Assessment of the COPD-calculator using a customized version of the NHSx DTAC Framework

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Abstract

Healthcare Technology has grown incredibly fast for the past decades along with the revolution of the IT industry. We are moving into a very innovative future with regard to combining technology and healthcare. Developers have designed and developed many tools and technology to help increase the quality of healthcare and to ease the workflow of healthcare systems. In particular, there has been a major focus on developing a system/tool to assist in decision-making, often referred to as a clinical decision support (CDS) systems. Many studies addresses the lack of comprehensive frameworks to evaluate such systems. A comprehensive evaluation framework can improve the design and implementation of a CDS, and can provide potential benefit to clinicians and patients. One such comprehensive evaluation framework is the NHSx DTAC developed for use in the UK.

We conducted a literature research to identify potential problems with, and shortcomings of, current frameworks and evaluations of healthcare technology systems. The main focus of this thesis was to apply a customized version of the NHSx DTAC framework to assess a Norwegian CDS system, the COPD-calculator. The evaluation process was divided into two parts and yielded a given score for each criteria the calculator fulfilled. The first part of evaluation received 54.1666% and the second part received 70.5882%.

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Chapter 1

Introduction

1.1 Motivation

AI researchers and clinicians have for nearly 60 years envisioned the day that computers could assist with decisions in complex clinical situations [1]. It was not until the 1980s that clinicians first used computerized clinical decision support systems (CDSS). Since then, there has been a rapid evolution [2].

Clinical decision support (CDS) includes a variety of tools and provides healthcare professionals and patients with various types of information that can support and contribute to better decision-making at the point of care. CDS systems (CDSSs), or functionalities, can manifest as computerized alerts and reminders, computerized guidelines, order sets, patient data reports, documentation templates, and clinical workflow tools [2]. The purpose of these tools is not to replace a healthcare professional's decision-making, but rather to support the involved healthcare workers (and the patients) in the process in order to give the best possible care [3].

The development of clinical decision support systems requires thoughtful design, implementation, and critical evaluation [4]. Possible benefits of using a CDS can include reducing errors in judgment, decision-making, and performance to increase patient safety. In addition, comes the potential to improve the quality of health care [5]. However, according to Kilsdonk et al. [6], there have been reports of over 50% failure rate in introducing CDSSs in clinical practice. Causes given for these failures include low ease of system use, neg-

ative end-user attitudes towards the system, and negative impact on clinical workflows [6].

According to Mengting Ji et al. [5] there is a lack of rigorous evaluations of the effectiveness and usability of CDSSs. In fact, a significant number of CDSSs have not shown important advances, where the worst-case scenario is that some systems might do more harm than having positive impacts [5].

The poor evaluation of CDSSs is an international issue. They are classified as "Software as a Medical Device (SaMD)". However, over the years, they have continued to be a "gray area" that does not require mandatory approval of a public organ. Fortunately, many public organs such as the US Food and Drug Administration (FDA), UK National Health Service (NHS), and European Union (EU) have put great efforts in working towards conforming edits to existing guidelines as well as establishing standards in the context of maximizing patient safety and implementing post-market surveillance [5].

In addition, current evaluations on CDSSs are not always based on comprehensive frameworks or convincing models, but are mostly limited to the quality of care improvement and costs reduction [5]. Hence, there is a need to evaluate significant parameters of the success of CDSSs in order to promote better development and implementation. The benefits of evaluating a CDSS include the ability to provide a taxonomy of features and attributes to use these further to characterize individual CDSS interventions and develop best practices, and predictive models of intervention success [7].

While CDS systems have been a primary focus, there exist other systems such as Decision Support Systems (DSSs) and mobile health (mHealth) applications that researchers and experts have dedicated their time to develop and propose evaluation frameworks. The different evaluation approaches regarding DSS and mHealth can be used in assessing a CDSS, especially in design and implementation, as there are many principles and functionalities that these systems have in common.

In related work, we conducted a review of different evaluation approaches and frameworks to assess mHealth [8]. The findings included several evaluation frameworks such as The Health IT Usability Evaluation Model (Health-ITUEM), AHP based approach, and National Institute for Health and Care Excellence guidance [9, 10, 11]. Investigating the findings from the review revealed the lack of comprehensiveness. The existing framework did not

consider areas such as data privacy, security, and confidentiality [8].

NHS has acknowledged these issues and has therefore established a unit called NHSx. The NHSx focuses, amongst others, on developing a comprehensive framework to evaluate healthcare-related services. In this, they have succeeded, as they launched a framework called Digital Technology Assessment Criteria (DTAC) earlier this year (2021) [12]. Therefore, this presents the opportunity to explore the comprehensiveness of this framework to provide evidence that recently developed frameworks are not limited to the only quality of care improvement and costs reduction.

1.2 Research Questions

The research questions of this thesis relate to the implementation and customization process of a framework and evaluation of a particular CDS application. More specifically, we will explore the following research questions:

RQ 1: What does the research literature tell about the need for good frameworks to evaluate eHealth applications in general, and CDS systems in particular?

RQ 2: How can the general UK NHSx DTAC framework be customized to be suitable for evaluating a particular national CDS application?

RQ 3: By using our customized version of NHSX DTAC (from RQ2) to evaluate the COPD calculator, how well does the COPD calculator score?

RQ 4: How suitable is NHSx DTAC as a framework for evaluating a CDSS like the COPD calculator?

1.3 Research Methodology

The process of this study started with a review of existing frameworks conducted in the extra-curriculum related to this master thesis. The conducted review included an overview of existing frameworks in systems/applications related to healthcare and to identify the lack of comprehensiveness of these frameworks. Later in the conducted review, we compared this against the NHSx DTAC to assess whether the NHSx DTAC is more comprehensive and suitable for usage in this master thesis.

The master thesis will present a description of the customization of the chosen existing framework. The customization process includes a discussion of the exclusion and inclusion of criteria. Hence, the customization must fit the Norwegian health technology and standards. Finally, we conduct a case study, where the proposed framework is used to evaluate a Norwegian clinical decision support tools.

The Norwegian clinical decision support tool chosen for this master thesis is a computerized clinical practice guideline (CPG) based CDS tool. Briefly described, a CPG is statements and recommendations to assist practitioners and patients in decision-making processes about appropriate health cares for specific circumstances [13, 14]. A computerized CPG-based CDS is the digital delivery mechanism to offer clinicians and healthcare providers medical information at the point of care.

1.4 Outline

This section presents an overview of this master thesis structure. A brief description of each chapter is presented here:

- **Chapter 1** - A description of motivation and problems, including research questions and methodology is presented.
- **Chapter 2** - Theoretical background information and related work are presented. Further, an introduction of a general clinical decision support system/tool (CDS) is described. Additionally, a presentation of a CDS tool, known as the COPD calculator is included. Finally, the lack of evaluation of these systems is discussed.
- **Chapter 3** - A presentation of the framework selected for evaluating the COPD calculator.
- **Chapter 4** - This chapter presents the process of customizing the framework, including criteria discussion. Then, a presentation of the final framework.
- **Chapter 5** - The evaluation process and the results are presented in this chapter.
- **Chapter 6** - This chapter presents the answers to the research ques-

tions, reflections, and limitations.

