▾ Week 3: Software in the Health Context

Overview

This week we focus on software - what it is, how it's made, and why its use in some specific domains - in this case healthcare - can require particular thought and planning.

Learning outcomes

After completing week 3, you should have made progress towards learning objective LO6: **Explore, capture and communicate system requirements related to patient pathways and stakeholder needs** and learning objective LO8: **Critically appraise the proposed design of a system and assess whether it is fit for purpose**

How this week relates to your assignment

The content and activities in this topic should help you to understand how to **capture and communicate the architectures of systems at a variety of different levels** and **for a variety of audiences**.

Materials and activities

Required material and activities are numbered to indicate the order in which you should ideally progress through them.

3.1 An Introduction to Software and Healthcare

In this lecture Grady Booch, Chief Scientist for Software Engineering at IBM, discusses the history of software and its role in the modern world. He also touches on future developments to provide an all-round introduction to what software is.

3.1.1 Online lecture: Grady Booch on The History (and the Future) of Software
The role in software in health is important to helping to record and define the complex systems and tools that we can use to ensure that people are kept safe and well, both as they are being treated and when they are going about their normal lives. In this next video we will take a short look at health software.

3.1.2 Online lecture: An Introduction to Software in Health
At this point you're meeting Gary Leeming. Gary was a long-standing member of the health informatics team at the University of Manchester and one of the co-creators of the HIST module. At the end of 2020 he left UoM to take on new operational challenges in running health- and community-related systems for real.

3.2 Understanding "Quality" in Health Software

There's an old saying in the clinical world that "the operation was successful; the patient died". We can apply the insights this gives us to the informatics space too. The first part involves recognising that "software quality" is "a thing", and we can work towards it in many technical ways. The second part alerts us to the fact that there's more to success than having software that's great in its own terms. The juxtaposition reminds us that our real aim goes beyond "good software" and has as its goal **software that is technically excellent but also that fits well into the clinical and socio-technical context in which it's intended to be used**.

The **NHSX Digital Technology Assessment Criteria** (**DTAC**) is a tool designed to help technology developers to assemble the evidence that supports their claims of quality.

https://www.nhsx.nhs.uk/key-tools-and-info/digital-technology-assessment-criteria-dtac/

3.2.1 Activity: What do you think makes quality software?

1. If you had to make the decision to procure a technological tool, what questions would you ask about it? What supporting data would you want to see in order to be sure that commissioning this was a good use of health service resources? Make some notes.
2. Read through the DTAC website, and in particular the DTAC Form.
3. What do you think of it?

    - Does it address anything you hadn't thought of?
    - Can you see any gaps or omissions in what it requires?
    - Are any of the gaps covered by other NHSX tools?

4. Compare what you found with others' findings by posting/comment in the forum below

Health Software Quality Discussion

In week four we'll shift the focus from software quality to look in more detail at how software is conceptualised, designed and built.

3.1.1 Online lecture: Grady Booch on The History (and the Future) of Software

https://www.youtube.com/watch?v=OdI7Ukf-Bf4

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3.1.2 Online lecture: An Introduction to Software in Health

https://www.youtube.com/watch?v=A8JoInSTSDM

What is software?

- Software code and algorithms are a part of every aspect of your life
- Software helps to manage and support complex systems
- Software in health has a role in keeping patient well and safe

Types of software

- Consumer software:
    - The end-user is the focus of the app
    - End-user usually buys apps or services
- Enterprise software:
    - The end-user is fulfilling a business objective
    - The software is purchased by an organisation
    - Although the focus of the software should be for the end user to complete a process/ solve a problem, sometimes this might conflict with the needs of the business which might end up outweighing the user's needs (e.g. additional fields might need to be filled in in order to better support business reporting, which could be beneficial for the business but might slow down the user).
- Both types have application in healthcare

Types of software

- Software must be safe to use (not cause harm to patients)
- Need for validation and testing (not only for safety and reliability but also for efficacy of the software: does it work to help patients or not?)
- Can be classed as a medical device (e.g. if a software is helping a clinician to make a decision about a patient, such as a drug-dose calculator): MHRA has published guidance on what a regulated medical device is.
- Must respect confidentiality and privacy (because a software or electronic system might store confidential data, it might be a target for potential theft)
- Security All these requirements combined might make difficult and/or expensive to maintain or update health software, leading to dangerous or unintended consequences

