Review of a site
Shipment Unexpected Occurrence

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MU-JHU Lab Location at IDI Building, Mulago Hospital
Makerere University – Johns Hopkins University (MU-JHU) Core clinical & research lab is located at the Infectious Diseases Institute (IDI), New Mulago Hospital, Kampala.

Began operation in 1989, acquired CAP accreditation 2003, fully complies to GCLP standards & US CLIA-88 requirements

Supported lab evaluations for over 60 clinical trials since inception 20 years ago. Employs 44 staff

Handles approx. 16,000 test requests monthly
Some past achievements/recognitions

- MTN best PT performance, May 2008
- MLO Lab of the year 2nd runner up, April 2008
- Zero deficiencies…CAP inspection, 2009
- MLO Lab of the year 1st runner up, April 2010
- Zero deficiencies…CAP inspection, June 2011
Prevalence of errors in perspective...

- ISO defines lab error as “any defect from ordering tests to reporting results and appropriate interpretation and reacting on these”
- US IOM estimated that 44,000-98,000 Americans die not from medical conditions they checked in with, but preventable medical errors, Khon & Donaldson, 2000
- This makes medical errors the eighth leading cause of death in America – no statistics available for other countries
- World lab error rates vary greatly (0.1 – 9.3)\%
Learning of the problem

- **What problem?** “Shipping gone wrong – Major sample mix up!”
- Notification received through an email from Ted on: 14 March 2011
- Our immediate impression was: “Total surprise!!!”
- Our immediate action was:
  - Contacted Shipping agents – World Courier for clarifications and explanations
  - Return email to Ted re-assuring our high alarm and attention to the matter.
  - Immediately begun our own investigations and audit of the shipment process gone wrong.
Description of the problem

- Samples and samples boxes received had unexpected, illogical, non-corroborating labeling information

- Moving to tackle the problem:
  - What has been reported wrong?
  - What actually went wrong?
  - How did any reported or confirmed error occur?
  - What could be done to resolve the problem and prevent chance for future recurrence?
What went wrong exactly?

- World courier and airlines staff made some gross errors:
  - There was opening of packaging and wrongly re-packaging and re-labeling.
  - Our samples ended up in a Johannesburg lab. MTN lab in Pittsburg received samples meant for a UK lab.
What went wrong exactly?

- Some few QC checks missed our attention such as LDMS number and shipping address cross checking.
  - LDMS tech addressed shipment to wrong Pittsburg lab because she made reference to an email received at the same time with the MTN shipping request also originating from Pittsburg.
  - The wrong lab shipment address also meant a wrong LDMS number. To correct this, the shipment data had to be un-done in the LDMS and then re-sent.
What could we have done differently?

- Nothing about world courier operations was/is so much within our control. However, we could assist them and the entire process by:-
  - Doing good work in preparing, “QC”…ing and correctly labeling our sample lists and boxes
  - Informing them well in time (at least 5 days prior) about shipment date.
  - Working with WC to complete and cross check the actual packaging and labeling of boxes
What could we have done differently?

- More thorough Lab QC checks.
  - The shipments officer being quite busy and not aware of such a problem having happened before, had completely “trusted” the LDMS and freezer room tech’s work.
  - The entire shipping process was reviewed and further amendments made to assure accuracy at all steps by increasing the number of checks at different levels
  - Begun to utilize the LDMS Shipment QC provision using bar-code reader.
Resulting policy & process changes

- A more comprehensive SOP tightening/closing all possible gaps.
- Better streamlining of shipment processes and responsibility roles of NL, PI’s, Lab management, Freezer room staff, data room staff.
- Elissa, 2004 urged that people have a great role in quality laboratory systems
- “Are we not smart enough? Are we lazy? Do we just not care?...It is not the people, it is the system” (David A. Novis, Sep. 2008)
Are you overworked?
Lessons learned

- Problems are capable of arising from the least expected source at any stage of any process in-spite of the amount of experience.
  "When you make a mistake, don’t chase after it, don’t try to defend it”

  “The best way to escape a problem is to face it and solve it” John C. Maxwell.

- There will never be a substitute for manual and thorough review of documentation at all stages however good, experienced, advanced we or our processes are.

- Our processes QA & QC strategies should be open to periodic constant review.
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Any Questions