- **Chapter 7** - A conclusion has been drawn.

Chapter 2

Background

2.1 Chronic Obstructive Pulmonary Disease(COPD)

2.1.1 COPD, the disease

Chronic Obstructive Pulmonary Disease, also known as COPD, is the term for a group of lung conditions that causes breathing difficulties [15]. Diseases such as Chronic bronchitis and emphysema are different types of COPD. In most cases, COPD mainly affects people in middle-aged or older adults who smoke.

The main symptoms of COPD [15]:

- increasing breathlessness
- a persistent chesty cough with phlegm (some people may dismiss this as just a "smoker's cough")
- frequent chest infections
- persistent wheezing

The disease occurs when the lungs become inflamed, damaged, and narrowed. This is a progressive disease, and in most cases, it worsens over time [15].

In 2016, COPD was ranked by the World Health Organization (WHO) as the world's third leading cause of death. According to WHO, the disease

claimed 3.0 million lives in 2016 [16]. The mortality of COPD is higher than lung cancer and diabetes.

Diagnosing COPD disease can be challenging. It can easily be mistaken for asthma because of the inability to breathe properly [17, 18]. A proper examination of the lungs and correct diagnosis is crucial for the patient.

One of the most preferred methods to examine lung function is spirometry [17]. Spirometry is a breathing exercise where the physician simply measures the speed and volume of the air the patient breaths in and out [15]. The readings are then compared with normal results for the patient's age to receive the correct diagnosis.

There is currently no cure for COPD, but treatment can help delay the symptoms and progression of the condition [15]. Treatments include a total stop of smoke, which is the most effective way to prevent COPD progression. Furthermore, there exist many medications to treat COPD. Inhalers and tablets can help to make breathing easier and reduce the risk for infections [17, 15].

Pulmonary rehabilitation is another treatment option for cases where only medications and exercise advice are not sufficient. The rehabilitation program is a specialized program of exercise and education designed to help patients with lung problems such as COPD [15]. The program is typically a session that lasts at least 6 weeks.

Surgery or a lung transplant is another available option, but this often concerns very few cases [15].

An early diagnosis is crucial to treatment options. Because it is a progressive disease, early detection and diagnoses are necessary to prevent irreversible, disabling lung function loss [16]. A common cause of delayed diagnosis is that many often think becoming gradually breathless is due to the aging process. This can result in delayed treatments and smoking cessation [18]. Patients with COPD often struggle with their daily lives and activities because of the symptoms and lower quality of life. Hence, early detection implies early treatment. To succeed in early detection of the condition, it requires more frequent use of spirometry in examinations conducted by physicians [17]. It requires frequent use on the same basis as when the physicians measure blood pressure. Every adult over the age of 35 who smokes or has malicious occupational exposure, and at the same time, has respiratory symptoms should

be offered examination [17].

2.1.2 Current status on COPD in Norway

According to Norwegian studies, ca. 5% of the adult population have clinical symptoms of COPD. This is equivalent to 300.000 Norwegian citizens. Furthermore, 25% of the cases are unaware that they might have a COPD condition [17].

Moreover, according to the public health report published by the Norwegian Institute of Public Health (NIPH), approximately 6% of the population aged over 40 have COPD disease [19]. This corresponds to 150.000 people in Norway, and that between 50-70 thousand of these were treated for COPD in the health service [19].

2.2 ICT Applications and Tools to support COPD Diagnosis, Treatment Plans, and Monitoring

The usage of computer-based methods in medical diagnosis is increasing. Gradually, they are improving the quality of medical services by utilizing the larger datasets of symptoms and patient history, as well as diagnostic test results for diagnosis [20]. According to McCabe et al. [21], there has been increasing use of Information and Communications Technology (ICT) to manage many chronic illnesses, such as asthma, cardiac diseases, and COPD.

Several applications that support decision-making in diagnosis and/or treatment planning of COPD have previously been presented in scientific literature [20, 22, 23, 24, 25, 26, 27, 28, 29, 30] . In the following sections, three of these applications will be presented. The first two are aiming at supporting diagnosis, and the third is addressing patient management.

2.2.1 An Expert Diagnostic System to Automatically Identify Asthma and Chronic Obstructive Pulmonary Disease in Clinical Settings

Badnjevic et al. [20] present a development of Expert Diagnostic System (EDS) based on a combination of artificial neural network (ANN) and fuzzy logic (FL) algorithms. The study aimed to evaluate the impact of introducing EDS into a healthcare system by testing the hypothesis that an accurate EDS could differentiate patients with asthma, COPD, and a normal lung function with a classification rate of over 90%. The conducted study took place in Bosnia and Herzegovina in 2016.

A block diagram of the EDS is presented in the figure 2.1. It consists of (1) a pre-classification algorithm used to determine whether confirmatory respiratory function tests are needed based on a symptom questionnaire and (2) a classifier based on a combination of a single-layer ANN and FL [20].

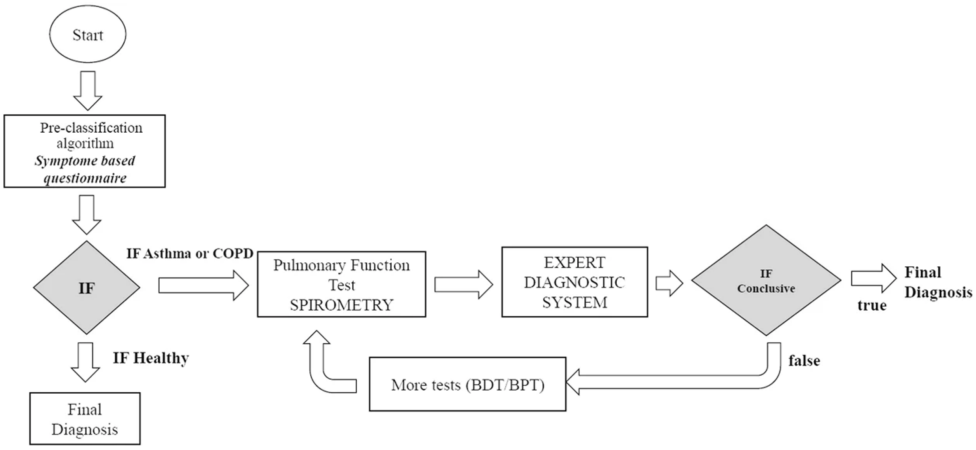

Figure 2.1: A block diagram of the entire EDS in Badnjevic et al. [20]

The EDS was tested on 1650 patients, and the results showed that the presented system could achieve a classification rate well above 90%. Out of 1495 patients with some respiratory disease, 1442 were correctly classified, resulting in a sensitivity of 96.45% [20]. Further, out of 859 patients with a confirmed diagnosis of asthma, 96.62% were correctly classified. Moreover, 96.22% of 636 confirmed COPD patients were correctly classified. In addition, 98.71% of the 155 patients with normal lung function were correctly

classified [20].