Wannacry

- In May 2017, NHS was one of the alrgest agencies affected by the Wannacry ransomware
- Desktop computers, scanners, refrigerators and other equipment was affected (all running Windows XP as their OS).
- NHS organisations had to cancel services

Software platforms

- Software code needs to run on hardware

- It is necessary to understand on which platform the software needs to run and the impact of the platform on the delivery of the software
- There are multiple platforms to run code:

    - Desktop computers
    - Web-based applications
    - Mobile
    - Internet of Things (IoT) and devices
    - Cloud

Desktop software

- An application that runs on a standard PC operating system such as Windows, Linux and MacOS
- Back-office software (accounting, HR, time recording, etc)
- Health-specific software (EPR, patient admission systems, imaging, pathology, bed management)
- Desktop software is usually purchased with a licence, adding another layer of bureaucracy that needs to be understood.

Web-based software

- Software developed with web-based technology (e.g. HTML and JavaScript)
- Can be deployed via desktop wrapper or internet browser (software needs to be validated againts a specific browser version)
- Can be hosted locally (not necessarily on the internet, but for example on an internal server on the local company network)
- Applications accessed externally must be accessed via carefully controlled user accounts, whihc might be external to a company's internal user admin system
- Example: https://www.patientview.org/ (web application to provide renal paitents access to their test results online)

Mobile software

- Runs on smart phones and tablets
- Designed to be easy to use
- Large consumer-software focus
- Increasing growth in enterprise and health app
- NHS Digital and NICE have begun to explore how to validate mobile apps, with support from companies such as ORCHA, to ensure they are safe and that they have the right outcomes for patients
- Use of smartphones and tablets at the bed side and in other points of care are also inceasing

Devices and IoT

- Internet of Things: devices/technologies that are connected to (and share their data with) the Internet (e.g Nest a smart thermostat, Smart Fridges, Smart Watched, etc)
- Application in health thorugh connected devices (heart rate monitors, blood pressure, blood sugar, weight scales)
- Growth area of development, especially for long term conditions requiring self-management at home https://www.hanselman.com/blog/the-extremely-promising-state-of-diabetes-technology-in-2018

Cloud software

- i.e. running applications on someone else's computer (e.g. AWS, Microsoft, Google, UKCloud).
- Allows for cost efficiencies (charge by machine usage), greater storage and quick/automated scalability
- It has led to the development of new technology approaches, such as containerisation, which supports efficiency in how applications can be written, deployed and shared.
- Risk of governance: where is the data stored?
- Security (key privacy and security concerns since the hardware is not owned by whom runs the software: e.g. questions of personal data sovereignty, who has remote/physical access to the machines that store/process the data, data repatriation: how do we get our data back should we decide to move to a different service)
- However, many of the traditional challenges including network monitoring, virus detection etc will directly be handled by
- Software as a Service (SaaS), software solutions deployed in the Cloud, all handled remotely

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3.2 Understanding "Quality" in Health Software: Digital Technology Assessment Criteria (DTAC)

The Digital Technology Assessment Criteria for health and social care (DTAC) gives staff, patients and citizens confidence that the digital health tools they use meet our **clinical safety**, **data protection**, **technical security**, **interoperability** and **usability and accessibility standards**.

The DTAC brings together **legislation** and **good practice** in these areas. It is the new national baseline criteria for digital health technologies entering into the NHS and social care.

The DTAC is designed to be used by healthcare organisations to assess suppliers at the point of procurement or as part of a due diligence process, to make sure new digital technologies meet our minimum baseline standards. For developers, it sets out what is expected for entry into the NHS and social care.

Why we have introduced the DTAC

- The DTAC was developed in response to developers and those making buying and commissioning decisions looking to NHSX for clear direction on **how to build and buy good digital health technologies.** We listened to innovators who are seeking to understand what the NHS is looking for when it buys technologies to enable them to build it into their product development 'by design'. Those buying technologies told us they wanted a proportionate and tangible criteria that was simple to apply and assess against, encompassing all digital health technologies, to ensure that the products they select are safe and built well.

By setting a **national baseline**, the intention is now to smooth the path between development and procurement so that the NHS and social care may realise the benefits that digital technologies can bring.

We first introduced the DTAC in beta in October 2020, and incorporated feedback before launching the first official version in February 2021.

