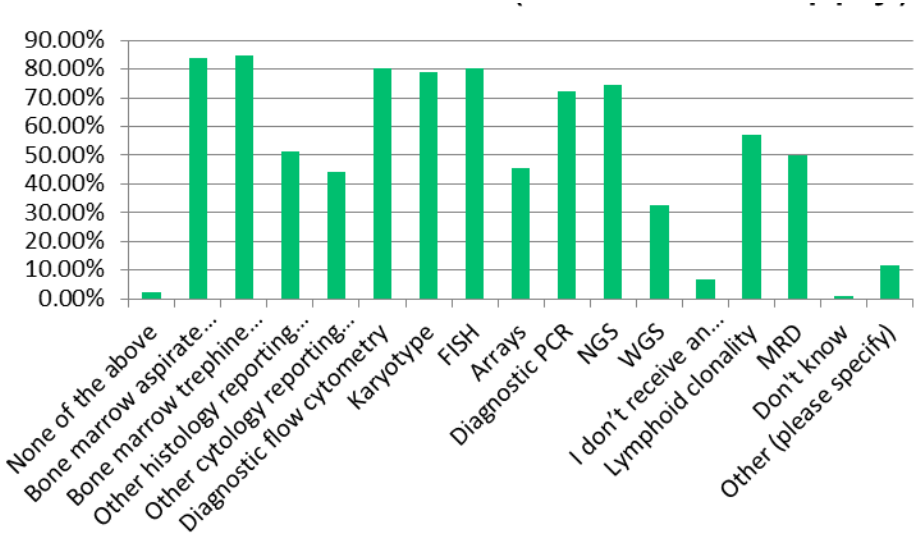
Q9 – Do you get an integrated report from your SIHMDS service?



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

Q10 – What is included in your integrated report?

None of the above	2.3%	2
Bone marrow aspirate reporting	83.7%	72
Bone marrow trephine reporting	84.8%	73
Other histology reporting in relation to haematopathology including lymph nodes/immunohistochemistry	51.1%	44
Other cytology reporting in relation of haematopathology, including CSF/fluid samples	44.2%	38
Diagnostic flow cytometry	80.3%	69
Karyotype	79.1%	68
FISH	80.2%	69
Arrays	45.4%	39
Diagnostic PCR	72.1%	62
NGS	74.4%	64
WGS	32.6%	28
I don't receive an integrated report	7.0%	6
Lymphoid clonality	57.0%	49
MRD	50.0%	43
Don't know	1.2%	1
Other (please specify)	11.6%	10

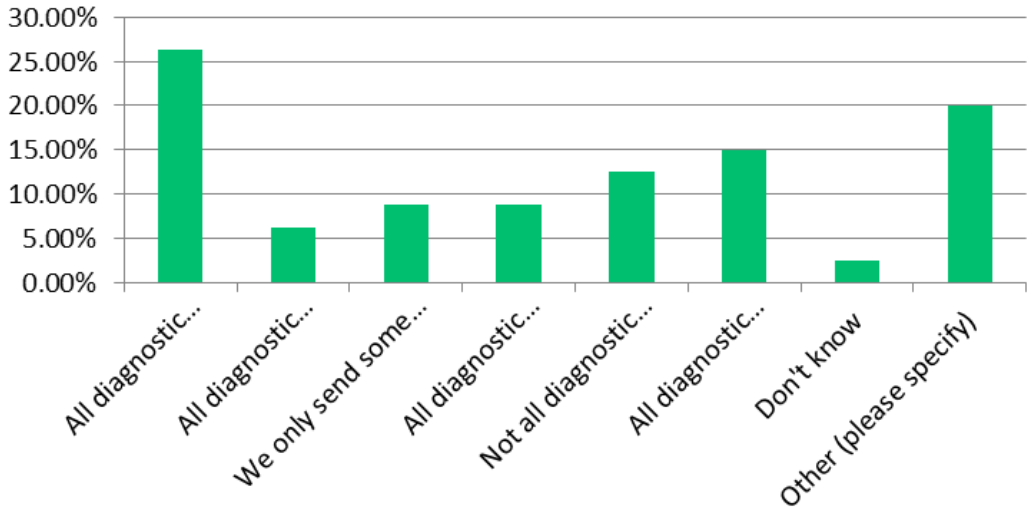


Other:

- "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"

Q11 – How do you use your SIHMDS for haem-onc diagnostics?

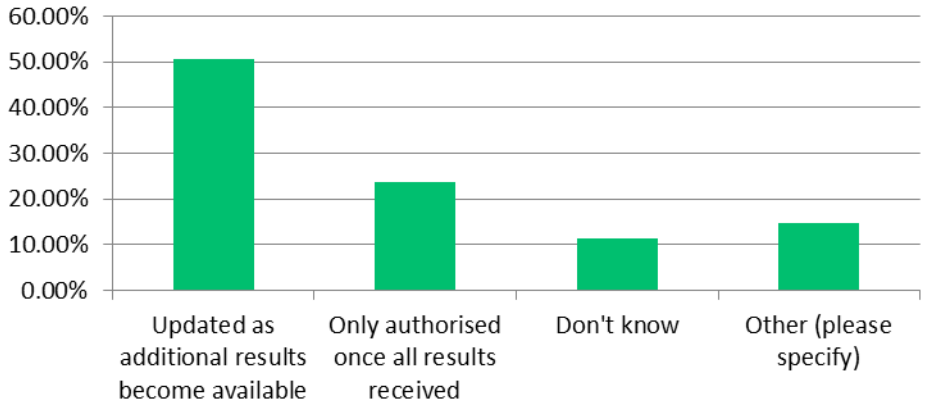
All diagnostic modalities are undertaken locally at the SIHMDS and we receive a fully integrated report	26.3%	21
All diagnostic modalities are undertaken at the SIHMDS but are not all returned in a single integrated report	6.3%	5
We only send some elements of the sample to our SIHMDS (please specify)	8.8%	7
All diagnostic modalities are undertaken 'in house' at the SIHMDS and we receive a fully integrated report	8.8%	7
Not all diagnostic modalities are undertaken 'in house' at the SIHMDS, but we receive a fully integrated report	12.5%	10
All diagnostic modalities are undertaken via a combination of local SIHMDS and reference centre testing, and we receive a fully integrated report	15.0%	12
Don't know	2.5%	2
Other (please specify)	20.0%	16



Other:

- No fully integrated report received
  - "Some modalities are undertaken locally, other are outsourced, there is no unified integrated report"
  - "we send to multiple places and lack an integrated report"
- Adult testing only
  - "We don't use our local SIHMDS as it only currently deals with adult cases, we only send second reporting requests (usually myeloid) or NGS panels there, plus some specialised flow such as PNH."

Q12 – Are integrated reports updated as further results are received?

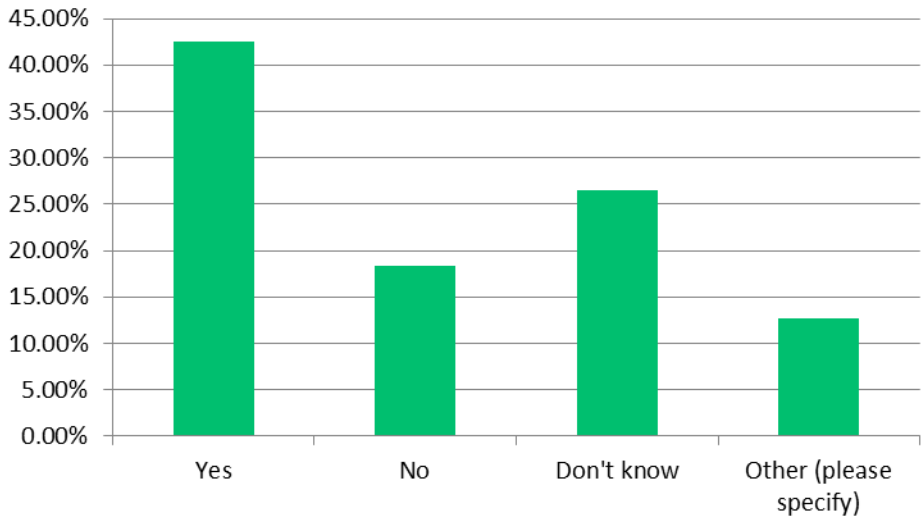


Updated as additional results become available	50.6%	45
Only authorised once all results received	23.6%	21
Don't know	11.2%	10
Other (please specify)	14.6%	13

Other:

- Variable
  - Some reports are held pending all results; others are issued as interim reports and updated with new results. All provisional and authorised results within the case are visible to clinical users
- Added as addenda
  - "they are added on, as addendum, but no effort is made to reach conclusion for NGS or WGS"
- No integrated report

Q13 – Are clinical staff alerted if an updated report is issued?

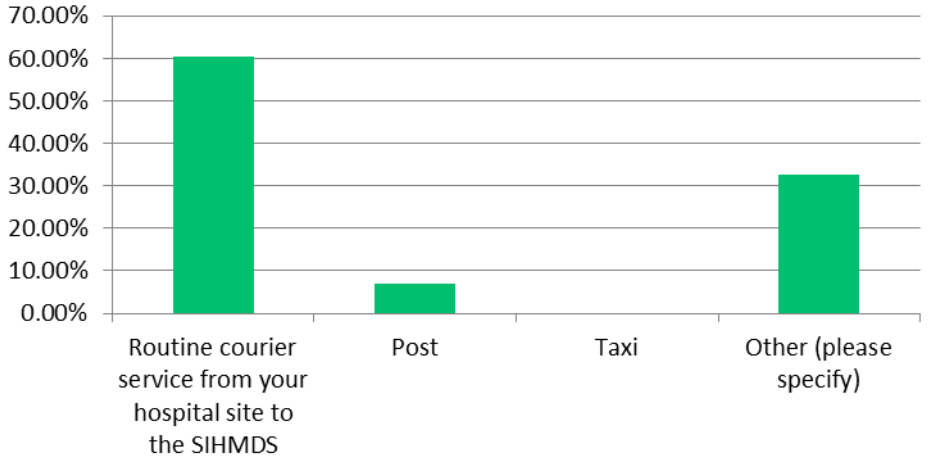


Yes	42.5%	37
No	18.4%	16
Don't know	26.4%	23
Other (please specify)	12.6%	11

Other:

- Certain scenarios/tests
  - "Urgent diagnosis telephoned as results become available, e.g flow cytometry confirms acute leukaemia, LN biopsy confirms high grade lymphoma, urgent genomics (FLT-3, PML-RARA)"
  - "…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 the diagnosis"
- "Only if clinical staffs sign up for email alert."

Q14 – If your SIHMDS is not located at your hospital site, how do you transport samples?

