SAMPLE EXCHANGE: IDEAS FOR A WAY FORWARD

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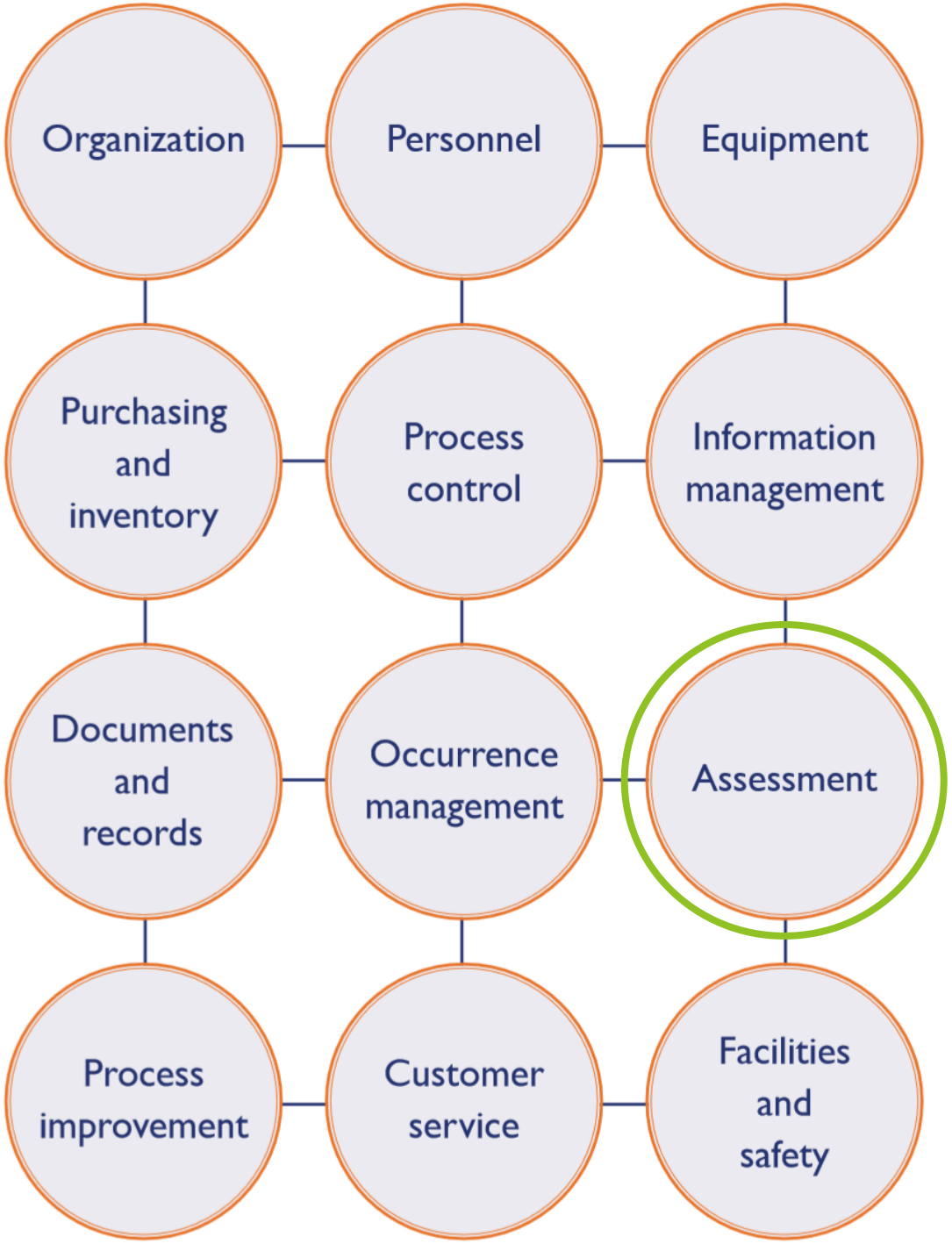
LABORATORY QUALITY

- Key performance indicators: User satisfaction survey, laboratory quality and turn around time.
- Accreditation: Confers reliability to results generated, proves conformance to high standards.
- Critical aspect of laboratory quality management – assessment.
- Means of assessment: Audits, reviews, iQC, EQA, Sample Exchange.



EXTERNAL QUALITY ASSESSMENT

- EQA Describes a method that compares a laboratory's results to a source outside the laboratory.
- Comparison is made to the performance of a peer group of laboratories or to the performance of a reference laboratory.

