Maintaining patient/transfusion safety during IT downtime

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Synopsis

- What do we rely on our IT systems for
- IT related guidelines and requirements
- Leeds LIMS failure
  - What happened
  - How did we cope
  - Maintaining safety
- Summary

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The problem is with the pathology IT system

Some hospital appointments and surgery at Leeds hospitals have had to be postponed because of "significant" problems with an IT system.

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What do we rely on our IT systems to do?

- Laboratory Information Management Systems (LIMS)
  - Maintaining patient records
    - Demographic details
    - Laboratory test details
    - Antibody records and special requirements
  - Maintaining stock records
  - Compatibility testing
    - Checking ABO / D compatibility
    - Electronic issue rules
  - Printing compatibility labels
  - Traceability

Other systems

- Automated testing systems
- Blood Tracking
- Temperature monitoring
- Ordering
- Quality Management Systems

Is there any guidance?

- BSH Guideline
  - Guidelines for the specification, implementation and management of information technology systems in hospital transfusion laboratories. Dec 2014
- UKAS: ISO 15189
- BSQR Requirements
  - Blood Safety and Quality Regulations 2005 (SI 50/2005)
- MHRA Requirements / Guidance
  - Eudralex
  - Blood compliance report

BSH IT Guidelines

- System availability and business continuity
  - Appropriate fall back and support arrangements…
  - …Ensure continued service delivery in the absence of the IT system…
  - Risk assessments associated with system failure used to inform system design, implementation and backup and recovery procedures…
- ISO 15189(2012)
  - The laboratory shall have documented contingency plans to maintain services in event of failures or downtime in information systems that affects the laboratory‘s ability to provide service.

When disaster strikes, what is the plan?

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When LIMS fails; this is the plan

- Suspend routine testing
- Test urgent requests only
- Use a manual recording system
- Suspend Electronic Issue; serological crossmatch all red cells
- When IT is running again, catch up

How long will this plan work?

- Few hours? – Yes
- 24 hours? – Yes
- 48 hours? – Just about

- 1 week? – No
- 2 weeks? – No!
- 6 weeks? – Definitely not!

So what happened at Leeds?

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Pathology IT system

- LIMS at Leeds Teaching Hospitals NHS Trust
  - iLab TP (Telepath)
  - Current hardware ~6 years old
  - System been in place ~30-35 years

- Friday 16th Sept 2016 12:30pm
  - Telepath crashed for all Pathology departments across all sites

What had gone wrong?

- Multiple drives had failed
- CSC worked all weekend to fit new hard drives
- Tried to restore system and databases from back-ups
  - Back-ups not complete not possible to restore system!
  - Complete rebuild required
  - May take up to 6 weeks!

New recovery plan

Return to manual system

- Does everyone really know how to do this?
- Where and how do you record things?
- How do you deal with special requirements?
- What about transfusion history?
- Who's got an antibody?
- Where are all the staff we need?

Early conclusion

- We cannot provide a normal transfusion service safely

- Involve Trust's Senior Management Team and Clinical Teams
  - Routine surgery deferred (147 procedures postponed)
  - Daily clinical meetings to decide on surgical cases

Testing

- All patients assumed to be recently transfused
  - All samples are only valid for 72 hours

- Tested
  - Requests for components
  - Urgent ‘high risk’ group and save samples
  - Cords and Kleihauers
  - Given laboratory accession numbers as normal
  - Used automated grouping systems – manual transcription or printing of results

- Untested samples
  - Given lab accession number
  - If remained unused – discarded after 72 hours
- In both cases forms stored in alphabetical order, samples in numerical order

Compatibility testing

- All red cells – IAT crossmatch
  - Definitely no EI

- Patients with antibodies or special requirements
  - Had an excel spreadsheet previously gathered from Telepath (although 3 months since last gather)
  - Users asked to put special requirements on request form

Labelling components / products

- Had a back-up printing system for multiple labels for same patient

  Or
- Handwritten, single labels

- Photocopies taken of all bags reserved and retained with the request form

Stock management

- Records of new stock received
  - Manually checked delivery notes
  - EDN barcodes retained
- Batched products
  - Records of what has been received
- Expired or wasted units
  - Kept quarantined or photocopied

Problems

- Ran out of ink cartridges and toner very quickly
- Workload – over ordering to compensate for time delays
- National Transfusion Committee Guideline for triage of red cell transfusion:
  - Every single patient going to theatre was crossmatched for at least 2 units.
  - Blood stocks depleted rapidly

What went well

- Raised the profile of Transfusion in the Trust
  - Transfusion Senior lab staff were summoned daily to Trust's silver command meeting
  - The Chief Exec. told other managers that Blood Bank was his number one priority
- BBTS
  - Occurred during BBTS conference in Harrogate
  - Harrogate District Hospital agreed to test all LTHT Ante-Natal samples

What went well – staff

- Staff togetherness / empowerment
  - Effort over and above working long shifts
  - Blood Bank staff encouraged to produce documents to use
    - If a document or template was needed
      - Produce it and send it to document managers for entry into our QMS
  - Trust IT and Pathology IT staff worked together to resolve the problem

The end in sight?

- On Friday 23rd September, Blood Transfusion database was rebuilt (completed 16:30)
- Validation took 8 hours
- Full use from 02:30 Saturday
- Blood Transfusion lost 36 hours of data
- Worked backwards from BloodTrack to update Telepath for the missing 36 hours

The end in sight?

- We used photocopies of the components to retrospectively update Telepath
- We did not enter the G&S results into Telepath, unless components had been reserved (too numerous)
- We entered a comment to explain that EI was not available on these samples
- Took approx. 3 weeks to fully update and check that all components were accounted for
- Operated 72 hour rule until update complete

Errors

- 29 Errors, 23 potentially avoidable
  - 12 special requirements not met (irradiated and/or HEV Neg, or phenotyped matched)
  - 8 crossmatching errors post return of Telepath
  - 4 patients with historic antibodies (2x anti-K, 2x anti-C), no longer detectable received blood – all units were antigen negative by chance
  - 2 labelling errors detected
  - 1 testing error (abbreviated group only performed)
  - 1 unit transfused on expired sample (>72 hours old)
  - 1 wrong group transfused (A Pos to A Neg male), error in transcription of results

Summary

- Risk assess the loss of your IT systems
- Ensure good processes in IT department
  - Maintenance
  - Back-up
- Have a good disaster recovery plan
- Have a robust manual back-up system
  - Cope with short or long downtimes
  - Test to see if it works
- When IT fails involve clinicians in decision making
  - Who to test
  - Who to transfuse

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