The installment at healthcare institutions in Bosnia and Herzegovina indicated high potential in everyday use in clinical practices. The result showed that very high savings on respiratory function tests could be achieved and the quality of care is not affected [20]. The EDS diagnosed 1123 reports out of 1495 samples, without performing respiratory functions tests. Comparing this result to diagnosis performed by medical professionals, the use of respiratory functions tests decreased by 49.23% [20].

2.2.2 Diagnosing COPD Using Mobile Phones

Hasan et al. [22] presents the design and implementation of a mobile phone application that utilizes its built-in microphone to record the user's exhalation. The recording is then analyzed on the application using advanced algorithms to assess the lung's functionality and the possibility that a user might be suffering from COPD [22]. Furthermore, the application allows the data to be shared with specialized physicians in order to receive a consultation.

Another functionality of the application is using a proximity sensor in the phone to identify how close the phone should be placed to the user's face during the exhalation. This mechanism improves the accuracy and consistency of the system.

An overview of this COPD Diagnosis System is shown in the figure 2.2. The following steps after recording the exhalation include analyzing the recording and assessing the COPD diagnosis. In addition, the data obtained from the application is securely sent to a remote server using Wi-Fi or 3G (which was the current technology at the time) connection and stored in the server's database [22]. The database can be accessed through a website that allows both patients and physicians to access the records. To limit access to the database, the website has an authentication system and a database that stores the records by the users and physicians. The physician also has the ability to provide feedback and advice on a user's record when granted access. In addition, the spirometry results are also stored on a local database on the mobile phone, which allows the user to access their results in offline mode [22].

The proposed mobile application solution for diagnosing COPD demonstrated

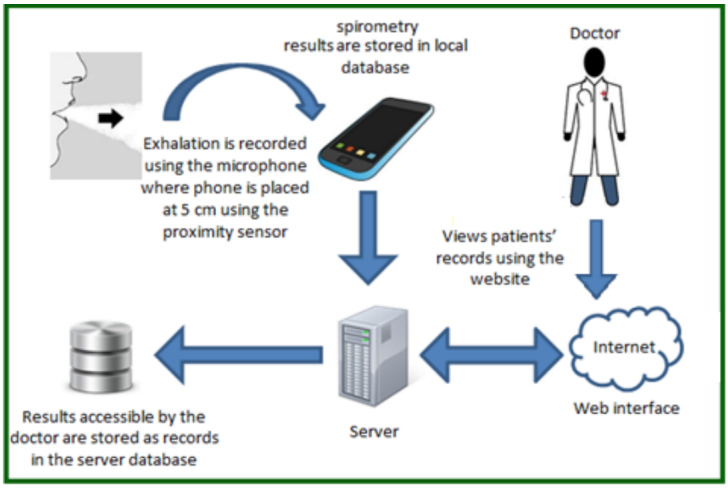

Figure 2.2: An overview of the COPD Diagnosis System in Hasan et al. [22]

a potentially efficient and user-friendly approach. 18.66% samples out of 134 healthy samples were identified as possible COPD patients, while a traditional spirometry test/ spirometer identified 16.97% samples out of 271 healthy samples as possible COPD [22]. The results suggest that about 95% of the time the results of the phone matched the traditional spirometry test/-clinical spirometer results [22].

2.2.3 Clinical Decision Support Systems for preventive management of COPD patients

Velickovski et al. [23] presents a clinical decision support tool which can assist in the adherence to best-practice medicine in critical decision points during the execution of a care pathway. The aim of the paper is to design, develop and assess a Clinical Decision Support System (CDSS) offering a suite of services for early detection and assessment of COPD. It must be mentioned that this work is related to the the SYNERGY-COPD project [31].

The solution suggests a service-oriented architecture that separates the CDSS from an external health information system (HIS), but integrates them using standardized, service-based interfaces. The interface encodes the clinical data and recommendations in a formal representation using ontologies and

vocabulary. Further, the CDSS is interfaced through a web service protocol, with clinical data being exchanged through an interoperable format. The diagram in the figure 2.3 illustrates the architecture.

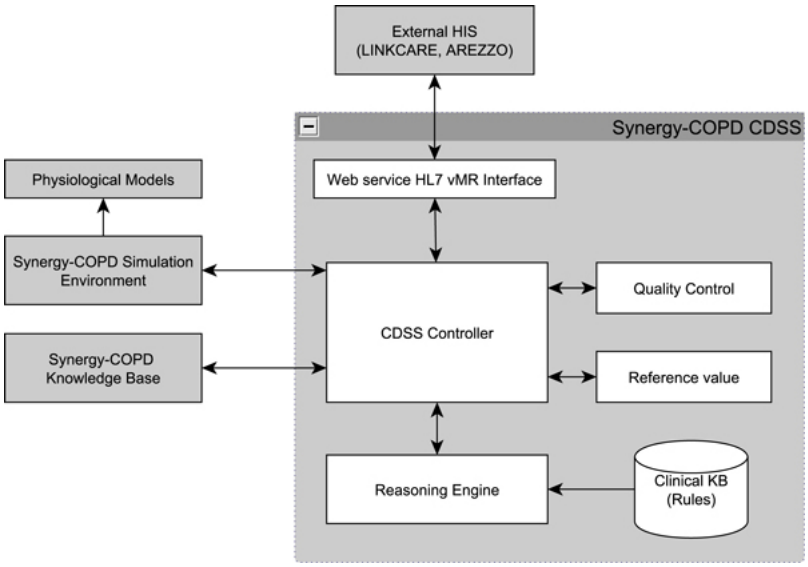

Figure 2.3: CDSS architecture depicting internal modules, external user HIS, and external supporting Synergy-COPD systems in Velickovski et al. [23].

A brief description of the architecture is that the CDSS controller is responsible for coordinating all the communication between internal components and external systems during the execution of a decision support task [23]. The Reasoning Engine is the most important component in the system, which contains the ruled-based reasoning paradigm. In other words, the algorithm or inference methods used in this CDSS are captured through a collection of IF-THEN expressions.

As a result, decision support web services were deployed in a secured environment online for the preventive management of COPD patients. Further, the web services were integrated with two existing HISs, all web services into the Linkcare platform and the spirometry quality control web service into Arezzo Pathways.

