Software Quality
Reflective Journal

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Contents

Chapter 1

Introduction

This document is a portfolio for CS4157, Software Quality, taught by Dr. Ita Richardson. It aims to illustrate and summarise the key concepts explored, and the learning process, within the module. Each week will be a briefly summary of the key points that I took from the lectures, and a discussion on any papers, and how useful, or useless, I found them. Summaries of meetings held by the group tasked with the module project will also be listed.

Chapter 2

Week 1

2.1 Learnings

The three key things I took from this weeks lecture were:

1. Eliminate testing by refining process
    - By following a quality process and focusing on quality throughout, the need for testing can be reduced.
2. Other things in software system
    - Be ware of other items in the software system: hardware, users, environment etc
3. Problem based learning
    - Tackle the issue and learn how to solve the problem by working on the problem

2.2 Paper

The paper that was looked at this week was "Understanding the implementation of software process improvement innovations in software organisations" (Kautz and Nielsen 2004). The goal of the paper is to "achieve a better understanding of the processes influencing the introduction, organizational implementation and adoption of software process improvement innovations in and by software companies" (Kautz and Nielsen 2004).

I found the paper a bit difficult to read, as it focused on a number of research methodologies that I am not familiar with, but I did like the breakdown on types of innovation.

Individualistic Perspective assumes that single individuals that the main source of innovation within an organisational structure. Actions by these people are "not seen to be constrained by external factors" (Kautz and Nielsen 2004). These individuals are self guiding, and focused, and any decisions they make are made in order to "maximise value or utility" (Kautz and Nielsen 2004)

Structuralist Perspective assumes that "innovation is determined by objectively existing organizational characteristics" (Kautz and Nielsen 2004). This view seems to place the chance of innovation on factors within the organisation, such as an "organisations size, its task structure differentiation, its task complexity, its employees job specialization and their professionalism" (Kautz and Nielsen 2004).

Interactive Process Perspective assumes innovation is "dynamic, continuous phenomenon of change over time" that is a result of both individual and organisational factors (Kautz and Nielsen 2004). It focuses on the interactions between individual and organisations. Innovation is the result of the "continuous interaction of the actions of individuals, structural influences and innovation itself" (Kautz and Nielsen 2004).

2.3 Meeting

No meeting held this week.

Chapter 3

Week 2

3.1 Learnings

1. Quality priority depends on perspective
    - I defined quality as the amount of reliability that a product or service has
2. When is it really important to ensure high quality?
    - The output, where it is being used? - Example: salt from fast food dissolved seat belts. All possibilities cannot be tested for!
3. 'Good Enough' software - for the purpose it is built for
    - Functions are right, the cycle time is right, the quality is right, development productivity is right - capability of process.

3.2 Paper

This weeks paper was "Evaluation of Connected Health Technology" (O'Neill et al. 2012). It noted that many people who develop connected health solutions (CHS) "are not from a primarily health technology related background" (O'Neill et al. 2012). They tend to originate from engineering and IT disciplines, as well as the mobile technology and sensor sectors. This paper showed the range of knowledge needed to correctly evaluate a CHS.

- Knowledge of research governance and ethics
- Project management

- Statistical knowledge
- Technology knowledge
- Clinical experience
- Design and implementation of pre and post evaluation questionnaires
- Regulatory knowledge
- Procurement of consumables or technology.
- (O'Neill et al. 2012)

I also spoke with a psychiatric nurse about connected health briefly, and her thoughts are summarised below:

Can you think of anything in your line of work that would benefit from a system link this, a condition that requires 24 hour monitoring but the nursing levels couldn't support that level of monitoring?

We actually have something like this in work already it wouldn't be as advanced as the YouTube clip but it's along the same lines. It's in some houses at night where there aren't staff and if it detects movement it alarms and a staff member goes to the house,there's motion detectors around the house, I don't fully agree with them because in our case in work they're using them in houses where there are people with epilepsy and they may have silent seizures which the technology isn't going to pick up maybe if it was more advanced it might but it's not at that level at the moment so there's high risks being taken to save money on staff.