- **EXAMPLES OF EQA METHODS:**

  - Proficiency testing
  - Re-testing by reference laboratory
  - Sample Exchange

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EQA CONTINUED…….

- **Proficiency Testing:**

External provider - unknown samples sent to a set of laboratories. Results of all laboratories analysed, compared and reported to the laboratories.

- **Re-testing by reference laboratory:**

Samples that have been analyzed are retested by reference laboratory, allowing for interlaboratory comparison.

- **Sample Exchange:**

Interlaboratory comparison by exchanging samples among a set of laboratories. Usually for specialized tests for which no proficiency testing is available.

ISO 15189:2012(E)

5.6.3.1 Participation

- *The laboratory shall participate in an interlaboratory comparison programme appropriate to the examination and interpretation of results.*

- *Interlaboratory comparison programme chosen by the laboratory shall provide clinically relevant challenges that mimic patient samples and have the effect of checking pre-examination and post-examination procedures.*

- *Whenever interlaboratory comparison is not available, the laboratory shall develop other approaches and provide objective evidence for determining the acceptability of examination results. Wherever possible, this mechanism shall utilize appropriate materials, e.g. exchange of samples with other laboratories.*

Our Sample Exchange Scheme

New Sample Exchange Scheme started in 2017 for:

- Biotinidase activity measurement for Biotinidase deficiency
- Beutler test for classical galactosaemia (Galactose-1-Phosphate Uridyl Transgferase GAL-1-PUT).
- Red cell Plasmalogens for peroxisomal disorders.

Original participating labs:

- Willink Biochemical Genetics, Manchester.
- Clinical Chemistry & Sheffield Diagnostic Genetic Service.
- Biochemical Genetics, Leeds.
- Clinical Chemistry, Nottingham.
- Dept. of Biochemical and Immunology, Cardiff.

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Sample Exchange Schedule

Assay	Frequency	Month
Gal-1-PUT (Beutler)	Twice a year	April, October
Biotinidase	Twice a year	April, October
Plasmalogens	Twice a year	April, October

Sample Exchange Blank Template

Sample Exchange Example Report

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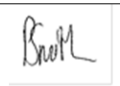
Sample Exchange Agreement

Lab Lead	Correspondence Address	Assays	Signature & Date
Hetalika Jajal / Daniel Blythe Specialist Biomedical Scientist	Willink Biochemical Genetics Laboratory Manchester Centre for Genomic Medicine, St Mary's Hospital Manchester University Hospitals NHS Foundation Trust Oxford Road, Manchester M13 9WL Tel: 0161 701 2142 Fax: 0161 701 2303 Hetalika.jajal@mft.nhs.uk Daniel.Blythe@mft.nhs.uk	Gal-1-Put Biotinidase Plasmalogens	
Helen Chapman	Clinical Chemistry & Sheffield Diagnostic Genetics Service Sheffield Children's NHS Foundation Trust Western Bank Sheffield S10 2TH 0114 2717405 Helen.chapman3@sch.nhs.uk	Gal-1-Put Biotinidase Plasmalogens	
Janet Mitchell / Ian Sherratt Biomedical Scientist	Biochemical Genetics Department of Biochemical Genetics Block 46 St. James's University Hospital Leeds LS9 7TF Metabolic Laboratory tel: 0113-206 4256 janet.mitchell@leedsth.nhs.uk ian.sherratt@leedsth.nhs.uk	GIPUT Biotinidase	
Donna Fullerton Consultant Clinical Scientist	Clinical Chemistry: City Campus Nottingham University Hospitals NHS Trust Hucknall Road Nottingham NG5 1PB Tel: 0115 969 1169 ext 55080 Donna.fullerton3@nuh.nhs.uk	GIPUT Biotinidase	
Heather Wheatley (Senior Biomedical Scientist) -	Department of Biochemical and Immunology University Hospital of Wales Heath Park Cardiff CF14 4XW Heather.Wheatley@wales.nhs.uk Tel 029 20743560	GIPUT Biotinidase	
Paul Smith Consultant Clinical Scientist and Forensic Toxicologist	Department of Chemical Pathology and Metabolic Diseases University Hospitals of Leicester NHS Trust Infirmary Square Leicester LE1 5WW paul.r.smith@uhl-tr.nhs.uk Tel: 0116 258 5772	Gal-1-Put	
Louise Allen *Senior Biomedical Scientist* *Inherited Metabolic Disease Laboratory* *Newborn Screening and Biochemical Genetics Department*	Inherited Metabolic Disease Laboratory Newborn Screening and Biochemical Genetics Department Birmingham Childrens Hospital louise.allen5@.nhs.net *Telephone 0121 333 9942*	Biotinidase	