During validation of the CDSS diagnosis service, a validation set containing 323 cases was used. The CDSS reported 111 diagnosis recommendations as likely COPD and 222 recommendations as unlikely COPD. 297 cases were

correctly matched, which is equivalent to 95% when comparing results against the respiratory specialist classification of the case. Sensitivity and specificity calculations were calculated to be 90% and 96%, respectively.

The current research has generated a CDSS capable of addressing important COPD management issues in case-finding, diagnosis, and stratification. The CDSS indicates the ability to issue recommendations with a high degree of accuracy to support COPD diagnosis. Moreover, the integration has shown success in implementing the CDSS web services. The response time of CDSS for all decision support services was acceptable (within seconds) to the clinical task at the point of care, thus allowing seamless integration into the existing HIS.

2.2.4 A general description of Clinical Decision Support Systems and/or functionalities

A traditional CDSS is defined as software designed to directly aid clinical decision-making by providing patient-specific assessments or recommendations to the clinician [2]. These assessments and/or recommendations are based on matching the characteristics of the individual patient to a computerized clinical knowledge base. Current CDS systems are primarily used at the point of care and are intended for clinicians to combine their knowledge with the information or suggestions provided by the CDSS [2].

CDS systems have the potential to enhance healthcare and are intended to improve the clinical workflow, as well as the implementation of evidence-based recommendations [23, 32]. In addition, it is supposed to improve healthcare delivery by enhancing medical decisions with targeted clinical knowledge, patient information, and other health information [2].

The functions provided by CDS systems are vast, including diagnostic, alarm systems, disease management, and much more [2]. For example, as mentioned in section 1.1, these functions can provide services such as computerized alerts and reminders, computerized guidelines, order sets, patient data reports, etc.

The addressed functions such as alerts and reminders are intended to urge clinicians into providing preventive care such as vaccinations or other medical events. According to Sutton et al. [2], CDSS improves patient safety through reminder and alert systems. Alerts and reminders can also help reducing

medication administration errors by for example notifying potential errors in prescriptions or other orders, which can result in increased efficiency [2, 33].

Furthermore, computerized guidelines are addressed as a function provided by a CDSS. According to Sutton et al. [2], there are evidence of studies that a CDSS can increase adherence to clinical guidelines. This is significant because traditional clinical guidelines and care pathways have been shown to be difficult to implement in practice with low clinician adherence [2]. It can be challenging for clinicians always to stay updated on changes in guidelines. The rules implicitly encoded in clinical guidelines can be encoded into a CDSS [2]. Such a CDSS includes various standardized order sets for a targeted case, alerts to a specific protocol for the patients it pertains to, reminders for testing, etc. Furthermore, CDSSs can assist with managing patients on treatment protocols, tracking and placing orders, follow-up for referrals, and ensuring preventative care [2].

Moreover, CDSS can provide support in the decision-making of diagnosis. Traditionally, such systems provide computerized recommendations or consultation or filtering steps, taking into account the provided data/user selections, and then output a list of possible or probable diagnoses [2]. With the great implementation of such systems, they can provide patient safety, reduce time and resources associated with misdiagnosis and increase preventive care.

2.3 Introducing the COPD calculator

CodeLab is a Norwegian Company established in 2013 that specializes in advanced software development. KBB Medic is another Norwegian company established in 2013 by a group of lunge specialists and IT experts. Their focus is to develop IT platforms for health information and decision support [34]. Further, they collaborated on creating a website known as MEDGuideline [35] and is a placeholder for decision support tools that they offer, which launched in 2020. Together KBB Medic and CodeLab developed the Chronic Obstructive Pulmonary Disease (COPD)-calculator and is a part of the MEDGuideline network.

The COPD calculator is a web application diagnostic support tool with clinical guidelines implemented as a knowledge base. The application is intended

to calculate the possible risk of COPD of a patient and then suggest treatments and medications to the selected treatment accordingly. The COPD calculator identifies as a CDS tool because of its ability to give diagnostic support and suggestion for treatments [34]. The calculator is supposedly a stand-alone application and it is not integrated with any EHR or CPOE.

The development of the COPD calculator was intended to solve the demand for a more effective and way for supporting the diagnosis of COPD disease. In addition, the tool's usage is only meant for the attending clinician to ensure the quality of their decision at the point of care [34].

The knowledge base in this calculator is based on The Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines including the revised Norwegian COPD guide, and the Norwegian Blue Prescription Regulations [35]. These guidelines together consist of over 200 pages of text. The challenge of clinical guidelines is the frequent change, which is difficult for a clinician to always be up to date [36]. In addition, the large amount of text is very time-consuming if going through manually. In order to make this more effective, the developers decided to hard-code the guidelines into the COPD calculator. The algorithm takes the clinical data as input provided by the attending clinician, and the guidelines into consideration and later gives a diagnosis. The tool can give a quality assured diagnosis in a short amount of time, it also presents a great overview of valid treatments and gives the physician a summary of the diagnosis, chosen treatment(s), and recommendations.

The workflow when using the COPD calculator is as follows:

1. Collect data and information from the input field chosen by the attending clinician.
2. Based on the given information the algorithm calculates the risk with regard to the programmed guidelines.
3. The output is quality assured diagnosis
4. After diagnosis, the application will display medication suggestions according to the given diagnosis.
5. Then the physician will get a journal summary with recommendations, referrals, and follow-ups.

2.3.1 Implementation of the COPD

The implementation of the COPD calculator used an open platform for building web applications in Java, known as Vaadin [37]. The platform integrates web components, frameworks, and tools into one complete and meaningful web development stack [38].

This master thesis will focus only on the algorithm regarding diagnosis and treatment. As mentioned earlier, the knowledge base of the COPD calculator is based on different guidelines related to COPD. These guidelines are hard-coded into the web application. Moreover, these guidelines are considered as "TreatmentRule" when calculating the COPD probability of a patient.

The algorithm for the calculation of the diagnosis considers a "TreatmentRule rule". This rule selects a guideline in which the calculation of the COPD probability will be based, as shown in the figure 2.4. Further, the implementation gets the spirometry values FEV1 (the amount of air you can force from your lungs in one second) and FVC (the amount of air you can force from your lungs in six seconds) as an input from the user interface, in which the variables will be used to calculate the probability [39]. In standard COPD diagnosis, FEV1 is divided by FVC, and if the result is lower than 0.7, then it is a positive COPD diagnosis. This is a practical method to make the diagnosis with a simple calculation.

As younger healthy persons have more flexible lungs and exhale faster than older people, this method will over-diagnose older people and under-diagnose younger people. A more correct threshold to use instead of 0.7 is the "lower limit of normal". This value is a rather complicated calculation based on studies on big populations. The calculation is too complicated for a general practitioner in everyday health care, but is perfect for a digital decision support tool and is supported in the COPD-calculator.

Moreover, the diagnosis is used further to create a treatment plan. The figures 2.5 and 2.6 display a partial code segment to calculate the medication options to a certain guideline and be included in the treatment plan. We will briefly describe the logic behind the medication options.