3.3 Meeting

Date: Feb 6th
Attendees: Chris, Cian, Shane
Absent: Brian
Notetaker: Cian
Chairperson: Chris

Actions for Next Week

1. Each person to find and summarise a paper relating to Connected Health
2. Set up a Google Doc which contains a section for each of the following:
    - Documents Read

    - Meeting Minutes
    - Main Software Quality Plan Document
3. Find a working example of a Software Quality Plan
4. Make sure all members can access the UL Library
5. Chris to talk to a Psychiatric Nurse regarding the project
6. Research existing products
7. Type up the meeting minutes document

Brainstorming on domain for CH

- Alzheimers - Virtual Fencing
- People on Clinical Trials - Monitor changes
- Blind / Deaf People - System to notify them of things they can't notice
- Morbidly Obese People - Monitor bed sores etc
- Air Monitoring - Cleanliness, humidity
- Sleep Apnea - System to wake sufferers of this ailment.

General System Ideas

Store information regarding the changes in medication and compare that to the changes in the person.

Chapter 4

Week 3

4.1 Learnings

1. Project Capability
    - How good is the project, and the company who make it?
2. Project Maturity
    - The maturity of the company - new, start up, experience etc.
3. Total Quality Management
    - Collection of processes to achieve quality

4.2 Paper

The paper reviewed this week was "Assessing the Impact of Continuous Quality Improvement/Total Quality Management: Concept versus Implementation" (Shortell et al. 1995). This paper discussed the outcomes on a sample of hospitals using TQM processes, and "focuses on factors influencing the implementation of quality improvement activities and the perceived impact on human resources development, patient care outcomes, and financial outcomes" (Shortell et al. 1995). The goal was that to use of TQM tools would "result in an ability to both maintain and improve quality while controlling increases in costs" (Shortell et al. 1995). While this is an older paper, an interesting statistic that was highlighted was that the majority of sampled with "69 percent actively begun to implement the basic components of TQM" (Shortell et al. 1995).

An interesting point was the use of employee empowerment and involvement to drive the TQM process. The division of the culture within a organisation into four areas

was also interesting, but was based on a considerable amount of other papers that I felt were outside the scope of this module, and were based on (Quinn and Kimberly 1984).

1. Group Culture - Based on "norms and values associated with affiliation, teamwork, and participation" (Shortell et al. 1995)
2. Development Culture - Based "on risk taking innovation and change" (Shortell et al. 1995)
3. Hierarchical Culture - Based on "reflecting the norms and values associated with bureaucracy" (Shortell et al. 1995)
4. Rational Culture - A culture based on "emphasizing efficiency and achievement"(Shortell et al. 1995)

The paper got a bit heavier in terms of analysis after this and it was a bit difficult to follow without having the experience and domain knowledge needed to perform a similar study.

4.3 Meeting

Date: Feb 13th
Attendees: Chris, Cian, Shane
Absent: Brian
Notetaker: Shane
Chairperson: Cian

Feedback from Ita

Feedback from nurse was useful and in the right direction for the kind of risks we should be thinking about.

Our Plan needs to be able to detect the problems that could occur.

Risks/Patient Safety

1. Focusing too much on interoperability, not enough on client safety
2. Conflict of laws between countries, acceptance criterias differ
3. Data representation
    - What is the recommended/normal amount of times people wake at night

4. Misconfiguration of system
5. Misuse (Malicious or otherwise) of both information and the system.
6. Ease of use, Domain knowledge
7. Reimbursement, doctors need to be paid.
8. Reliability of internet, bandwidth and connectivity.
9. Confidentiality/Invasiveness
10. Encryption/Security
11. Guidelines for diagnosis
12. Attach patients to people under NDA.
13. Four Threats
    - Confidentiality
    - Integrity
    - Availability
    - Quality of the software quality plan
14. The main point is to improve patient outcome.

Actions

- Chris - look into ethical Approval
- Web of science, each reading a paper - with a view towards risk.
- Research ethics

Chapter 5

Week 4

5.1 Learnings

1. Improved process leads to improved product
    - Improved manufacturing process leads to improved product. Why not the same with software?
2. Regulations for software
    - FDA in America, EU directives within the EU.

5.2 Paper

The paper looked at this week was "The influence of EU law on the social character of health care systems in the European Union" (Mossialos 2001), specifically Chapter 5 pertaining to medical devices.

The paper concerned the way that the EU controlled the regulation of medical devices, and how it is changing. It spoke of how deregulation is occuring at a national level, with decisions regarding medical devices being made as a whole. This is an attempt to "harmonise and standardize" medical devices across the Community (Mossialos 2001). Discussion of the learnings are in section 5.4.

