Review of a site Shipment Un-expected Occurrence

MU-JHU Core Laboratory at the IDI

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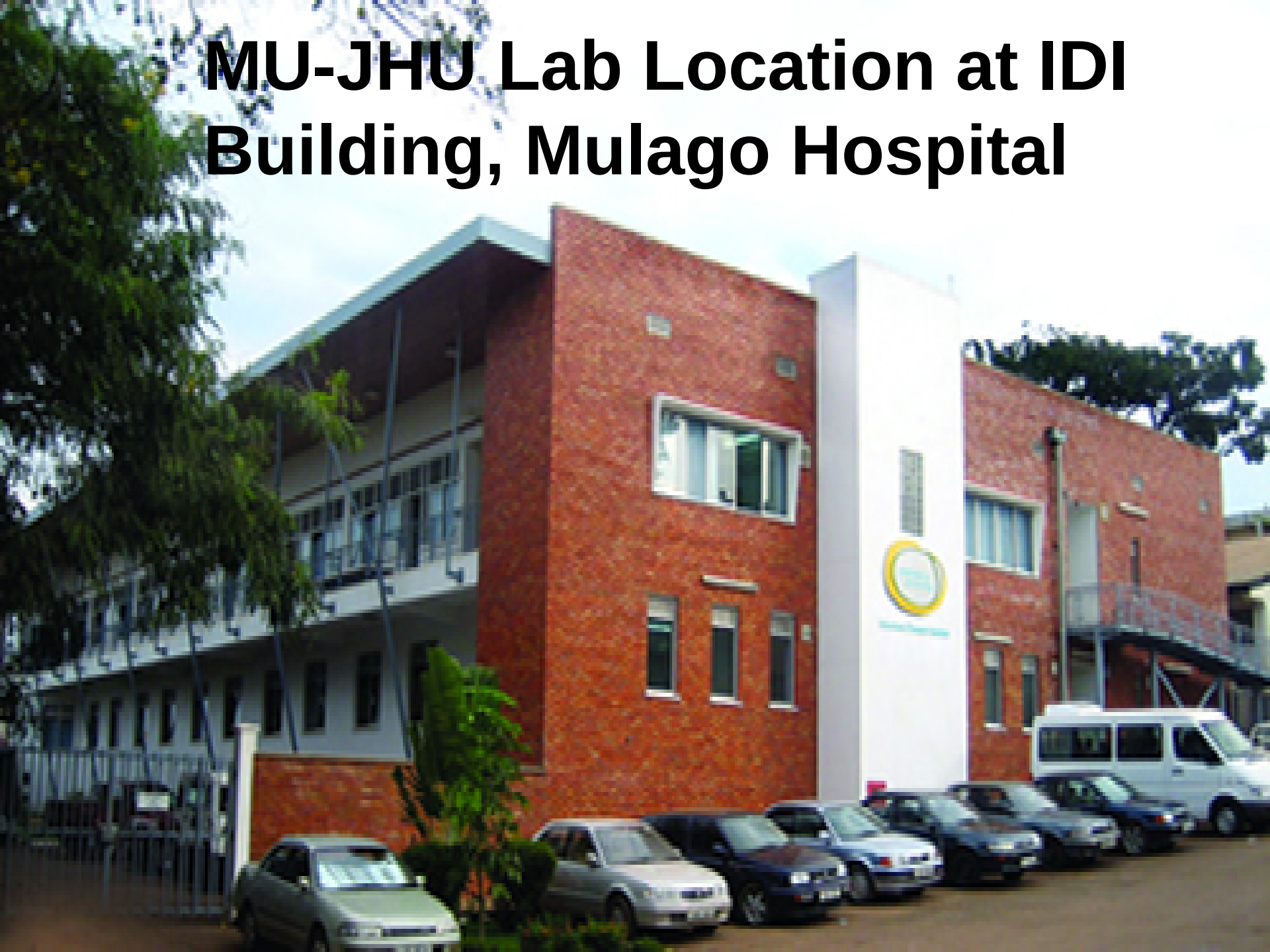
Kampala Uganda

MU-JHU Lab Location at IDI Building, Mulago Hospital



Introduction

- 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? ***"Shipment 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 un-expected, 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.

Acknowledgements

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- Thank you!
- Any Questions