CMPUT 605
Ethics in the Software Development Life Cycle: A Case Study of Health Informatics Systems

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Review of Last Meeting

- Look at FDA document
- Other literature found
Summary of FDA Document

- **Purpose**
  - Software defects and recalls/corrections
  - Minimize software errors/failures
  - Life cycle and risk management

- **Outcomes**
  - Less risk to patients and users
  - Reduced liability to manufacturers
  - Reduced costs

- **Software validation**
  - Requirements and specifications
  - Plans and procedures
  - Activities and tasks

- **Objective supporting evidence**
  - Independent validation versus self-evaluation
Life Cycle Activities

- Quality planning
- Requirements
- Design
- Coding
- Testing
- Installation
- Maintenance
Quality planning

- Plans and procedures for ensuring quality, acceptance criteria, risks and assumptions
Requirements

- Identify and document intended use, inputs, outputs, constraints, defaults
- Requirements are consistent, measurable, and verifiable
“The software design needs to address human factors. User error caused by designs that are either overly complex or contrary to users' intuitive expectations for operation is one of the most persistent and critical problems encountered by FDA.”
Coding

- Coding guidelines, documentation
- Traceability analysis for design to code transformations
Testing

- Test plans and test cases
Installation

- Testing on-site
- User training, ease of use
Maintenance

- Corrective, perfective, adaptive
- Revision of all existing plans
Conclusion

- Ethical issues
  - Accuracy
  - Accessibility