5.3 Meeting

Date: Feb 20th
Attendees: Chris, Cian, Shane, Brian
Notetaker: Chris

Chairperson: Brian

Identify one aspect of a software quality plan

1. Risk Management and Identification
2. Data Privacy
3. Staff Training
4. Actual Users of the system
5. Software and Hardware
6. System Usage
7. Device Classifications (C1, C2, C3)
8. Different Knowledge bases (eg doctor, nurse, carer, soft engineer)
9. Location/Environment (home vs hospital, small vs large) - CIAN
10. Ethical Approval
11. Legal Issues

Examples

- Hardware: how to deal with repairs? Severity (monitor vs server)
- Software: How easy to fix on the spot? How easy to get back up and running if it falls down?
- Identity risks, manage risks, prevent risks, level of risk
- Adherence to regulations
- Testing controls

Actions

- 1000 words on selected topic
- Data Privacy - Brian
- Software and Hardware - Shane
- Device Classification - Chris
- Location and Environment - Cian

5.4 Device Classification Assignment

One aspect that needs to be considered as part of any software quality plan is the type of medical devices being used, and their use within the connected health system. It is important that any devices used within a connected health system adhere to guidelines set out in MEDDEV 2.4/1 Rev. 9. These guidelines help to govern the quality of devices used for medical reasons, and if a device is unclassified, then it would lead to more work in the setup of the system to ensure that said device is safe for use within a medical setting. The European Union requirements for classification of medical devices are set out in Annex IX of the Council Directive 93/42/EEC, while the Food and Drug Administration (FDA) is responsible for this in the United State. In Canada, the Medical Devices Bureau of Health Canada is responsible, while section 41BD of the Therapeutic Goods Act 1989 and Regulation 3.2 of the Therapeutic Goods Regulations 2002 outlines the usage of such devices in Australia, and is under the control of the Therapeutic Goods Administration. It is important that when designing a connected health solution that you are cognisant of the classification of each device, especially if you wish to use the solution in multiple jurisdictions.

Devices are categorised based of what risk is attached to its usage. Class I is a low risk device, Class II is medium risk, Class IIb is higher risk and Class III is highest risk. There are a number of rules which aid the classification of a device. Rules 1 through 4 identify a non-invasive device. An example of this would be a hearing aid. Rules 5 to 8 refer to invasive devices, which is any device intended, by the manufacturer, to be used, in whole or part, to penetrate the body of a human being through a body orifice or through the surface of the body. A key example of this would be an injection. Rules 9-12 cover what are called Active Devices. These refer to devices that are active and implantable. A pacemaker would be an example of an active device. Rules 13 through 18 are special rules. These deal with devices that cover a range of possibilities

- Devices incorporating integral medicinal substances liable to act in an ancillary way on the human body
- Devices used for contraception or prevention of STDs.
- Devices for disinfecting medical devices
- Devices for recording X-Ray diagnostic images
- Devices using non-viable animal tissues or derivatives
- Blood bags

In relation to these devices, a plan needs to be established on how to deal with their handling, storage, disposal, and any training that may be needed by the user, or given to the user. An obvious example is any situation dealing with bladder problems the patient may have a drainage bag and catheter. There would need to be awareness of how to correctly prepare these devices on a patient, and to ensure their proper installation, usage and disposal, and any lack of attention to these areas would lead to high risk of infection. In terms of developing a quality plan for a connected health system, its vitally important that these issues are part of any plan. While the how and why of the classification of devices is not an issue within the scope of the plan, how to deal with, manage, and use these devices is very much an issue that needs to be addressed. The range of devices will differ greatly depending on the connected health system, the environment of the system and even on a patient to patient basis, so in this situation, it is important to break down the system to granular devices and ensure compliance.

Chapter 6

Week 5

6.1 Learnings

1. Business importance of software increasing
    - 90% of the cost of a car is software
2. Business Benefits
    - Return on investment increases, productivity increases, overall effect decrease. More money, less work with a good process.
3. Software Process Improvement
    - Productivity up, Defects down, Error Rates down, Costs down, On Time Deliverables up, Rework down and savings in test time.
4. Software Process Models
    - Capability Maturity Model, ISO 15504, Configuration Management, Assessment of System

6.2 Meeting

This weeks meeting focused on the presentation of current findings for the Software Quality plan and paper.

Date: Feb 20th
Attendees: Chris, Cian, Shane, Brian
Notetaker: Cian
Chairperson: Shane

What is your presentation content?

1. Dealing with classified devices
    - CMMI
    - FDA
    - Differences
2. Data Privacy Issues
    - Network Security
3. Environmental Effects
    - Location
    - Installation
    - When things break, and the impact that has on the system
4. Hardware and Software Issues
5. Crisis Management
    - Automation
    - Who to call?