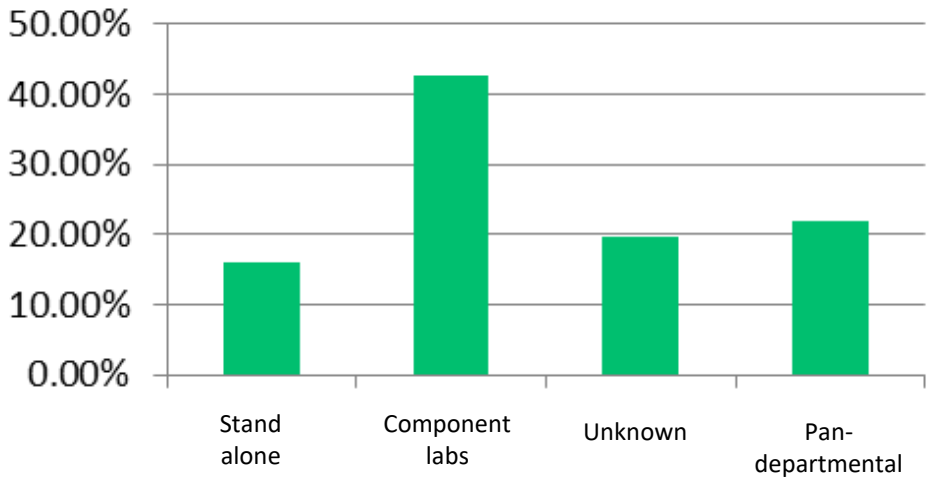


Routine courier service from your hospital site to the SIHMDS	60.3%	35
Post	6.9%	4
Taxi	0.0%	0
Other (please specify)	32.8%	19

Other:

- Combination of methods
  - "Some testing performed on the hospital site other testing sent by routine courier service, post or courier"
- "Volunteer courier service provides both regular and ad hoc deliveries."

Q15 – How is your SIHMDS laboratory ISO15189:2012 accredited?



As a stand-alone SIHMDS service	16.1%	14
Individual component laboratory accreditations	42.5%	37
Unknown	19.5%	17
pan-departmental accreditation, e.g. pathology, blood sciences (please specify)	21.8%	19

Q16 – Do you think there should be specific UKAS standards for SIHMDS laboratories?

No – 23.6%

- "Having it as part of the general medical laboratory review process is adequate"
- "…The 'business' of the lab should not affect QMS and test accreditation. It is a quality standard"
- "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 …"
- "…the specific SIHMDS standards sit with Peer Review but I do feel that UKAS inspectors should be aware of what an SIHMDS is"
- "No- the current structures don't support that thinking…However, there should be standards that should be included in the current ISO 15189… (e.g. integrated reports, genomics validation etc.)"

Q16 – Do you think there should be specific UKAS standards for SIHMDS laboratories?

Undecided – 6.9%

- "I dont know, but would feel right"
- "…there should be assessment of the integration aspect of the SIHMDS though this should not be done through UKAS."
- "Depends on how specific these would be …"
- "If they are based on appropriate clinical guidelines and support best practice it seems fitting."
- "…this could be difficult to implement given the flexibility that has been required since the advent of the GLH model"
- "…peer review for SIHMDS has fallen by the wayside, I would like to see some form of systematic accreditation for all SIHMDSs…"
- "Not specific standards but there could be accreditation for the provision of an integrated report on the schedule of accreditation"

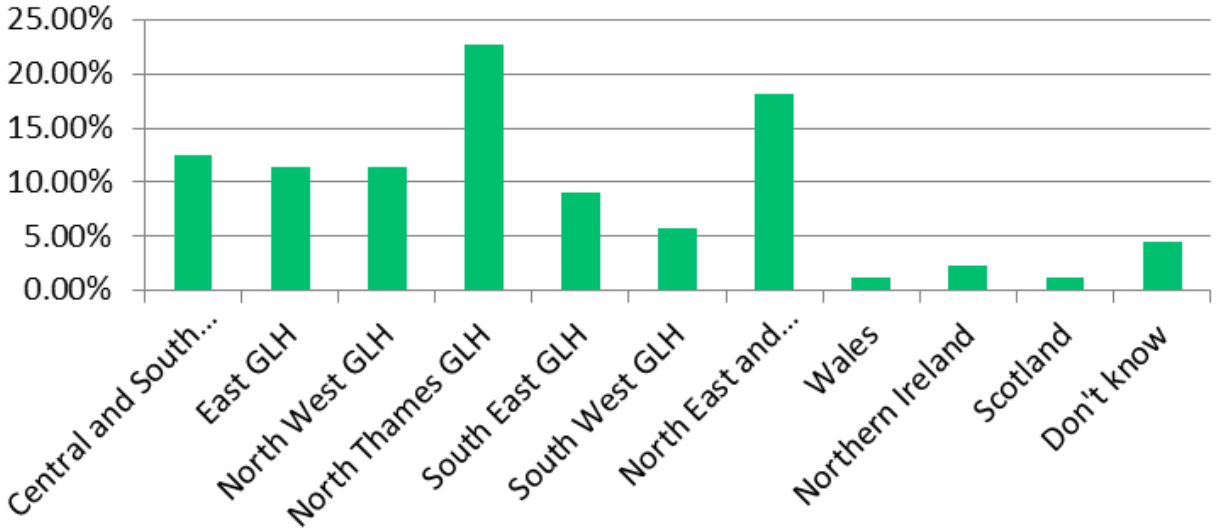
Q16 – Do you think there should be specific UKAS standards for SIHMDS laboratories?

Yes – 69.5%

- "It would be useful yes as long as it was complimentary to other standards"
- "…assessors should assess against NICE guidance NG47 as well as ISO15189"
- **"…**this would help standardise and provide clear expectations of what an SIHMDS should provide (including governance and leadership)"
- "Yes, but our extension to scope changes too often and UKAS needs to be more flexible"
- "Yes, integration/integrated functioning of SIHMDS is key; not exactly standardised across the UK . SIHMDS are not directly comparable at present with respect to WHO diagnostic subtypes or patient outcomes; UKAS standards would be the 1st step."

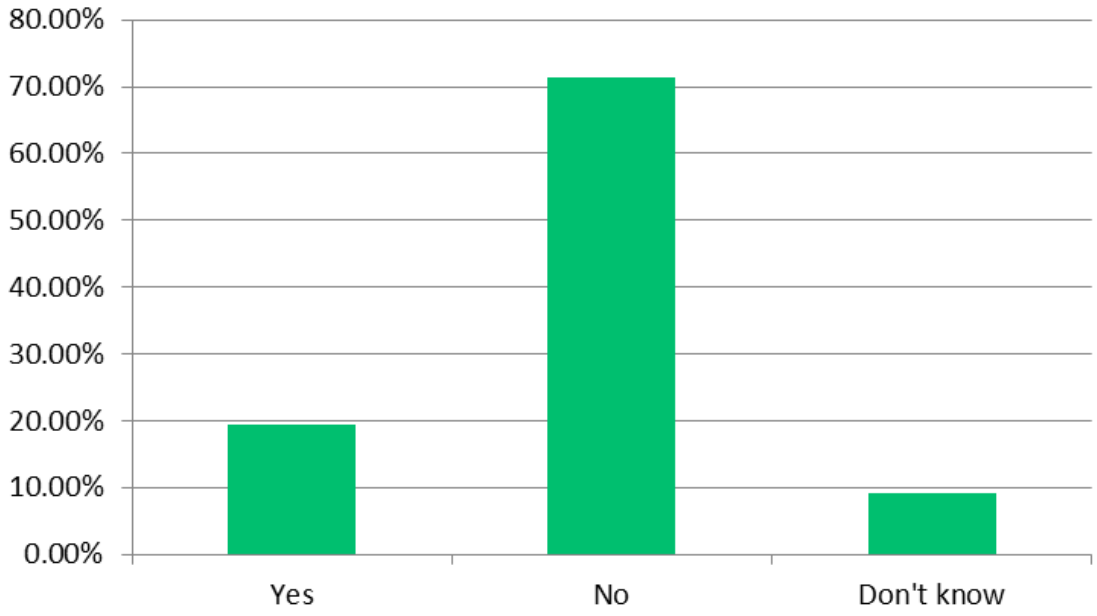
Genomic Section

Q17 – What region is your GLH in?



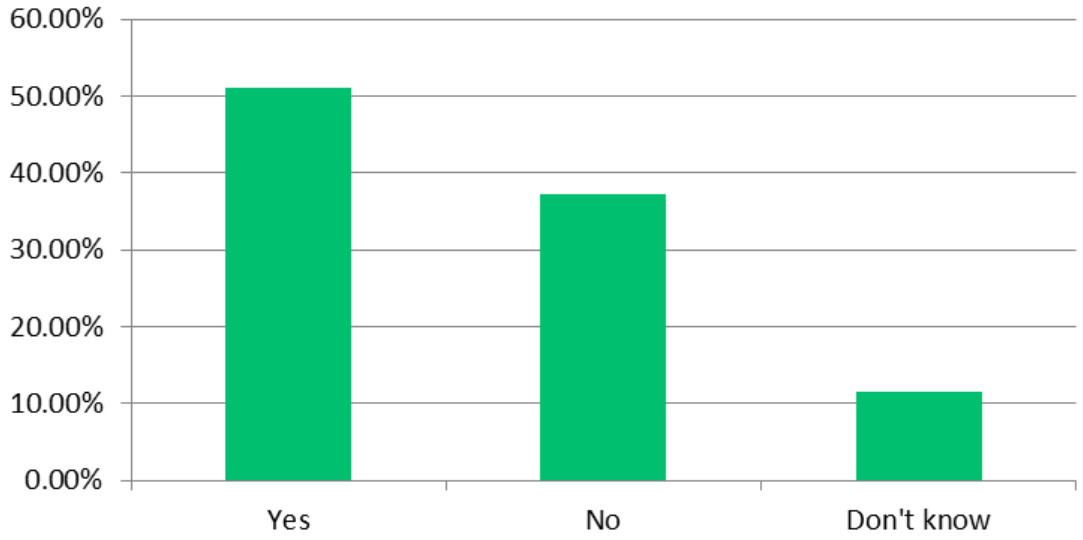
Central and South GLH	12.5%	11
East GLH	11.4%	10
North West GLH	11.4%	10
North Thames GLH	22.7%	20
South East GLH	9.1%	8
South West GLH	5.7%	5
North East and Yorkshire GLH	18.2%	16
Wales	1.1%	1
Northern Ireland	2.3%	2
Scotland	1.1%	1
Don't know	4.6%	4

Q18 – Is your SIHMDS service located at the same site as a GLH?



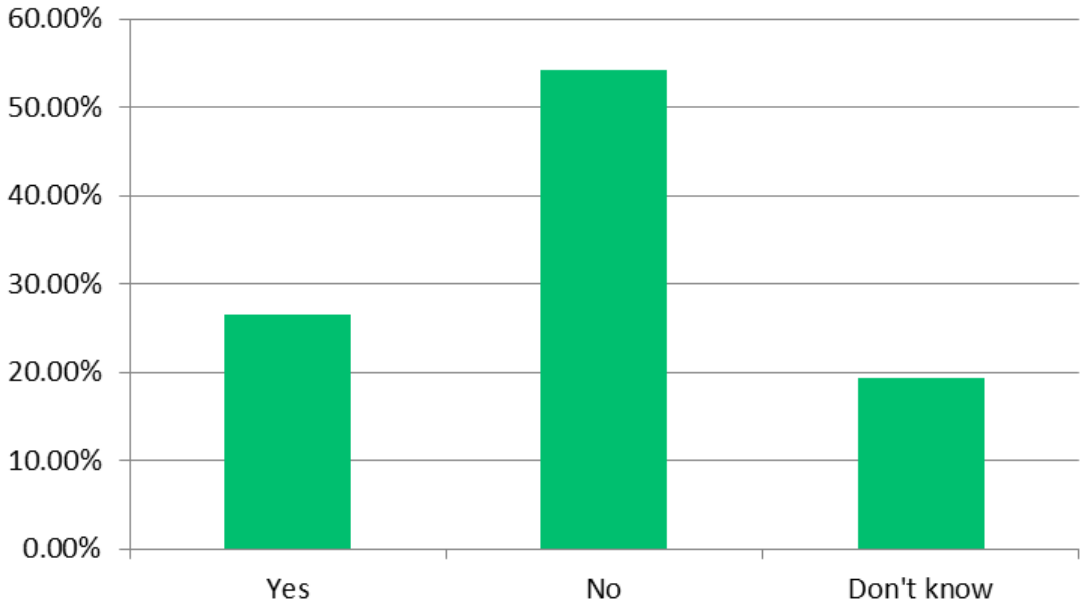
Yes	19.5%	17
No	71.3%	62
Don't know	9.2%	8

Q19 – Is your SIHMDS service located at the same site as a LGL?