In order to generate medication options recommended by guidelines, the calculator must take the variable "diagnosis" and "CalculatorController c" into consideration. The usage of the resource class "CalculatorController

```
public Diagnosis calculate(TreatmentRule rule) {

    //FEV1 Calculations
    double findExpectedFev1 = ethnicity.findExpectedFev1(male, age, getHeightCm() );
    double fev1pct          = fev1 / findExpectedFev1;
    double fev1FvcFactor    = fev1 / fvc;

    double lower_limit_normal = male ? LowerLimitOfNormal_Men.LLN(age, getHeightCm(), ethnicity) : LowerLimitOfNormal_Women.LLN(age, getHeightCm(), ethnicity);
    double limit = Math.max(0.7, lower_limit_normal);

    //Calculate Probability
    CopdProbablity probability;
    CopdProbablity gold_probability = (fev1FvcFactor < 0.7 && age > 39) ? CopdProbablity.PROBABLE : CopdProbablity.NOT_PROBABLE;
    CopdProbablity lln_probability  = (fev1FvcFactor < lower_limit_normal && age > 39) ? CopdProbablity.PROBABLE : CopdProbablity.NOT_PROBABLE;

    if ( fev1FvcFactor < limit && age > 39) {
        probability = CopdProbablity.PROBABLE;
    } else {
        if ( fev1FvcFactor >= limit && fev1pct >= 0.8) {
            probability = CopdProbablity.NOT_PROBABLE;
        } else {
            probability = CopdProbablity.UNSURE;
        }
    }

    //Calculate Seriousness
    CopdSeriousness seriousness = getCopdGrade(true);

    //Calculate Treatment Group
    CopdTreatmentGroup treatmentGroup = CopdTreatmentGroup.A;
```

Figure 2.4: A screenshot of partial code to calculate the diagnosis of COPD.

c" in this context is because of the function implemented to translate for different languages. In the figure 2.5, the function "GOLD2019" shows the implementation of different cases of medication options available to the specified guideline based on the diagnosis output. Another factor that affects the choice of medication-related to the diagnosis is the variable "Treatment-Group". This calculates the medication options based on exacerbations input retrieved from the patient. There are four categories, A, B, C, and D, under which the patient can fall under. A small code segment of the beginning of calculating the treatment group is visible in the figure 2.4.

Further, this function "GOLD2019" together with the calculated diagnosis gives a treatment output.

```
private void GOLD2019(Diagnosis diagnosis, CalculatorController c) {

        int fev1 = diagnosis.getFev1Pct();

        neededGuide = "";

        switch (diagnosis.getTreatmentGroup()) {

        case A:
        default:

                // First choices
                addFirstChoice(DrugType.LAMA);
                addFirstChoice(DrugType.LABA);
                incompatible.add(DrugType.LABA, DrugType.LAMA);

                guide = c.TR(ID.TREATMENT_GOLD2019_A_FIRST);
                neededGuide = c.TR(ID.TREATMENT_GOLD2019_A_NEEDED);

                break;

        case B:
                // First choices
                addFirstChoice(DrugType.LAMA);
                addFirstChoice(DrugType.LABA);

                // Extended choices
                addExtendedChoice(DrugType.LABA_LAMA);

                guide = c.TR(ID.TREATMENT_GOLD2019_B_FIRST);
                extendedGuide = c.TR(ID.TREATMENT_GOLD2019_B_EXTENDED);
                extendedTitle = c.TR(ID.TREATMENT_GOLD2019_B_EXTENDED_TITLE);
                break;

        case C:
                // First choices
                addFirstChoice(DrugType.LAMA);

                // Extended choices
                addExtendedChoice(DrugType.LABA);
                addExtendedChoice(DrugType.LABA_LAMA);
                addExtendedChoice(DrugType.ICS_LABA);
                addExtendedChoice(DrugType.LAMA_LABA_ICS);
                addExtendedChoice(DrugType.ICS_LAMA);
                addExtendedChoice(DrugType.MACROLIDE);

                guide = c.TR(ID.TREATMENT_GOLD2019_C_FIRST);
                extendedGuide = c.TR(ID.TREATMENT_GOLD2019_C_EXTENDED);
```

Figure 2.5: A screenshot of the partial code of implementing the medications recommended accordingly to the guideline of selection in the treatment plan.

```
                extendedTitle = c.TR(ID.TREATMENT_GOLD2019_CD_EXTENDED_TITLE);

                // less than 50% gets PDE-4 on second choices list
                if (fev1 < 50) {
                        addExtendedChoice(DrugType.PDE_4);
                        extendedGuide = extendedGuide.concat(" "
                                        + c.TR(ID.TREATMENT_GOLD_PDE4));
                }
                break;

        case D:
                // First choices
                addFirstChoice(DrugType.LAMA);
                addFirstChoice(DrugType.LABA_LAMA);
                addFirstChoice(DrugType.LABA);
                addFirstChoice(DrugType.ICS_LABA);

                // Extended choices
                addExtendedChoice(DrugType.LAMA_LABA_ICS);
                addExtendedChoice(DrugType.ICS_LAMA);
                addExtendedChoice(DrugType.MACROLIDE);

                guide = c.TR(ID.TREATMENT_GOLD2019_D_FIRST);
                extendedGuide = c.TR(ID.TREATMENT_GOLD2019_D_EXTENDED);
                extendedTitle = c.TR(ID.TREATMENT_GOLD2019_CD_EXTENDED_TITLE);

                // less than 50% gets PDE-4 on second choices list
                if (fev1 < 50) {
                        addExtendedChoice(DrugType.PDE_4);
                        extendedGuide = extendedGuide.concat(" "
                                        + c.TR(ID.TREATMENT_GOLD_PDE4));
                }

                break;
        }
```

Figure 2.6: A continuation of the partial code of implementing the medications is recommended accordingly to the guideline of selection in the treatment plan.

2.3.2 Navigating through the COPD calculator

When entering the MEDGuideline website, there exists an overview of decision support tools created by KBB Medic and CodeLab. Further, the COPD calculator was selected, and the website was redirected to the front page of the COPD calculator as shown in the figure 2.7. Moreover, the page is displayed with three options for the user, in this case, the clinician, to choose between. The left-most column state in Norwegian "NY PASIENT", translated into English is NEW PATIENT. Further, the middle column states "OPPGFØLGNING", the direct translation is FOLLOW-UPS, and the rightmost column state "ÅRSKONTROLL" , translated as "YEARLY CONTROL".