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Sample Exchange Rota

Date	Distributing lab	GIPUT	Biotinidase	Plasmalogen
October 2017	Manchester	Y	Y	Y
April 2018	Sheffield	Y	Y	Y
October 2018	Cardiff		Y	
	Leicester	Y		
	Manchester			Y
April 2019	Leeds	Y	Y	
	Sheffield			Y
October 2019	Nottingham	Y	Y	
	Manchester			Y
April 2020	Birmingham		Y	
	Leicester	Y		
	Sheffield			Y
October 2020	Manchester	Y	Y	Y

GIPUTS send to :Sheffield, Manchester, Leeds, Cardiff, Nottingham, Leicester

Biotinidase send to: Sheffield, Manchester, Leeds, Cardiff, Nottingham

Plasmalogens send to: Sheffield and Manchester

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Current scheme (pros)

- Fulfils UKAS requirements
- No cost to scheme users.
- Free and voluntary
- Not formal EQA Scheme
- Flexible to user requirements

Expectations from participants

- Follow and implement the sample exchange rota
- Distribute samples and let participants know when to receive samples
- Once received, analyse samples within laboratory specified turn around time
- Fill in the template with your results, reference range, interpretation and comments. Send back to distributing laboratory.
- Distributing laboratory compiles results from all lab, interprets consensus and reports back to all participating labs.
- Individual labs expected to keep record of their own performance. If not in consensus, keep records of actions taken to trouble-shoot or identify reasons for being out of consensus.

Potential issues

- No distribution of samples.
  - Distribution cycle break-down
- Samples distributed but consensus report not compiled.
- Non-participation
- Assay failures
- Increased workload

Any of the above could lead to all participating labs being UKAS non-compliant.

No formal warning would be issued by scheme, but UKAS could pick this up as non-compliance during inspection.

Feedback from formal EQA schemes

- 7 laboratories in this exchange scheme.
- Mentioned to UKNEQAS during Roadshow in Oct 2019. Don’t want to step on anyone’s toes!
- Due to low number of participants, unlikely to create interest with UKNEQAS or ERNDIM.
- Would likely think 3 samples twice a year is not enough!
- UKNEQAS sent a questionnaire asking if labs would like to have sample exchange schemes for certain analytes. No positive reply for IEM analytes.

Improvement Suggestions

- One lab taking responsibility for one assay
  - Not distribute every time, but send reminders for distribution,
  - Data collection and analysis
  - Consensus reporting.
- Standardise sample delivery.
  - All samples to be sent frozen to avoid deterioration? Deteriorated samples have caused varying results in past.
  - Delivery time - either send all samples by courier or by first class
- Should samples be tested before being sent out?
- Standardise sample storage.
- Any other schemes going on for assays other than these mentioned here?

Sample treatment for positives

- Good to have positives from known patients (when possible)
- Plasmalogen samples: Manchester wash red cells from pooled EDTA samples twice in normal saline and send frozen. Sheffield prev. distributed positive samples.
- Beutler samples: Whole blood collected in Lithium Heparin tube from healthy volunteer. Washed red cells are heat treated to develop deficient activity (absent or diminished fluorescence).
- Biotinidase samples: Plasma in Lithium Heparin tube from healthy volunteer. Keeping this plasma sample at room temperature 2-3 weeks can create deficient samples (Low biotinidase activity).

SAMPLE EXCHANGE QUESTIONNAIRE

1) Please state your name and laboratory address.

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2) Do you participate in any other sample exchange scheme for any inborn errors of metabolites analytes. If yes, please list the analytes below along with participating laboratory names.

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3) What are your sample type requirements and minimum sample volumes for the following tests:

a) Beutler: ……

b) Biotinidase: ……

c) Plasmalogen: ……

4) If you had to oversee one analyte (send reminders for distribution, data collection, reporting), which analyte would you prefer?

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5) How do you create positive result for Beutler?

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6) How do you create positive result for Biotinidase?

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7) How do you create positive result for Plasmalogen?

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8) How would you prefer to send samples during delivery? (Frozen, on dry ice or ambient temp).

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9) What delivery method would you recommend for standardizing delivery time? (Courier, first class post or second-class post).

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10) How would you prefer to store samples after receipt and prior to analyses? (-80^{0}C, -20^{0}C, refrigerated (8^{0}C) or at room temperature).

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More improvement ideas Welcome

THANK YOU. ANY QUESTIONS?

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