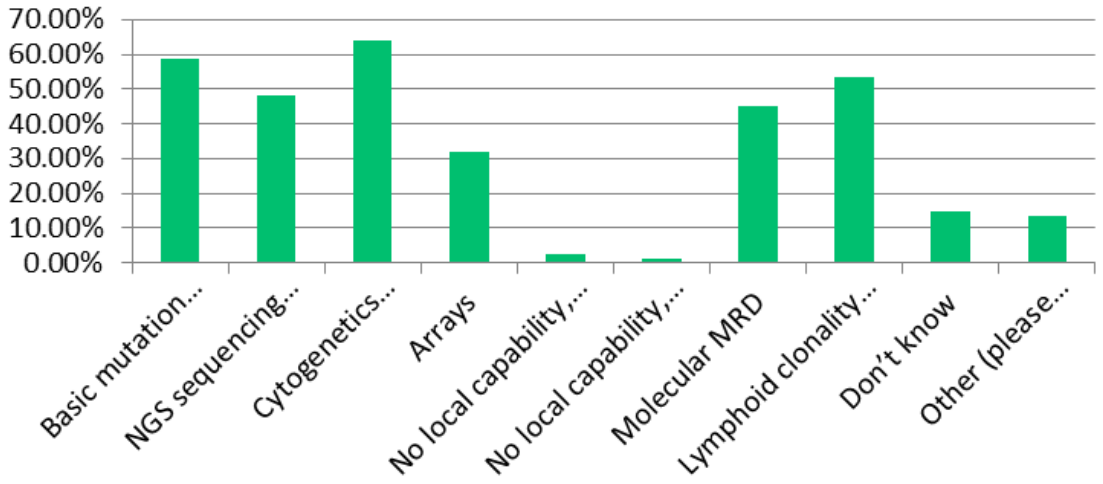
Yes	51.2%	44
No	37.2%	32
Don't know	11.6%	10

Q20 – Is your SIHMDS service on a separate site to both GLH and LGL?



Yes	26.5%	22
No	54.2%	45
Don't know	19.3%	16

Q21 – Does your SIHMDS have any local molecular testing capabilities?

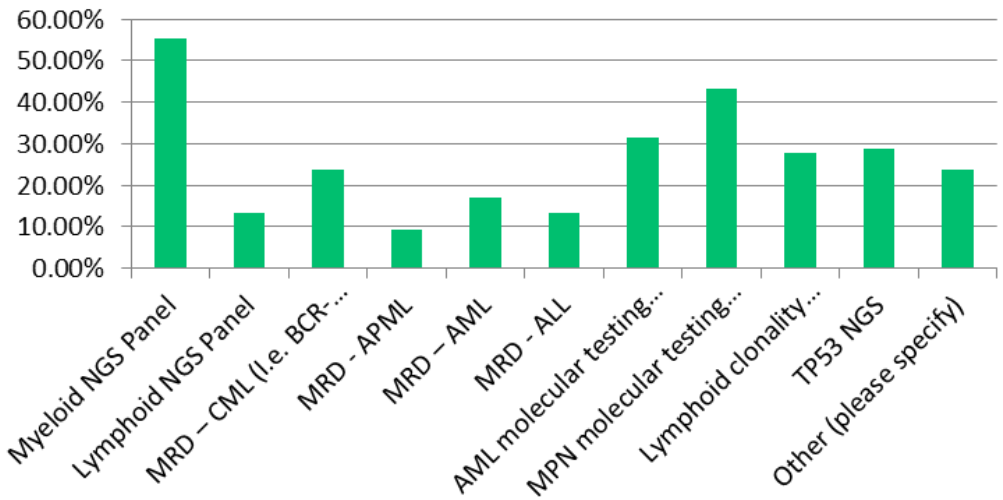


Basic mutation analysis	58.7%	44
NGS sequencing capacity	48.0%	36
Cytogenetics (karyotype/FISH)	64.0%	48
Arrays	32.0%	24
No local capability, all testing sent to GLH	2.7%	2
No local capability, testing sent to combination of GLH and other external centres	1.3%	1
Molecular MRD	45.3%	34
Lymphoid clonality assessment	53.3%	40
Don't know	14.7%	11
Other (please specify)	13.3%	10

Other:

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

Q22 – Which of the following do you most commonly request from GLH? *(Top 3 choices)*

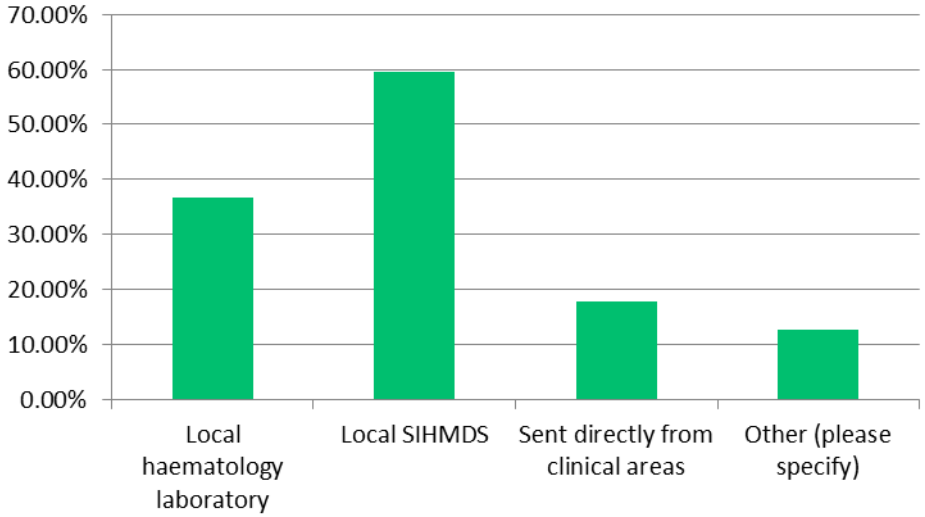


Myeloid NGS Panel	55.3%	42
Lymphoid NGS Panel	13.2%	10
MRD – CML (I.e. BCR-ABL)	23.7%	18
MRD - APML	9.2%	7
MRD – AML	17.1%	13
MRD - ALL	13.2%	10
AML molecular testing (FLT3/NPM1)	31.6%	24
MPN molecular testing (JAK2/CAL-R/MPL)	43.4%	33
Lymphoid clonality assessment	27.6%	21
TP53 NGS	29.0%	22
Other (please 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 **[]**. Clinical teams send directly and bypass the SIHMDS to reduce delays and maintain sample integrity"

Q23 – Who is responsible for sending samples to the GLH?

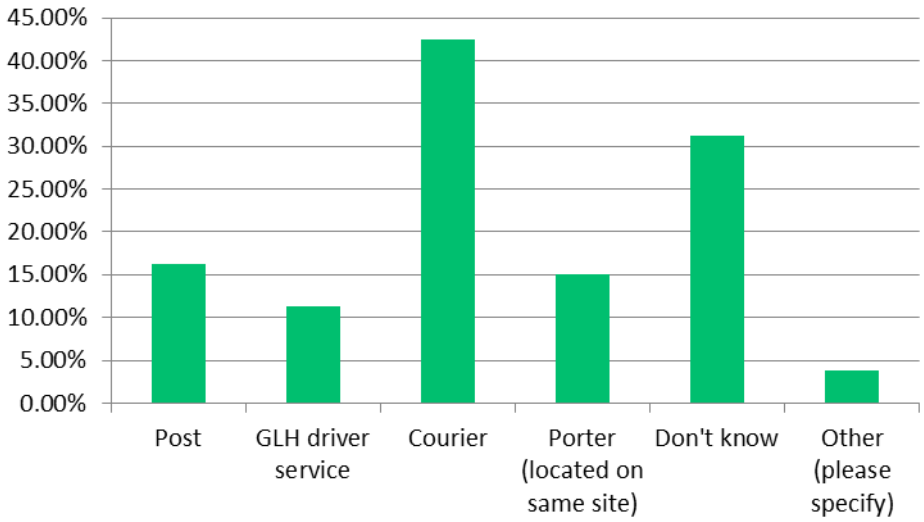


Local haematology laboratory	36.7%	29
Local SIHMDS	59.5%	47
Sent directly from clinical areas	17.7%	14
Other (please specify)	12.7%	10

Other:

- Cellular pathology
  - "… sends all formalin fixed paraffin embedded material"
- Local genomics service

Q24 – How are samples routinely transported to your GLH?

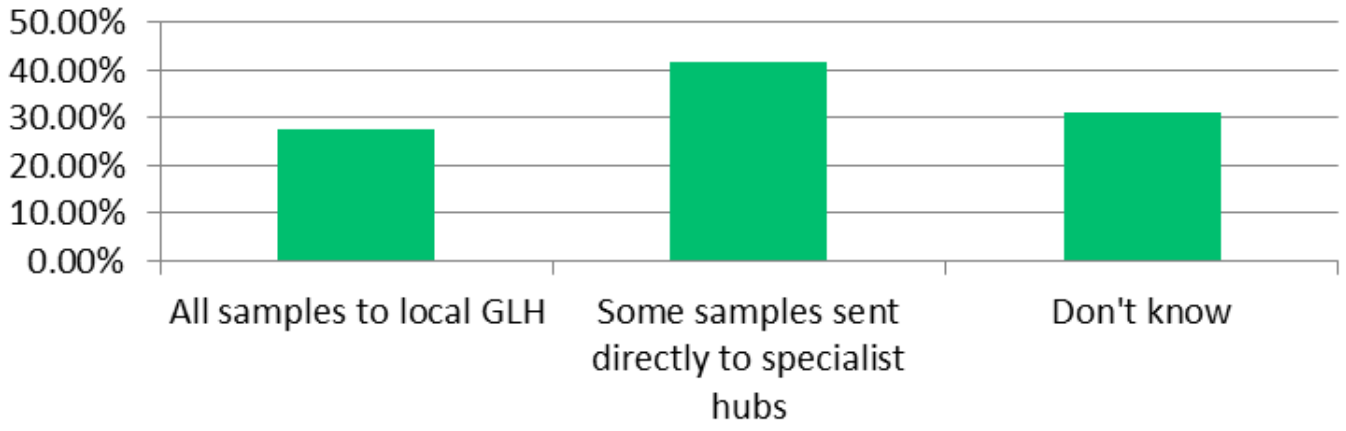


Post	16.3%	13
GLH driver service	11.3%	9
Courier	42.5%	34
Porter (located on same site)	15.0%	12
Don't know	31.3%	25
Other (please specify)	3.8%	3

Other:

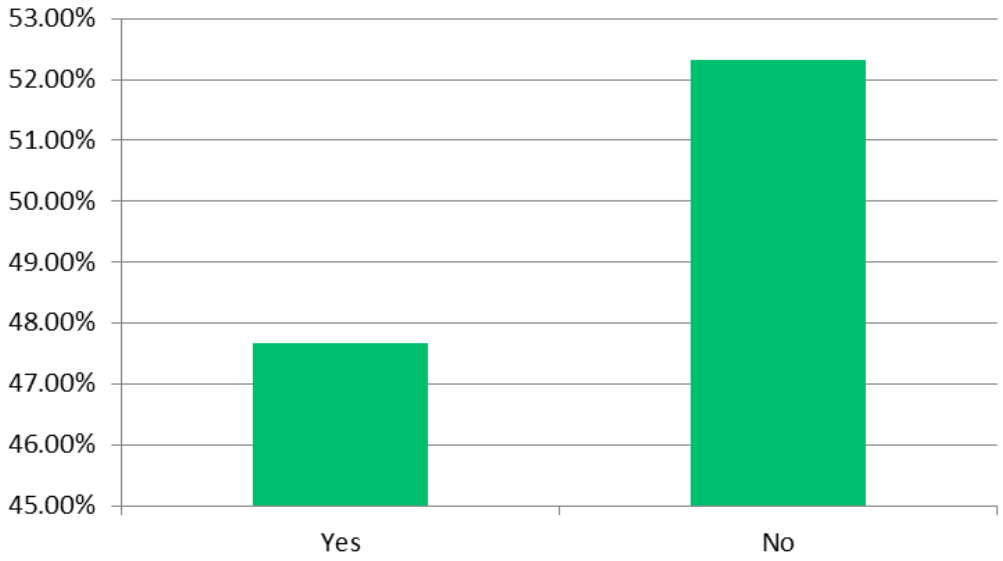
- Combination of methods
- No GLH testing required

Q25 – Do you send all samples for GLH analysis to your local hub, or direct to specialist centres?