We selected the "NEW PATIENT" option to demonstrate the calculator and ran a random example on the application. As shown in the figure 2.8, the

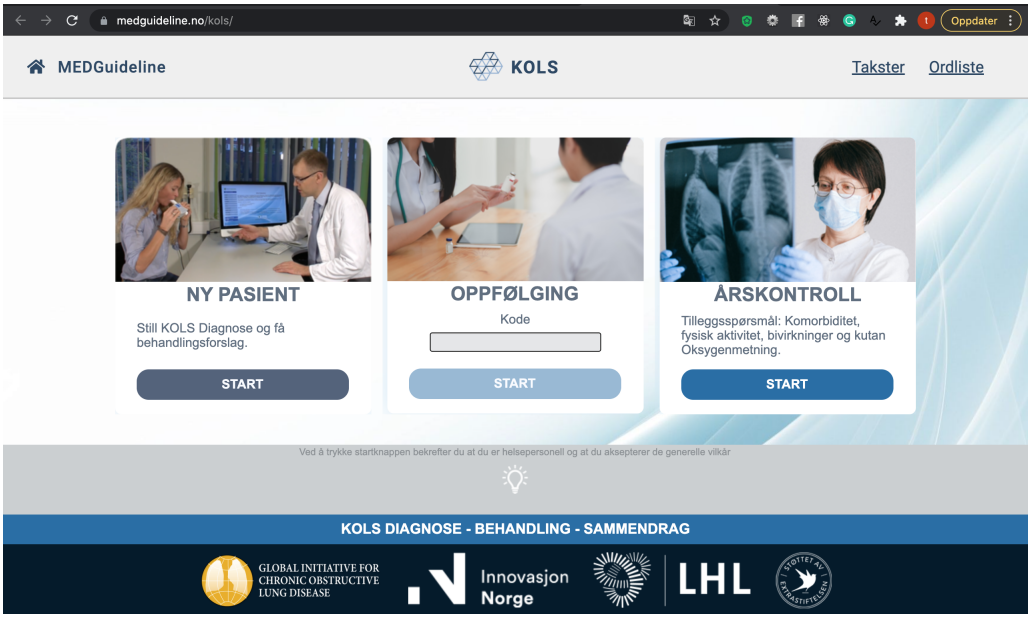

Figure 2.7: A screenshot of the front page of the COPD calculator showing the tree options.

user is presented with questions they must ask the patient to receive any results. There is an overview of questions on the left sidebar and the answers entered so far by the user. In this example, the patient is a "Kvinne", a "woman" in English translation. Further, the patient is Norwegian, 55 years old and 165 cm, she weighs 60 kg and is a smoker. Moreover, the clinician has to take spirometry of the possible COPD patient to answer the questions regarding FEV1, FVC, "Forverringer/Exacerbations", MMRC Score in the figure 2.8. Modified Medical Research Council Dyspnea Scale is MMRC, which is a classification of heavy exhalation related to COPD [40].

After entering the FEV1, FVC, exacerbations, and MMRC, the clinician can then receive the results as shown in the figure 2.9. Moreover, the figure 2.9 also displays "Resultatet er klart/The results are ready". Futhermore, the calculator also state that CAT and CCQ score are recommended if MMRC ¡ 2, because they can describes the symptoms better than MMRC score.

When selecting the button "Resultatet er klart/The results are ready", the clinician can view the results related to the patient, in this case, the example we used from the beginning is displayed. As shown in the figure 2.10 ,there is

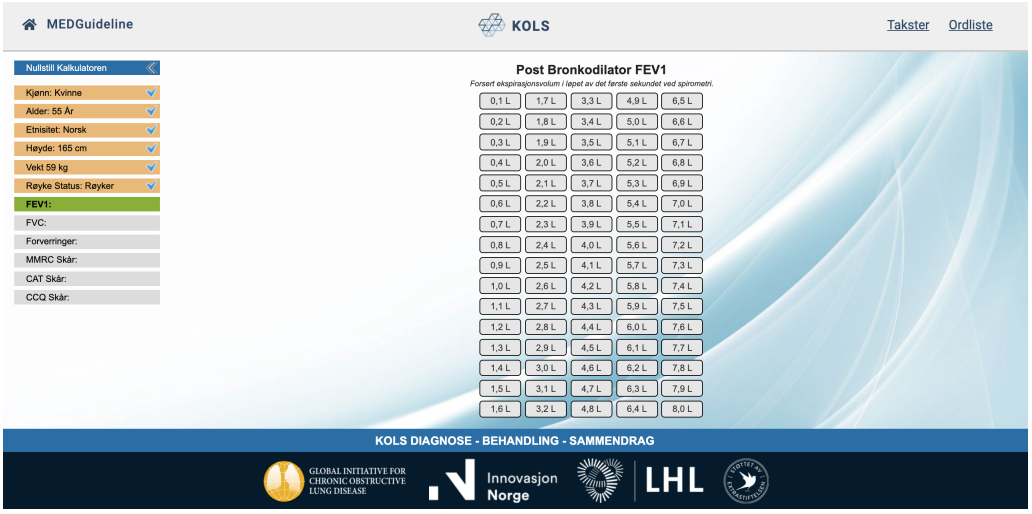

Figure 2.8: A screenshot of the questions that the clinician must be answered.

a description of the diagnosis and recommended treatments. A progression of the disease related to the patient is also displayed.

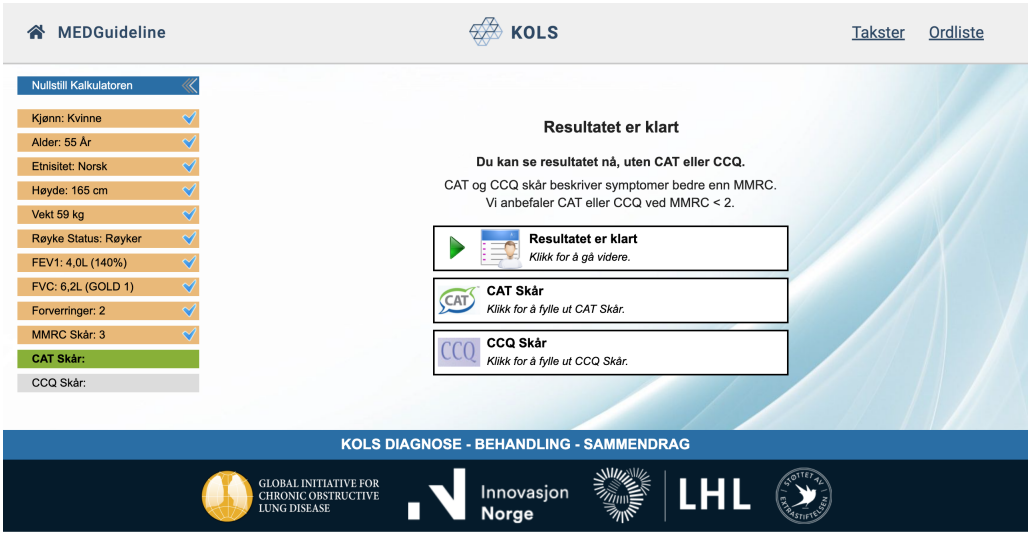

Figure 2.9: A screenshot of the answered questions is displayed on the left sidebar.