Recap: What have we covered?

- Hardware and Software - make more generic.
- Location and Environment
- Data Privacy
- Classification of Medical Devices
    - Regulations for these devices
    - Handling of devices
    - Storage of devices
    - Disposal of devices
    - Training
- Microsoft Excel as a Medical Device?

  - Used by Doctors
  - Cognisance of the intention of use
  - Burden of proof on company to prove fit for purpose.

Actions

- Brian - Ethical Approach
- Presentation - 5 slides each on topic from last weeks meeting
- Presentation Practice on Monday and Wednesday
- Time keeping - ensure under 20 minutes total

Chapter 7

Week 6

7.1 Learnings

This week was the preparation and practice of presentations in relation to the Software Quality plan being devised for this module. A 20 minute presentation was created with each team member taking 5 minutes on their chosen topic.

7.2 Paper

No paper read this week due to presentation practice and preparation. Previous weeks paper used to guide this.

7.3 Meeting

This weeks meeting focused on preparing the presentation content and practising.

Date: Feb 26th
Attendees: Chris, Cian, Shane, Brian
Notetaker: Brian
Chairperson: Shane

Order of the presentation

1. Shane - Hardware and Software
2. Cian - Environmental Factors

3. Brian - Data Privacy
4. Chris - Medical Devices

Other tasks were

- Merge Slides
- Create intro slide
- Create conclusion slide covering other topics not covered yet
- Cian wanted to dance, but it was vetoed

Chapter 8

Week 7

8.1 Learnings

Q&A Session on 14/04

- How to deal with risk?
  - Matrix used by NASA to assess risk in an environment
  - What's the worst case?
  - How likely is this to happen?
- How to manage stakeholders?
  - There should be one champion in a hospital to help lower stakeholder conflict.
- Privacy Issues
  - Password sharing
  - Sharing ID cards
  - Not logging out
  - Multiple logins to deal with one patient (Usability Vs Privacy concerns)

HIQA - Hospital Information Quality Assurance

Concept of two level password - Second one is full access, but usage is logged with meeting called on use to establish the reason for its use, and if it was valid.

8.2 Paper

Focus on CH talk and questioning this week

8.3 Meeting

None this week

8.4 Question Prep

1. How difficult is it to integrate a connected health solution with an existing system?
2. Failures in connected health system? How are failures handled? Repercussions?
3. Integration of IT and Healthcare - What usability issues arise and how are they handled?

Chapter 9

CH Talk and Q&A

The CH talk on 13/03 highlighted a number of areas of interest.

- Connected Stakeholders
  - All stakeholders are involved in the solution together. Each has a different knowledge area and expertise to bring to the system in order to make it work. Different disciplines of two presenters an example
- Empower the patient to be able to look after themselves. @home
- Evidence based standards - replace existing healthcare models
- Need to support deployment, adaptation and reimbursement.
- Need to illustrate the savings, to time, money and personnel, of a Connected Health Solution.
- Danger of siloed information

There were a number of challenges highlighted

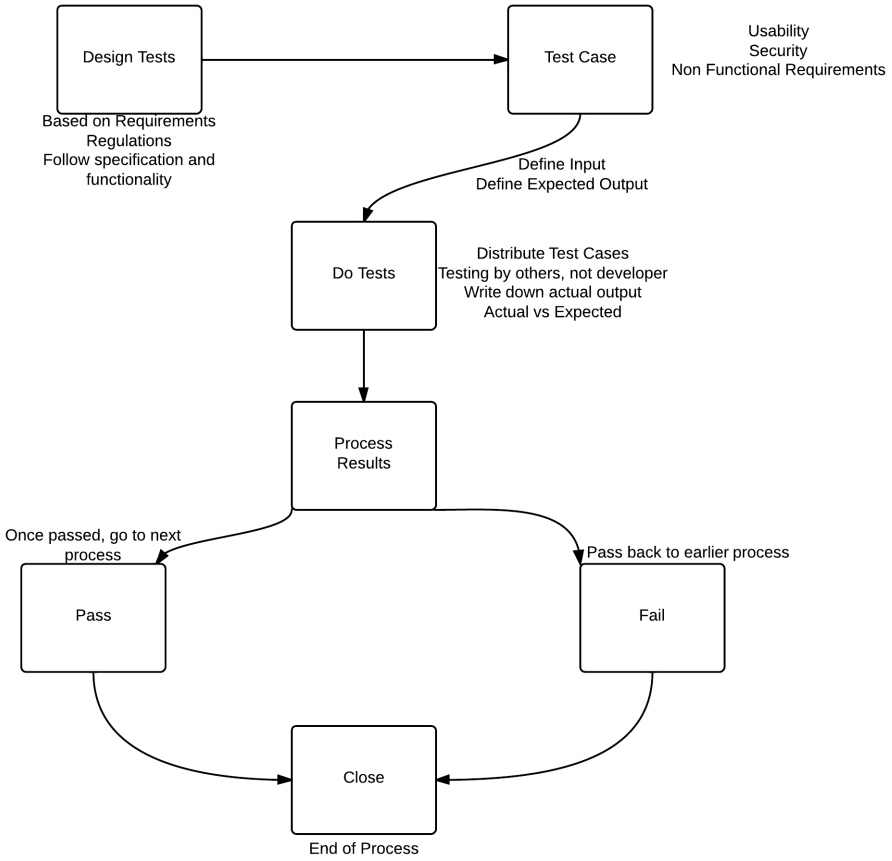
1. Fragmented Systems
2. No fixed pathways for CHS
3. Importing existing information
   - E-Health Records
   - CDROM and physical files
4. Lack of information provisioning carers