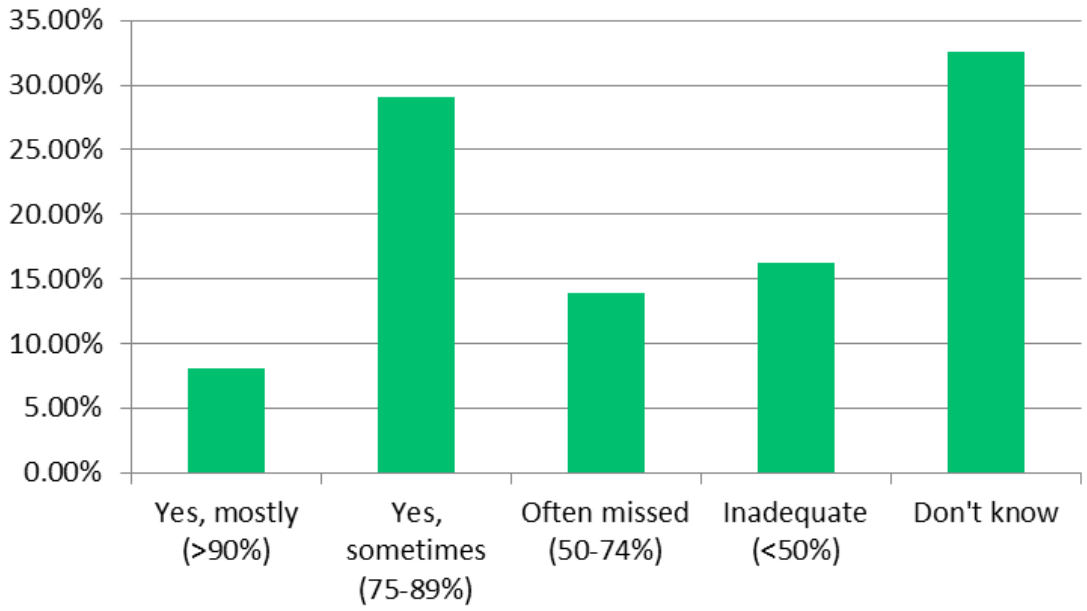
All samples to local GLH	27.4%	23
Some samples sent directly to specialist hubs	41.7%	35
Don't know	31.0%	26

Q26 – Are you aware of published GLH turnaround times?



Yes	47.7%	41
No	52.3%	45

Q27 – Do you feel GLH turnaround times are met?



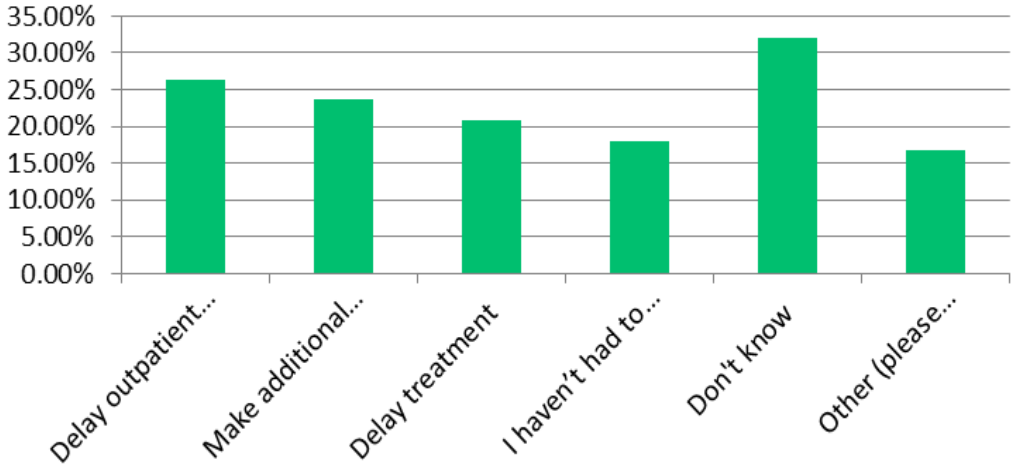
Yes, mostly (>90%)	8.1%	7
Yes, sometimes (75-89%)	29.1%	25
Often missed (50-74%)	14.0%	12
Inadequate (<50%)	16.3%	14
Don't know	32.6%	28

Q28 – If you feel turnaround times aren't mostly met, are any particular tests 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…"

Q29 – If TATs not sufficiently met, have you had to change clinical practice?

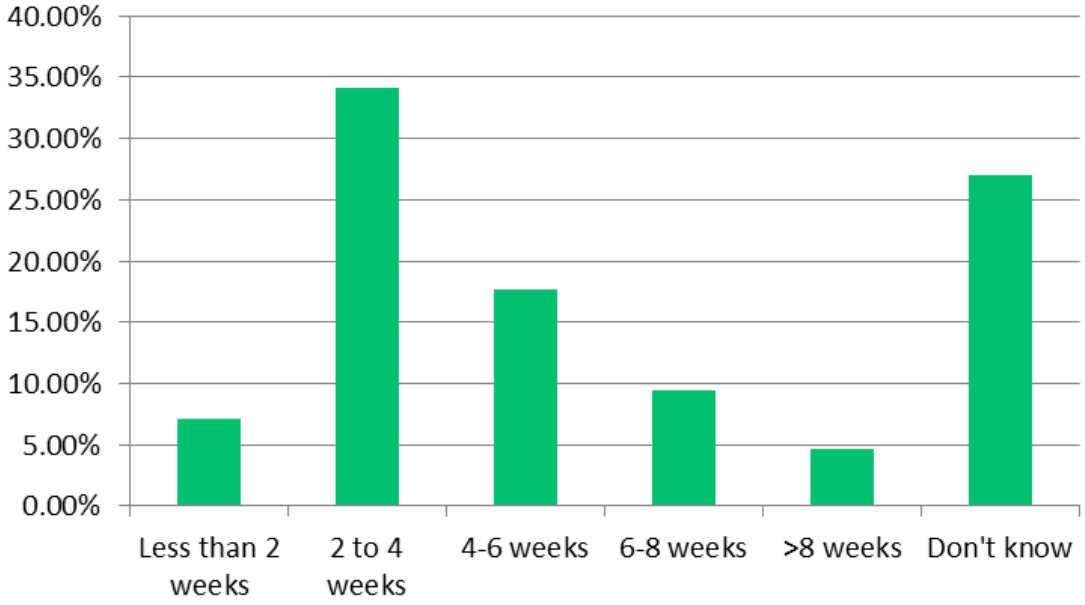


Delay outpatient appointments	26.4%	19
Make additional outpatient appointments	23.6%	17
Delay treatment	20.8%	15
I haven't had to change practice	18.1%	13
Don't know	31.9%	23
Other (please specify)	16.7%	12

Other:

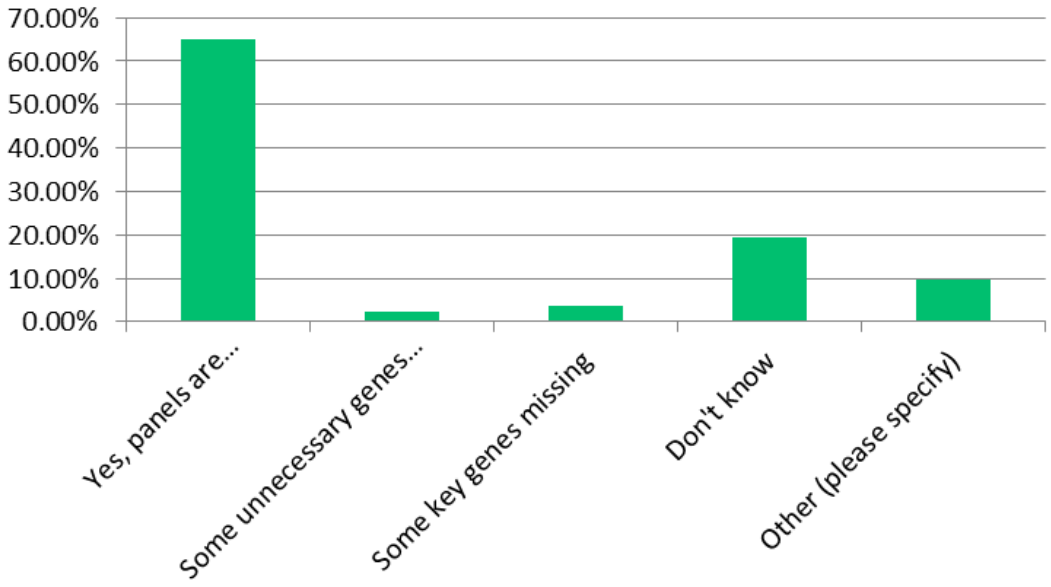
- Relist/delay MDT discussions
- Contribute to misdiagnosis
- Additional treatment
- "Usually have to send Lymphoid NGS (for TP53) earlier than otherwise clinically necessary if CLL treatment is anticipated in medium-term, to avoid delays."
- "do not send to GLH to prevent delays to patient care"

Q30 – How quickly are NGS panel results returned?



Less than 2 weeks	7.1%	6
2 to 4 weeks	34.1%	29
4-6 weeks	17.7%	15
6-8 weeks	9.4%	8
>8 weeks	4.7%	4
Don't know	27.1%	23

Q31 – Are you happy with the contents of NGS panels?