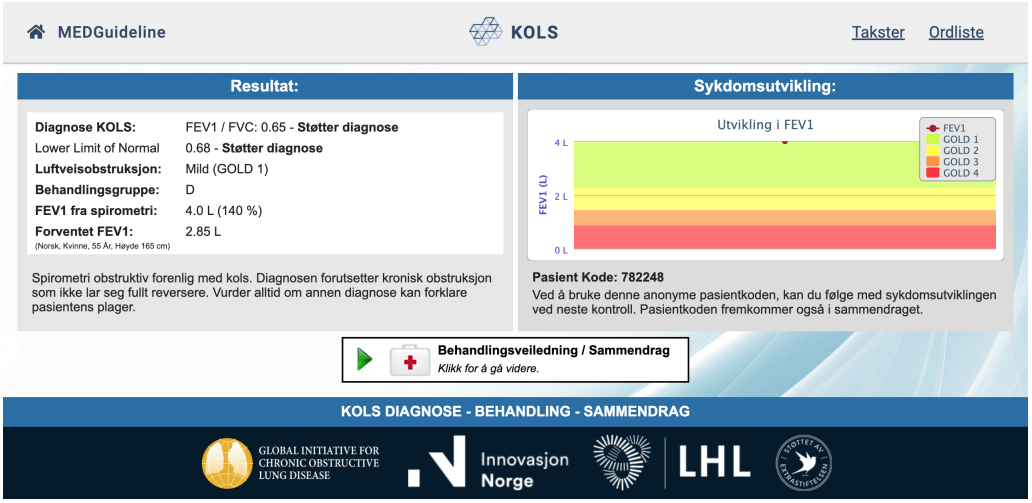

Figure 2.10: A screenshot of the results to the patient is used in this example is on the left. On the right, the progression of the disease related to the patient is displayed.

When selecting "Behandlingsveiledning/Sammendrag", translated to "Treatment recommendations/Summary", the clinician will receive an overview of medication available for recommendations according to the patient's diagnosis, as shown in the figure 2.11. Further, the application has a function implemented to reduce medication errors or exaggerate medication such as when selecting a medication. The application will disable the other options that are not compatible with the medication that the clinician has included in the treatment plan.

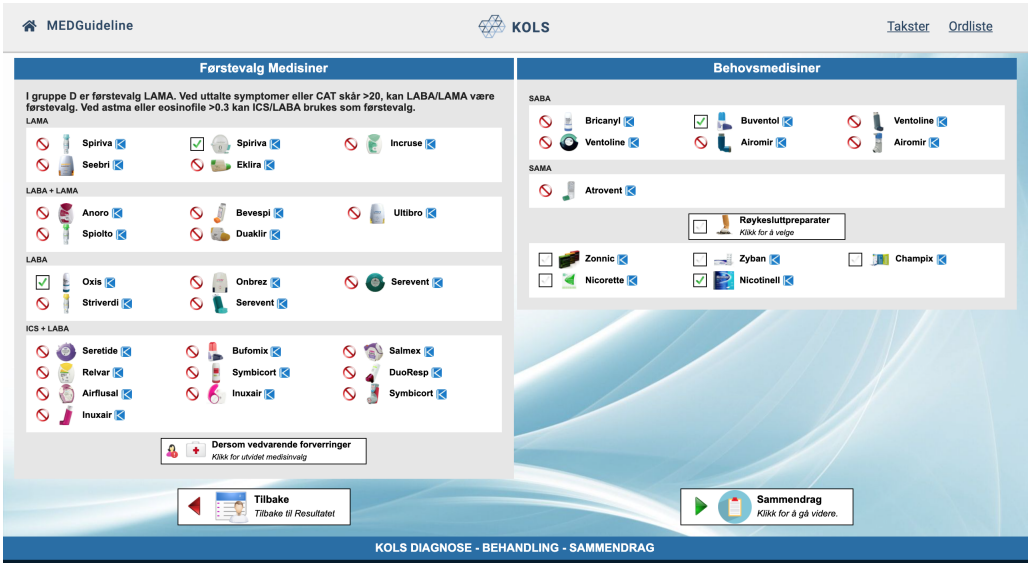

Figure 2.11: A screenshot of medication options

In the next step, the clinician can select the "Sammendrag/Summary"-button. The summary will display a description of the treatment plan including the diagnosis, medication selected, and other recommendations, as shown in the figure 2.12. Because the application is a standalone application and is not integrated with any EHR, the clinician must manually copy the summary into the wanted EHR. The reason for not integrating with an EHR is because Norway has not established a common way to share data securely, another reason is that there are several EHRs in use and not just one.

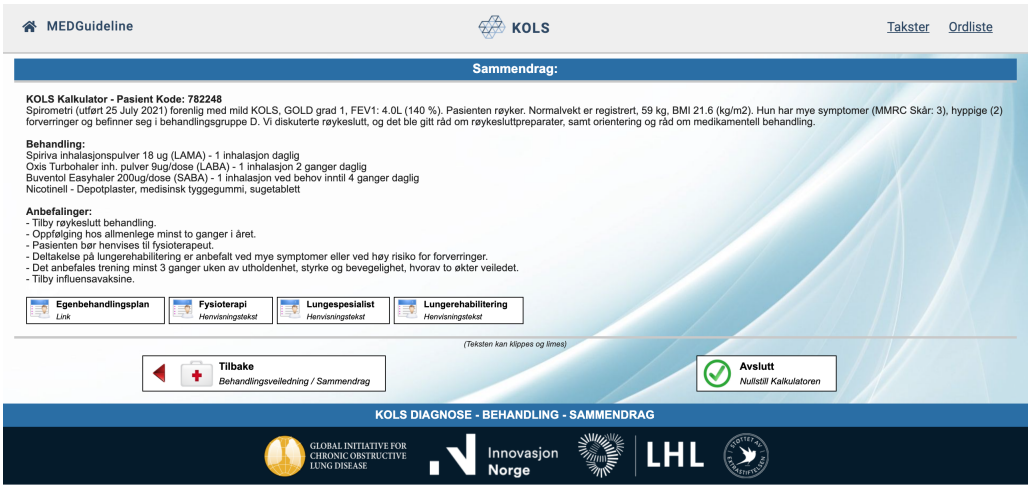

Figure 2.12: A screenshot of the Summary

A general description of CPG-based CDS

Clinical practice guidelines-based CDS is an effective approach, but still there exist ongoing implementation challenges that inhibit the wide dissemination of CPG-based CDS [13]. It requires significant effort to implement a shareable, scalable, computable, and actionable CPG as a CDS since there is no standard of how best to approach CPG-as-CDS implementations [13].