CH Deployment needs to be concerned with usability and acceptability. The *Delone and McLean* model for quality deployment utilised.

Chapter 10

Week 8

10.1 Learnings



10.2 Paper

I revisited a paper, "What do we know about defect detection methods?" (Runeson et al. 2006), that had been looked at in a previous module. This paper takes a number of studies on inspection methods and testing methods as a means of finding bugs. This paper focused on what detection methods were most useful at different phases of the software lifecycle. The two core methods were Testing and Inspection.

Their findings "showed no clear-cut answer to the question of which defect detection method to choose" (Runeson et al. 2006). It did show that for each phase that a certain method may be better at finding defects.

1. Requirements Defects
    - Inspection preferred due to "costs for requirements inspections are low compared to implementing incorrect requirements" (Runeson et al. 2006)
2. Design Defects
    - Studies indicated that "inspections are both more efficient and more effective than functional testing" (Runeson et al. 2006)
3. Code Defects
    - Function testing was found to be "more effective or efficient than inspection in most studies" (Runeson et al. 2006)

10.3 Meeting

No meeting this week.

Chapter 11

Week 9

11.1 Learnings

No lecture this week.

11.2 Paper

FYP!

11.3 Meeting

FYP!

Chapter 12

Week 10

12.1 Learnings

FYP Demo Day. No lecture this week.

12.2 Paper

FYP!

12.3 Meeting

FYP!

Chapter 13

Week 11

13.1 Learnings

1. Time to market for software very important
    - Potential losses can be large due to competitor advantages, cost of development, lost earnings
2. Global Distance in Global Software Development
    - Temporal Distance, Geographical Distance, Linguistic Distance and Cultural Distance all make up Global Distance.
3. Social Capital
    - Investment in people, and the relationships between them key to success of GSD.
4. Local Process may not work as a Global Process
    - Cognisance of different cultures and people important when defining a local process

13.2 Paper

A concept that was mentioned this week was that of Transactive Memory Systems, and how an organisation utilises them, or should utilise them, to manage people leaving a team. A paper I looked through was "Transactive memory systems in organizations: Matching tasks, expertise, and people" (Brandon and Hollingshead 2004).

Transactive Memory "is the shared division of cognitive labour with respect to the encoding, storage, retrieval and communication of information from different knowledge bases" (Brandon and Hollingshead 2004). Each member in a team contains their own knowledge, and this knowledge contributes to the overall success of a project. The project team then assigns tasks based on the perception of each others expertise. One of the key things needed for this type of system to work in an organisation is "cognitive interdependence" (Brandon and Hollingshead 2004), or that the members of the group know that they need each other.

13.3 Meeting

No meeting this week. Informal agreement to meet next week to focus on paper and quality plan process.

Chapter 14

Week 12

14.1 Learnings

1. Inevitable inefficiencies with software development.
    - Testing, and processes, minimise these but impossible to test completely.
2. Good Enough Software
    - Need to identify the purpose the software is needed for
3. While in an ideal world, testing is not needed if the process is sufficiently good, this is not the case.
    - Testing needs a structured process. Input, Expected Output, Results, Avoid Repetition.
4. Testing should be specialised department.
    - Programmers shouldn't be testing. Managers shouldn't be testing. Concentrate on the one job.

14.2 Paper

None

14.3 Meeting

None

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