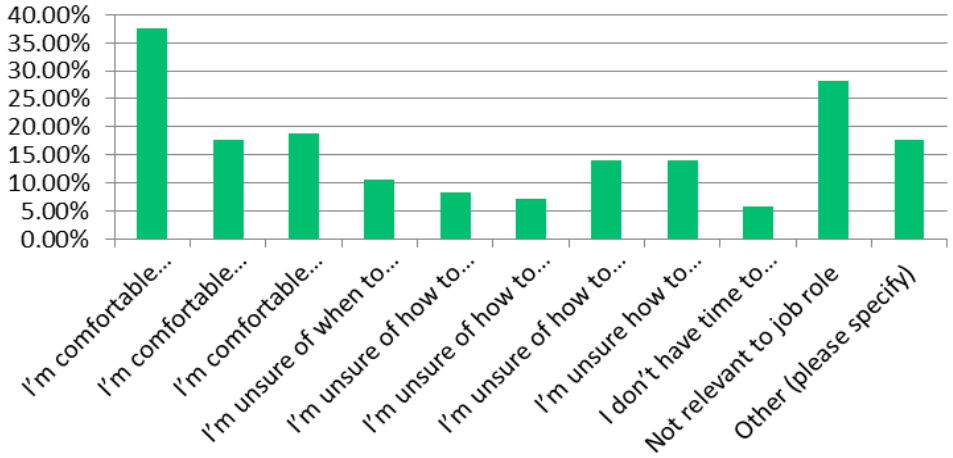


Yes, panels are comprehensive	65.1%	54
Some unnecessary genes included	2.4%	2
Some key genes missing	3.6%	3
Don't know	19.3%	16
Other (please specify)	9.6%	8

Other:

- Lymphoid NGS not available
- "Needs national modification for mds though with new diagnostic risk scores"
- Don't use GLH
  - "Don't use GLH all NGS is in house with <7 day"
  - "Our local GLH offers too many genes on large panels, which affects TATs, failure rate and sensitivity. Our local LGL SIHMDS offers a comprehensive NGS panel so no need to send to GLH Cancer Hub"

Q32 – 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

Q32 – What are your thoughts on WGS?

Other:

- 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.”
  - “WGS is academically interesting but for the majority of patients does not change immediate clinical management “
  - “WGS is a research tool primarily. Limited evidence of its utility as a one off in haem malignancy diagnosis.”
  - “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.”
  - “Its a research tool, not routine diagnostics.”
  - “WGS is a research tool/pilot currently. It may have promise in teh future, but is burdensome”
  - “Largely academic, issues of applying to tissue, unlikely to yield clinically significant or actionable mutations in significant numbers at this time”

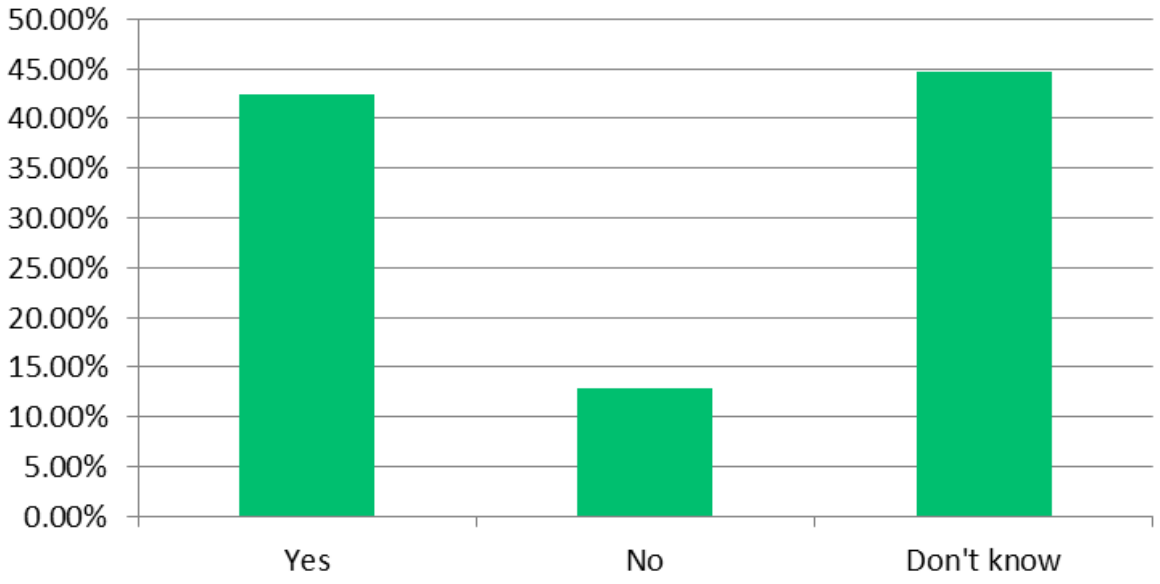
Q32 – What are your thoughts on WGS?

Other:

- Impacts on other investigations
  - “Don't think it is working for Haem Onc in clinical setting as bascially 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
  - “rarely required”
  - “I understand the principals but for my clinical cohort it’s not available so haven’t done it directly.”
  - “We don't have access to exome sequencing or targeted sequencing; hence WGS is not a consideration presently.”
  - “WGS not currently offered in **[]**”

Q33 – Is there an established referral pathway to clinical genetics if constitutional abnormalities found?



Yes	42.4%	36
No	12.9%	11
Don't know	44.7%	38

Q34 – Do you think there are any 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….”
  - “Requires pt informed consent at a difficult time of diagnosis”
  - “Time taken to complete all of the consent forms…”

- Clinical Utility
  - “little engagement by clinicians, they don’t see WGS is producing anything valuable to their practice and even if something interesting is found it can be at least 6 months until results are available at my local GLH.”
  - “… the perception of lack of utility, in part driven by the long turn around times and results which lack clinical actionability”
  - “The TAT for WGS means this is not always clinically relevant, but it is always completed as an adjunct to SOC testing.”
  - “Greater training of clinicians on how to interpret and act on the results”

Q34 – Do you think there are any barriers to WGS?

- Time/resource availability
  - "No additional resource available to implement WGS. No additional scientific staff available to analysis and report."
  - "Lack of staff"
  - "Clinician time and resources (needs coordination between IP and OP setting often)"
  - "…concern locally about resources available to support investigation/counselling of unexpected constitutional symptoms"

- Requesting/Testing pathways
  - "The fact that NGIS (national genomics informatics system) will sit outside of existing electronic requesting pathways that are in use for the rest of pathology. I think clinicians will be reluctant to use multiple different systems. NGIS does not fit with the SIHMDS model…"
  - "…the pathway seems to be messy as there are lots of potential routes and tests have to go through many hands…"
  - "…Requires direct communication between clinical teams and GLH. SIHMDS will post the sample but are not generally involved in coordinating the process"

Q34 – Do you think there are any barriers to WGS?

- Access to testing
  - “Histopathologists have little access…should be accessible to all medical professionals that deal with cancer”
  - “…lack of buy-in from DGH clinicians”

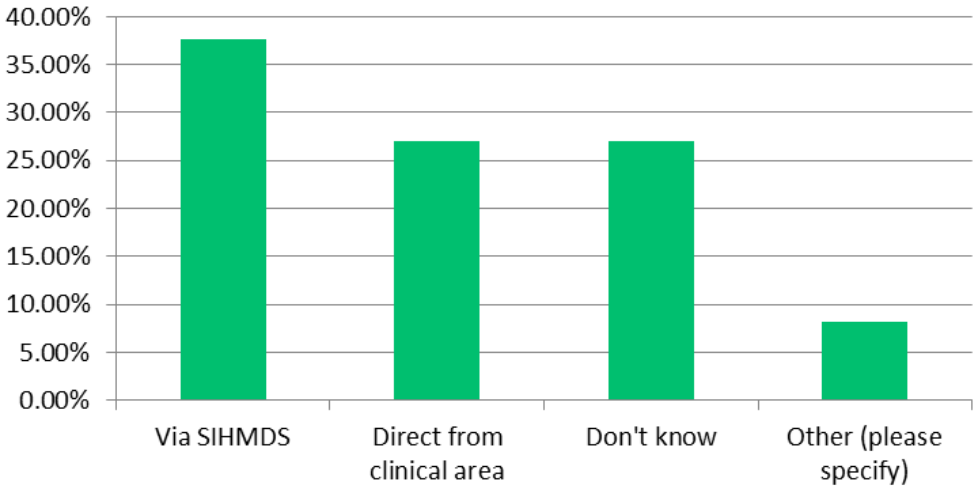
- Issues with testing
  - “biopsies are too small so not enough tissue to freeze”
  - “RNA based WGS on paraffin embedded material is functionally useless (33% fail rate) at the expense of diagnostic delay of at least 20-30 days”

- Germline sampling
  - “…It's manageable, but getting the skin biopsy done can be logistically challenging”
  - “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”
  - “…major issue is obtaining and handling (resources and pathways) fresh tissue”
  - “Time and staff able to do a skin biopsy”
  - “The germline sampling and ROD are probably reducing clinicians desire to send samples”

Q34 – Do you think there are any 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”

Q35 – Do you have a pathway for sending bone marrow failure/non-malignant investigations?



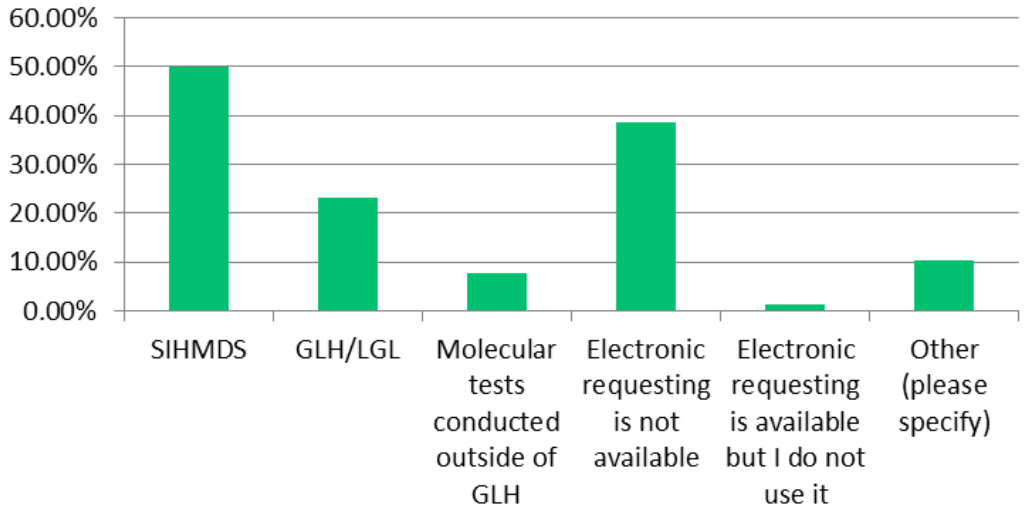
Via SIHMDS	37.7%	32
Direct from clinical area	27.1%	23
Don't know	27.1%	23
Other (please specify)	8.2%	7

Other:

- In house testing
- Via local genomics
- Ad hoc arrangements
  - "…some from various labs, others direct from clnical 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"

IT Section

Q36 - Do you use electronic requesting for SIHMDS/GLH/LGL tests?