The different parts of the DTAC

The assessment criteria is focused on **5 core areas**. Sections 1 to 4 form the assessed criteria, with a separate conformity rating provided around usability and accessibility:

1. **Clinical safety**: Products are assessed to ensure that baseline clinical safety measures are in place and that organisations undertake clinical risk management activities to manage this risk.
2. **Data protection** Products are assessed to ensure that data protection and privacy is 'by design' and the rights of individuals are protected.
3. **Technical assurance** Products are assessed to ensure that products are secure and stable.
4. **Interoperability** Products are assessed to ensure that data is communicated accurately and quickly whilst staying safe and secure.
5. **Usability and accessibility** Products are allocated a conformity rating having been benchmarked against good practice and the NHS service standard.

The DTAC includes company information and value proposition sections for context. Each of the scored and assessed sections contain:

- a reference code for each question
- the question for the developer to respond to
- whether evidence is required and is so the evidence
- response options or free text
- supporting information and guidance
- scoring criteria

Evidence standards framework for digital health technologies

We continue to work alongside other key stakeholders including the **Accelerated Access Collaborative** (**AAC**) to support innovators, the **Medicines and Healthcare products Regulatory Agency** (**MHRA**) and **NICE** to build on the [Evidence Standards Framework for digital health technologies](). This is a framework that describes the level of evidence needed to demonstrate effectiveness and value for digital technologies that have different functions and risks.

Guidance for using the DTAC

Information for tech developers

The DTAC provides a consistent question set and enables you to present the same consistent and proportionate set of evidence to organisations buying your digital health technologies. It sets out the standards expected for entry into the NHS and social care.

You should make sure your product meets the assessment criteria, gathering the required evidence - you may choose to use a third party to do this for you. You may be asked to provide this evidence during the procurement process.

Further guidance and support on building good technology by design can be found in [A guide to good practice for digital and data-driven health technologies]() published by the NHS AI Lab.

Information for people working in the NHS or social care

As part of each new procurement process or contract renewal, buyers of digital health technology should ask the developer to complete the DTAC by responding to the question set and providing the evidence required.

It is important, as with any procurement, that those with relevant subject matter expertise are involved in the assessment of digital health technologies, for example the clinical safety section should be assessed by a qualified Clinical Safety Officer.

Whilst the DTAC is intended to be a common baseline criteria in terms of safety and security, it is intended to be one part of procurement - it is not intended to be the complete question set for procurements and should be supplemented with additional specifications including any policy and regulatory requirements.

You should also ensure that you consider efficacy and the impact and evidence of such technologies. NHSX is working with NICE to build on the [Evidence Standards Framework for digital health technologies](). This is a framework that describes the level of evidence needed to demonstrate effectiveness and value for digital technologies that have different functions and risks.

The DTAC will ensure products meet our standards in: clinical safety, data protection, cyber security, interoperability and accessibility. Whilst it is not currently mandatory, the DTAC brings together legislation and recognised good practice into one place, helping the system to assess products quickly and consistently and you should consider the legislative requirements in any build.

Information for people working for a national NHS organisation or arms length body

NHSX will work with you to assess products that are being procured at a national level, for example, for new national procurement frameworks or dynamic purchasing systems. Please email dnhsx@nhsx.nhs.uk to find out more. This does not replace any Government Digital Standards requirements.

The DTAC will ensure products meet our standards in: clinical safety, data protection, cyber security, interoperability and accessibility. The DTAC brings together legislation and recognised good practice into one place, helping the system to assess products quickly and consistently.

Products that should be assessed using the DTAC

All new digital technology should be assessed using the DTAC, even if you are piloting or trialling it. If a developer has multiple products, each one would need to be assessed against the DTAC. Examples of products include: staff facing and patient facing digital tech, apps, systems, web based portals, stock control systems, and more.

We have linked the DTAC criteria to the definition of a Health IT System as defined in DCB0129 and DCB0160, being a product used to provide electronic information for health or social care purposes where the product may include hardware, software or a combination of both.

Our initial focus is on embedding the DTAC in the NHS and social care. We will be exploring opportunities for assessment passportablity in the future.

Digital tech already in use does not need to be retrospectively assessed but may need to be assessed at the point of a contract renewal or if commissioned by a different organisation.

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