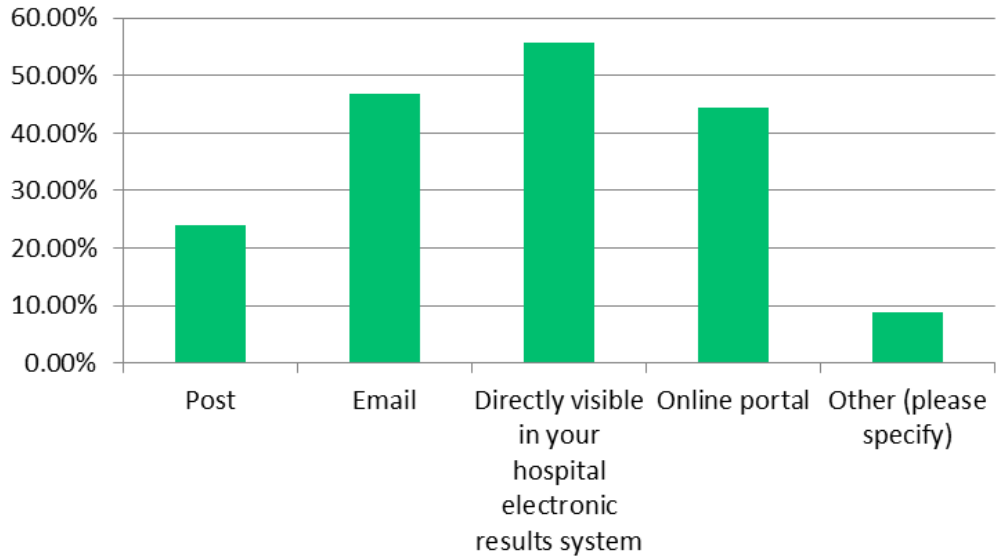


SIHMDS	50.0%	39
GLH/LGL	23.1%	18
Molecular tests conducted outside of GLH	7.7%	6
Electronic requesting is not available	38.5%	30
Electronic requesting is available but I do not use it	1.3%	1
Other (please specify)	10.3%	8

Other:

- Combination
  - "Molecular pathology department shares a LIMS with the rest of pathology and therefore requests can be made electronically. For other GLH laboratory tests paper requesting is used."
  - "Can be either paper/electronic"
- Not available
  - "no - we need better"

Q37 – How do you receive results from your SIHMDS?

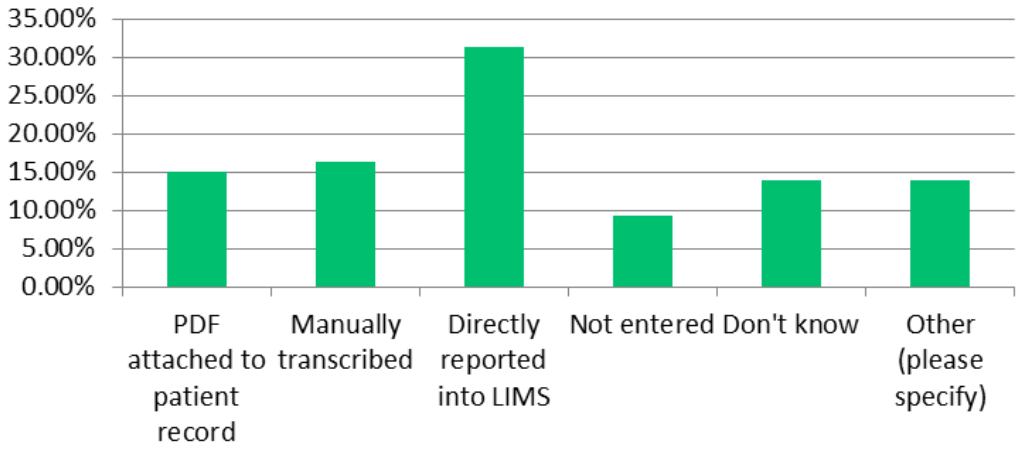


Post	24.1%	19
Email	46.8%	37
Directly visible in your hospital electronic results system	55.7%	44
Online portal	44.3%	35
Other (please specify)	8.9%	7

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"

Q38 – How are SIHMDS results entered into your LIMS?

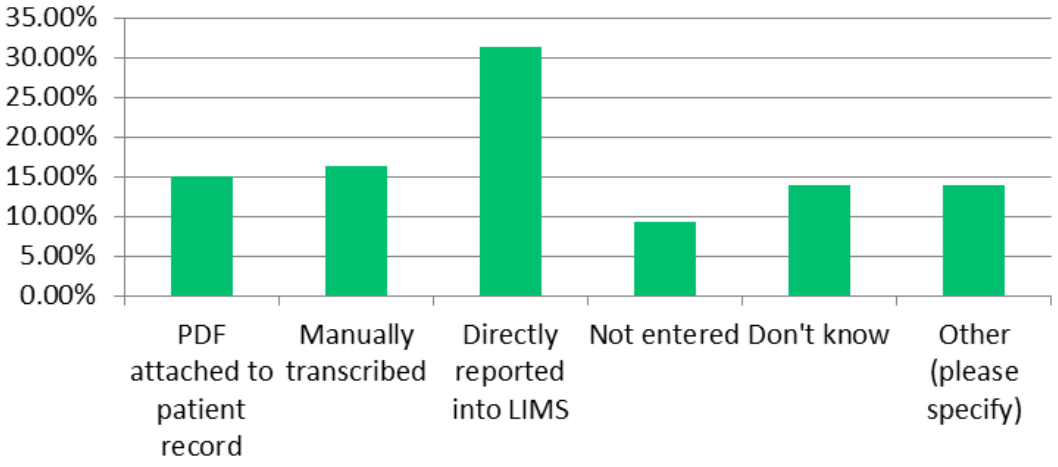


PDF attached to patient record	15.1%	13
Manually transcribed	16.3%	14
Directly reported into LIMS	31.4%	27
Not entered	9.3%	8
Don't know	14.0%	12
Other (please specify)	14.0%	12

Other:

- Combination
  - "In-house tests directly into LIMS. Entire reports are uploaded for referrals as well as summary being cut and paste directly into IR with reference to entire report. Occasionally manually transcribed if not received as pdf version(rare sendaways)"
  - "All results are present on the SIHMDS LIMS system. 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."

Q39 – How do clinicians receive results from GLH?

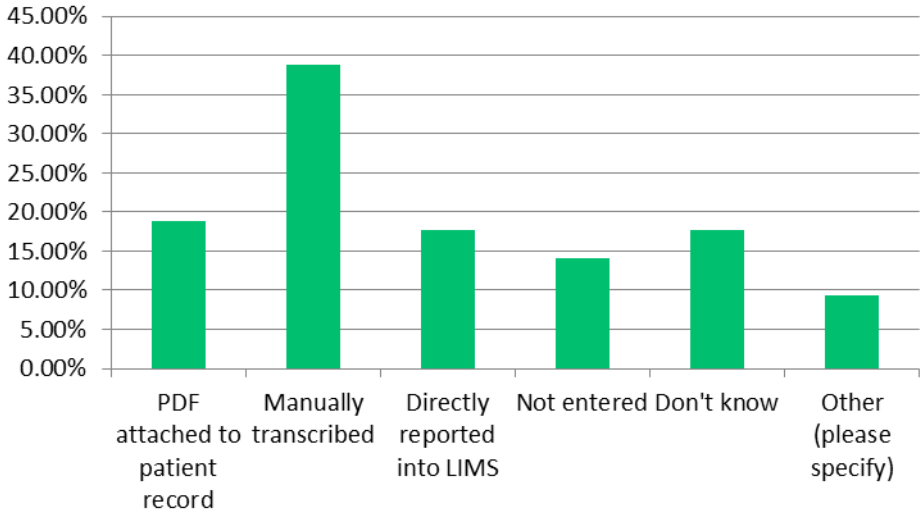


PDF attached to patient record	15.1%	13
Manually transcribed	16.3%	14
Directly reported into LIMS	31.4%	27
Not entered	9.3%	8
Don't know	14.0%	12
Other (please specify)	14.0%	12

Other:

- Don’t use GLH
  - “This is for **[]** MRD. Sending to our GLH is so rare.”
  - “Our SIHMDS is not part of GLH Cancer hub, which makes things easier”

Q40 – 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."

Q41 – How significant is the impact of not having an integrated IT network between GLH and SIHMD/LIMS?

Significant (79.2%)

- "This is a major issue, patient safety (transcription errors), huge resource, delays reports, hinders integration."
- "…this needs addressing at a national level"
- "Timeliness and ability to interrogate primary data for quality assurance and clinical interpretation is the central role of any oncogenomics MDT"
- "Reports are not always sent to correct contacts. Results are hard to track down and not easy to locate. Any data received as a PDF is not useful for auditing or data mining…"
- "Risk of the loss/errors/delay of data when transferring data between IT systems. True TATs is difficult to capture & monitor"

Q41 – How significant is the impact of not having an integrated IT network between GLH and SIHMD/LIMS?

Significant (79.2%)

- "If messaging standards (HL7) were created for genomics results then they could be incorporated in to pathology LIMS systems as well as genomics LIMS systems. This would facilitate electronic requesting and reporting as well as sample tracking. In addition it is very difficult to report molecular testing (as a GLH laboratory) without access to full clinical details."
- "…the whole report cannot be entered due to the line limit in our LIMS so only the headlines are copied across"
- "Very significant increase in time spent doing paperwork and chasing results. Many results are not incorporated into final report."
- "…lower quality of diagnosis, exposed to errors, incredible delays, lack of availability of diagnostic platforms, lack of capacity to develop based on clinical demand and rapidly introduce novel tests, lack of capacity for research"

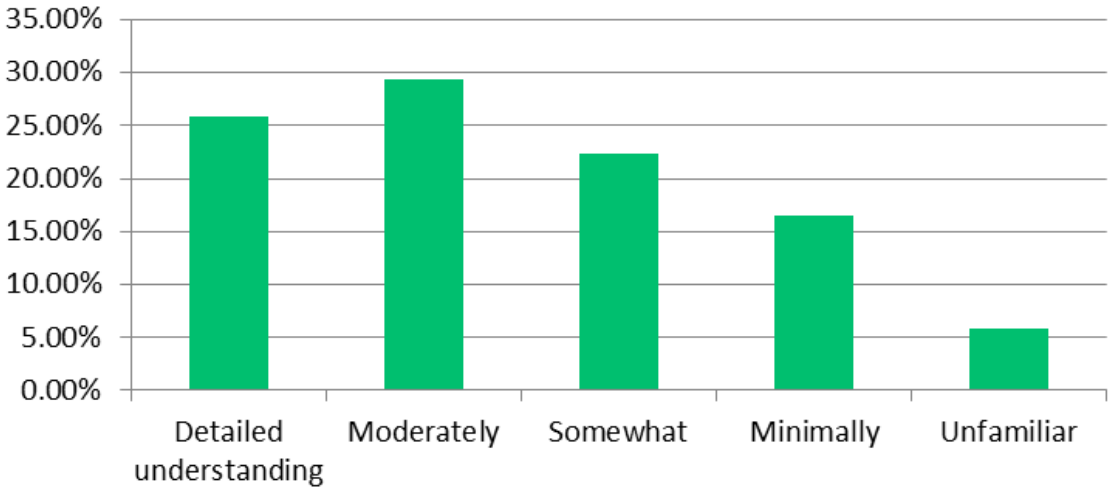
Q41 – How significant is the impact of not having an integrated IT network between GLH and SIHMD/LIMS?

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 ^^"

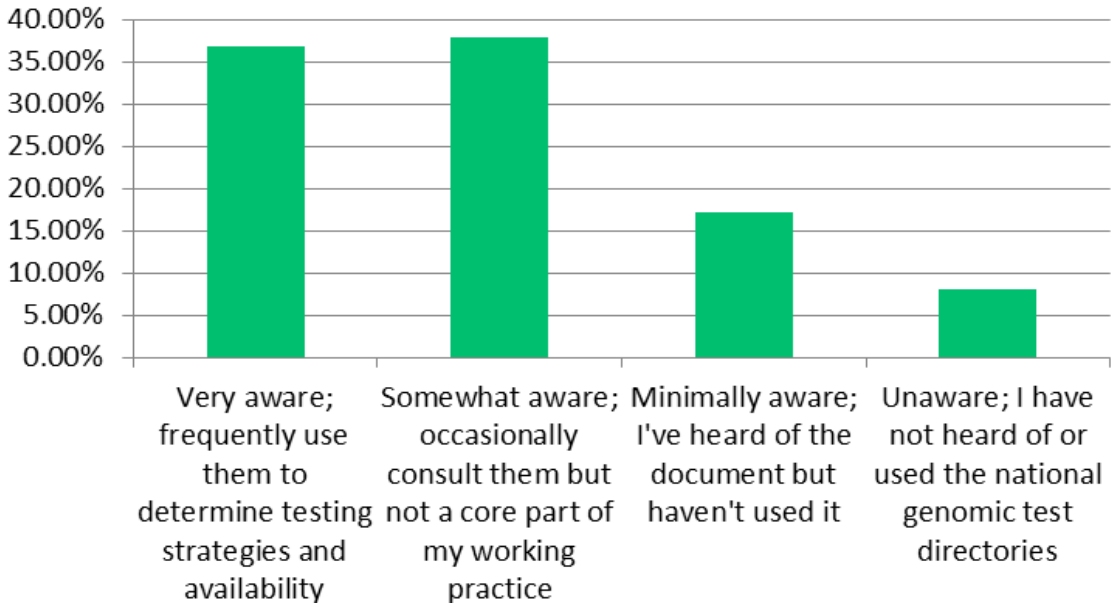
Genomic Reconfiguration Section

Q42 – How familiar are you with the GLH reconfiguration?



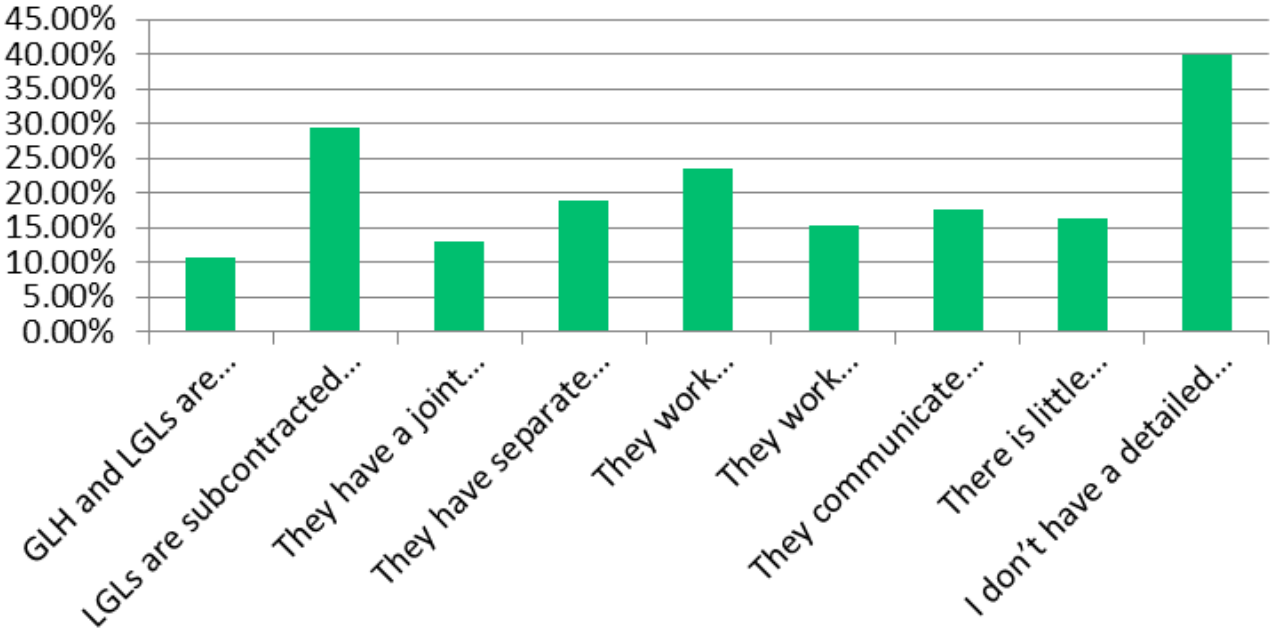
Detailed understanding	25.9%	22
Moderately	29.4%	25
Somewhat	22.4%	19
Minimally	16.5%	14
Unfamiliar	5.9%	5

Q43 – 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

Q44 – 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

Question 45 – Is there anything else you would like to highlight about the GLH/LGL relationship?

- “The services of the LGL are essential in maintaining a functional resilient service. There are specific areas that the GLH do not have expertise in, and where LGLs have expertise in these areas, it makes sense to keep those services in LGL rather than deliver a new (and sub-optimal) service from a GLH for the sole purpose of saying everything is centralised. There is too much emphasis on centralisation and not enough on rational approaches to maintaining expertise.”

- “Retention of genomic services is critical to hmds reporting. I am concerned regards clinical integration as more if these tests become contracted to hub models that have no clinical haematologist input “

- “Our SIHMDS was expecting to send all genomic testing to the LGL and the LGL reflex tests it did not offer. However we are having to send tests directly to the LGL, the GLH and to other GLHs for tests such as MRD that are not offered at our GLH. This is very time consuming. It requires complex tracking. It means that results for an integrated report can be returned in multiple manners - directly to LIMS, email of documents in various formats”

Question 45 – Is there anything else you would like to highlight about the GLH/LGL relationship?

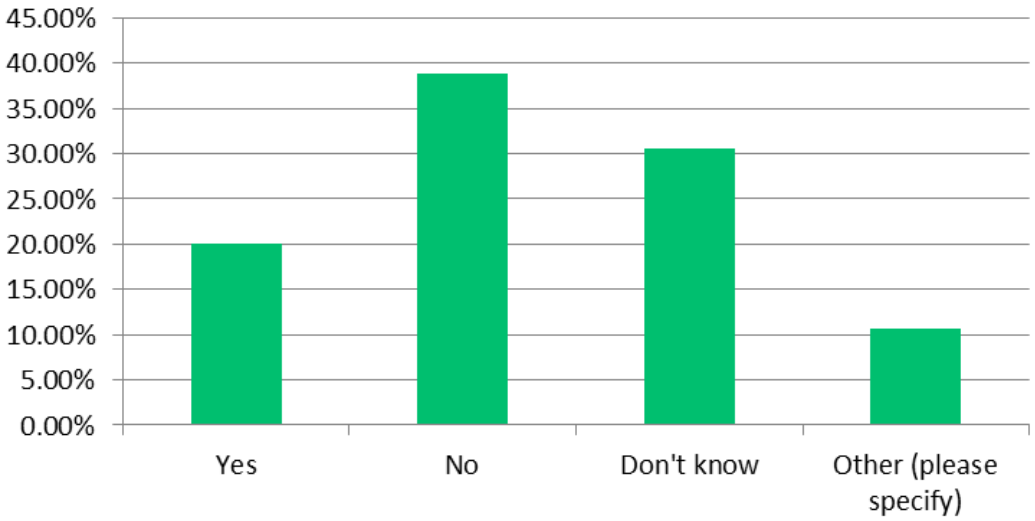
- “No unifying governance structure and no accountability if services cannot be provided at either end.”

- “Delays to certain samples a real issue - previously sent direct to test centre (in other location) but now via 2 hospitals before arriving with test centre so tests are not optimal, have failed due to sample quality meaning repeating testing for patients “

- “LGL has faster turnarounds, closer working with clinicians and better clinical context as they can call clinicians direct. Safer for patients”

- “… The SIHMDS director is responsible for the operation of the SIHMDS service, including the design of the diagnostic pathway, resource use and reporting standards within a single governance structure according to NG47...It should have a full range of age-appropriate specialist haematology and haematopathology input for diagnosis and the authorisation of integrated reports, have a full range of protocols covering specimen handling, diagnostic pathways and compilation of integrated reports and ensure that their location, organisation, infrastructure and culture allow effective day to day and ad hoc communication for rapid resolution of diagnostic uncertainty and accurate diagnosis. It is difficult to reconcile this with an external hub GLH lab with parallel governance structures. Is the SIHMDS or the GLH responsible?”

Q46 – 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

Q46 – Do you feel access to genomic testing has been improved by the Genomic Reconfiguration?

Other:

- Mixed effect
  - "Yes and no - better standardisation of tests, more equity of availability as central commissioning, but high demand and enforced repatriation / lab centralisation has led to longer TATs"
  - "no doubt improved in some areas of the country but has had no impact or even made worse in other areas of the country (esp **[]**) which were all already performing these tests"
  - "Probably a mixed effect. We had a locally developed Myeloid NGS which was lost during the reconfiguration, with a negative effect on turnaround times."

Q46 – Do you feel access to genomic testing has been improved by the Genomic Reconfiguration?

Other:

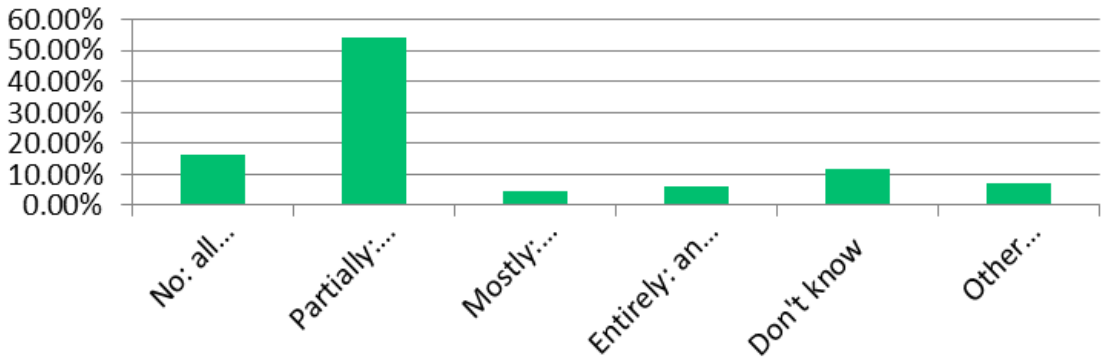
- Somewhat
  - “Some services are more easily available at other hubs than the local one.”
  - “Not sure, the testing has increased since the establishment of GLH, not necessarily because of these centers but as NGS is now more routine for patient management.”

Q46 – Do you feel access to genomic testing has been improved by the Genomic Reconfiguration?

Other:

- No
  - “I feel the process of reconfiguration has delays service development and in many tests delivers a poorer service that is now off site.”
  - “In **[]** it runs the risk of making things considerably worse and slower as risks mutilating effective and efficient SIHMDS services”
  - “there has been far too little focus on patient and clinician access to genomic testing, focus has been inappropriately focused on consolidation, at the expense of access”

Q47 – Do you think NG47 is compatible with SIHMDS labs sending genetic testing to GLHs?



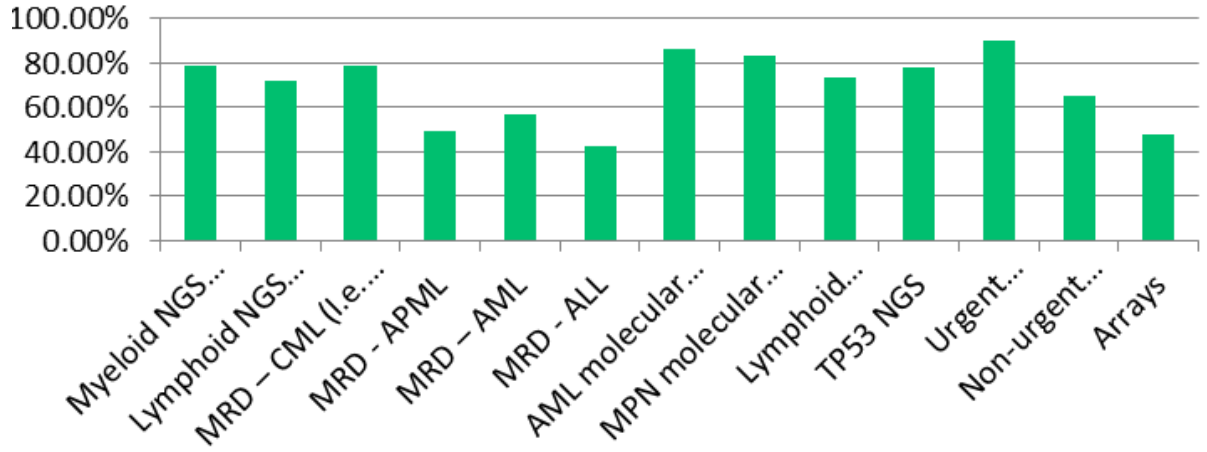
No: all SIHMDS should have the capacity to provide all genomic tests within the SIHMDS	16.5%	14
Partially: some rare haemato-oncology genomic tests can be performed outside the SIHMDS, but the majority should be provided within an SIHMDS	54.1%	46
Mostly: most genomic tests do not need to be performed within an SIHMDS	4.7%	4
Entirely: an SIHMDS does not need to provide any haemato-oncology genomic tests, if they are provided elsewhere in a cancer hub	5.9%	5
Don't know	11.8%	10
Other (please specify)	7.1%	6

Q47 – Do you think NG47 is compatible with SIHMDS labs sending genetic testing to GLHs?

Other:

- “Not sure. However, if SIHMDS send away majority of genomics tests to GLH cancer hub would they still be classed as SIHMDS? “
- “An HMDS does not need to provide any haem-onc tests if they are provided elsewhere but if they are able to and the tests meet standards/requirements then they should be allowed to”
- “The NG47 guidance requires the genomics testing to be performed as part of the diagnostic and follow up testing, as long as the testing is timely and reorted into the integrated reporting process the guidance is adhered too.”
- “According to the guidance it suggests SIHMDS should perform all genomic testing. However standardised reporting may help to integrate the results of testing performed elswhere into an integrated report such that the results can be interpreted in the context of other ancillary testing”

Q48 – What tests would you like to see provided by local SIHMDS 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

Q49 – How do you feel genomic laboratory configuration has impacted on SIHMDS development?

"It has been crippling. Relations between our SIHMDS and both the LGL and the GLH are strained. Our SIHMDS has struggled to establish clear pathways from the SIHMDS to the LGL and to the GLH. There is no joint governance structure for the LGL/GLH and no easy way to interact with the services, which are not meeting clinical need. TATs at both the LGL and GLH are very poor. the whole structure lacks IT connectivity, even between the SIHMDS and the LGL that re based on the same hospital campus but use different LIMS. There is very poor transport connectivity with the GLH and samples are having to be posted as the routine method of transport"

Q49 – How do you feel genomic laboratory configuration has impacted on SIHMDS development?

"The planning and communication has been sub-optimal, not guided by clinical needs and taking into account existing pathways and activity and this has unfortunately damaged working relationships and led to unintended and unanticipated consequences. I do think that the commissioning and funding of a national genomic medicine service with a nationally agreed and regularly updated test directory is a positive step and we need to find ways to work with this new system."

Q49 – How do you feel genomic laboratory configuration has impacted on SIHMDS development?

"Genomics reconfiguration has hindered the development of SIHMDS laboratories. SIHMDS staff and service users need to a have a strong understanding of genomics as its an integral part of the diagnostics of haemato-oncology. This knowledge and advice cannot be solely provided by the GLH. There is not the capacity within the GLH to support the SIHMDS and clinical teams. There is not the capacity to attend all the MDTs. It is vital that there is a close dialogue between all disciplines within the SIHMDS to achieve the correct diagnosis. The SIHMDS need to be able to reflex tests and change tests as and when required. This cannot always be done if a sample is sent away to the GLH …The configuration concept was not designed through clinical evidence and with the input of SIHMDS users or clinical teams. The concept was borne out of the reconfiguration of rare and inherited genetics which was already working in isolated silos."

Q50 – How do you feel developments in technology will change to model for how SIHMDS labs provide genomic testing?

"As technology becomes developed some tests will inevitably become more 'black-box' and easier to provide locally once again. Question will be do pathology labs locally have space, staff, expertise and desire to retake on this work, especially given likely future monetary constraints… Some work will remain best provided by GLH, this is not denied. However, as per us locally we are able to provide world class IGHV service for CLL - this not currently well acknowledged by our GLH or catered for in the idealised model."

Q50 – How do you feel developments in technology will change to model for how SIHMDS labs provide genomic testing?

"Rapid testing technologies, capable of running smaller batches of samples with a rapid TAT (overnight NGS, long read PCR) will allow the SIHMDS laboratories to provide much quicker TAT. The 24hr delay inevitable in sending samples to the GLH hub will become a much higher percentage of the time delay to a result as these technologies advance. The cost of the instrumentation and reagents will also reduce, meaning the financial impact of consolidation will be less"

Q50 – How do you feel developments in technology will change to model for how SIHMDS labs provide genomic testing?

"At the moment we are in a phase of centralisation but with workload volumes and complexity increasing I think it is essential that we retain regional expertise and that imminent technological advances will lead to some devolution of testing again."

"I'm sure over time new technologies, such as long read sequencing, NGS MRD, WGS, RNA fusion panels will change the technologies used for genomic testing and there will be reduction in G banding and FISH testing. These changes should be led by the clinicians and scientists of the SIHMDSs with specialist haem-onc knowledge."

Q50 – How do you feel developments in technology will change to model for how SIHMDS labs provide genomic testing?

"The need for rapid testing and more comprehensive testing will increase over time. Closer to patient testing, RNA testing and ct-DNA will increase. Delays due to transporting samples to a GLH hours from the bedside will not be possible as the samples will become too old. Consolidation into large factory-like laboratories does not always improve patient care"

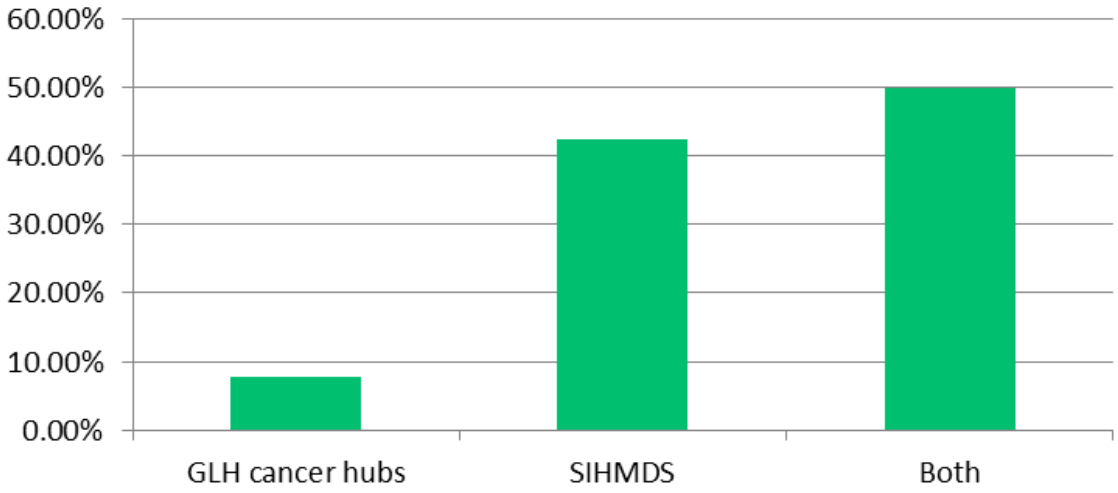
"…there is opportunity for funding and indeed more adventurous developments if managed in a consolidated, collaborative and innovative way."

"Virtual SIHMDS would be possible and co-location may not be necessary to achieve excellence"

Q50 – How do you feel developments in technology will change to 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"

Q51 – 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

Q52 – What else could be done to ensure equity of access to genomic testing?

Accreditation/Standards

- “Proper peer review with sihmds accreditation”
- “The main starting point is to ensure appropriate configuration and accreditation of SIHMDS services. There are probably very few in teh UK that come up to the required standard.”
- “The professional bodies including NICE, BSH, BLPG, Royal College of Pathologists and UKAS could mandate standards for Haemato-Oncology training and reporting through out UK.”
- “Establishing, monitoring and intervening on national standards for turnaround times for e.g. NGS.”
- “True accreditation / peer review of SIHMDSs would also help improve equity ensure adherence to the requirements / recommendations.”
- “all GLH need a good clinical governance structure”

Q52 – What else could be done to ensure equity of access to genomic testing?

IT

- “LIMS integration / M-ware to allow results to go directly between systems Enhanced genomic testing locally Investment in cloud-based technology so that results can be reported remotely”
- “generate cloud based national bioinformatic support.”
- “Broadly IT is key to streamlining request and result from and to local systems which will inevitably vary”
- “IT infrastructure “
- “IT networking to facilitate development of "factory style" processing wet lab/ and more local dry lab reporting/integration systems.”
- “Improved IT links between GLH Hub and SIHMDS LGL laboratories”

Q52 – What else could be done to ensure equity of access to genomic testing?

SIHMDS based Testing

- “Scrap the GLH model and support local SIHMDS development”
- “More resources to local SIHMDS capacity”
- “devolve and co-localise services”
- “Acknowledgement that some 'local' HMDS have very knowledgeable and skilled staff that are able to provide high standard of some 'specialist' tests. These should not be thrown out with the bathwater”
- “Let GLH concentrate on non-time critical tests like WGS but all rapid assays should be performed locally”
- “All haematological malignancies should be reported in SIHMDS. Still some areas (e.g. **[]**Hospital in **[]**) where lymphomas are sometimes locally reported for historical reasons, despite all our efforts to centralise. All pathology departments should have ability to freeze fresh tissue samples, to allow WGS if indicated.”
- “Allow high quality, efficient testing to be performed within the SIHMDS if this improves patient care. If testing within SIHMDS meets the National test directory and can be performed within a nationally agreed tariff it should be permitted. Rare or complex tests that SIHMDS services choose not to perform can be performed by a GLH model if that is beneficial to the patient but not because of a forced agenda by NHSE.”

Q52 – What else could be done to ensure equity of access to genomic testing?

Communication/Collaboration

- “Align it to patient pathways not genomics hubs!”
- “Utilise the local hubs more efficiently rather than closing them”
- “More collaboration between GLH and LGLs, and an acceptance that LGLs provide a level of resilience and expertise, rather than just seeing them as inferior to GLHs”
- “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”

Q52 – What else could be done to ensure equity of access to genomic testing?

Other

- “Paediatrics not really considered in the current model. Small number of centre geographically disparate. Tests offered locally only relevant to adults.”
- “Clinically informed, prioritised and led changes only from now on.”
- “The focus should be on ensuring all clinicians are accessing their local and NICE compliant SIHMDS. That will ensure equity of access to the correct genomic testing. Inappropriate focus on consolidation at cancer hubs deceases access. Scotland/Wales/N Ireland have been ignored by genomics commissioners and their patients deserve access to SIHMDS as well.”
- “Continual/ regular review of repertoire at glh vs local testing taking into account new clinical requirements and the changes in technology. Continual horizon scanning needed.”