Many studies have shown that if a CDS tool does not offer an executable recommendation relevant to the patient, it is likely to be dismissed and ignored [41]. Understandably, clinicians and healthcare providers find it hard to trust a CDS tool as there are tons of solutions like this on the market. Hence, the reason to assess a CDS tool. Evaluating a clinical decision support tool on different aspects, including the lacking areas, can help gain trust among clinicians and patients. With the right evaluation framework, it can ensure end-users safety and the tool's quality.

2.3.3 Result and success

According to the final report written in 2016 for ExtraStiftelsen Helse og Rehabilitering [42], the COPD calculator has been used more than 11.000 times. A good portion of these was registered as test-mode, while more than 6.000 registrations were in patient-mode, and more than 4.600 lung function

volume measured was in the category of COPD. Data gathered from this project has been presented to ATS in San Francisco [42].

The rapid growth of users after the short period of time of the release confirmed the need for this service. Overall this indicated a success. As of October 2019, the COPD calculator had already been used more than 28.000 times and was well received by Norwegian doctors [34].

2.3.4 Evaluation of the COPD

The COPD calculator has not yet been evaluated. CodeLab and KBB Medic have had major focus on the Conformité Européenne (CE) certificate. The CE certificate is a declaration of conformity, which specifies that the manufacturers or the representative from the organization can guarantee that every requirement attached to the product in the relevant directive/regulation is considered to be fulfilled [43].

Hence, their wish is to have a proper evaluation to ensure the quality of the product. In addition, they wish to receive feedback on necessary changes in order to achieve the CE mark.

2.4 General description of the lack of evaluations in CDS and apps/eHealth systems

A CDS should be judged on both clinical and nonclinical domains such as patient outcomes, end-user outcomes, functionality, workflow fit, and others [41]. Further, a successful CDS tool should solve the whole user problem or the issue it was built to address, be able to be measured and monitored, and should feel transparent, accessible, useful, and non-interruptive to the end-user [41].

In 2001, Kaplan [44] conducted a literature research on studies regarding evaluation of CDSSs. As a result of the literature research, she argues that there is a need for qualitative evaluations that examine the user-CDS interaction and its impact on the clinician, workflow and other organizational outcomes [45]. Further, she mentions that there exist few studies involving field tests of CDSSs and almost none in actual clinical settings with real patients [44].

According to Berner [45], there has been conducted many evaluations on the impact of CDS on health care quality in inpatient rather than ambulatory settings. There exists different evaluation methods and approaches towards assessing a CDS in general, one of these is Randomized Controlled Trials (RCT). RCT can be defined as "prospective studies that measure the effectiveness of a new intervention or treatment" [46]. However, as the approach is time-consuming and expensive, there have been conducted few RCTs on the impact of CDSs [45]. Moreover, Berner [45] states that the major research focus has been on the effects of COPD at the process of care and primarily on clinician decision making, rather than on outcomes or structures of a CDS system.

According to Enam et al. [47] evaluation of eHealth interventions is complex, as they often include multidisciplinary collaboration and are dependent on context, such as the country they are made for use in and other social aspects. Further, they conducted a systematic literature review, from this 64% of 25 case studies focused on clinical aspects, while only 20% of them focused on technological aspects [47]. The life cycle of a technological device/application/software/system usually has many phases. Hence, the architect of such a system requires an evaluation approach that considers other aspects than just the clinical.

In 2018, Greenes et al. list several issues as being partially responsible for the relatively slow adaptation and lack of impact of CDSSs, including deficiencies in leadership, recognition of purpose, understanding of human interaction and workflow implications of CDS, cognitive models of the role of CDS, and proprietary implementations with limited interoperability and sharing [7]. Greenes et al. suggest the development of an evaluation framework that addresses the identified issues and broadens the perspective of aspects of CDS.

The choice of using the NHSx DTAC was a result of the conducted review in our extra-curriculum [8]. The findings from the study proved that amongst other frameworks for evaluating applications, CDSS, and eHealth systems, there is a lack of focus on several areas. These areas included interoperability, data privacy and technical security [8]. Both Enam et al. and Greenes et al. state that other aspects than the clinical must be focused on [47, 7]. However, it must be noted that the existing frameworks do have many aspects that are important to provide evidence of effectiveness.

Further, we concluded that the lack of focus areas was well addressed in the NHSx DTAC. NHSx DTAC has made great efforts to learn from existing frameworks and proposed a solution that can help improve the lacking areas. Therefore, we will use this NHSx DTAC in the master thesis to evaluate the COPD calculator. The evaluation process will be described in chapter 5.

2.5 Chapter Summary

In this chapter, we introduced COPD disease and the need for an early diagnosis and treatment. Further, we introduced some examples of applications and tools to support the diagnosis of COPD disease. In addition, we described the general CDS systems and their functionalities in order to establish some understanding regarding such systems and the disease before introducing a CDS tool called the COPD calculator.

Moreover, we discussed the general lack of evaluations in CDS systems, applications, and eHealth systems. Further, we addressed the lack of comprehensive evaluation frameworks. In addition, we introduced a framework, that in our opinion, is very comprehensive, and we will use this framework to evaluate the COPD calculator.

In the next chapter, the NHSx DTAC will be introduced and well described in order to understand our argument of comprehensiveness.

Chapter 3

NHSx - Digital Technology Assessment Criteria

This chapter includes an introduction of the UK National Health Services and the unit NHSx.

3.1 NHS and NHSx

The National Health Services (NHS) is a comprehensive public health service that was established by the National Health Service act of 1946 [48]. It was launched by Aneurin Bevan, the Minister of Health, in 1948. The motivation behind the establishment was to provide good, solid and reliable healthcare for every citizen [49].

The advancing technology initiated the progress of creating a unit that focused majorly on the digitization of health services. Therefore, a unit under the name NHSx was created. The "x" in NHSx stands for "user experience". Furthermore, since NHSx is a part of NHS, they have to report to the Secretary of State and the Chief Executive of NHS England and NHS Improvement.

This unit is leading the development of the world's largest digital health and social care transformation program [12]. NHSx consists of members with a broad aspect of skills and expertise, including clinicians, technologists, policy experts, developers, data scientists, and project managers. Their focus is to

expedite the process of the digital transformation of the NHS and social care. Another focus area is to improve health and care productivity with digital technology. Further, NHSx has responsibilities such as coordination and consistency, setting standards, driving implementation, cyber policy, and much more [12].

In Norway, we have the Norwegian Directorate of Health (NDH), which is equivalent to the UK National Health Services. The NDH aims to better the quality of the health service and improve the health of the citizens and the community through targeted activities across services, sectors, and administrative levels. [50].

Furthermore, equivalent to the NHSx is the Norwegian Directorate of e-Health. The Directorate is a professional and authority body under the Ministry of Health and Care Services [51]. Moreover, The Directorate focuses on strengthening the digitization of the health and care sector to support effective and coherent health care services. In addition, The Directorate shall facilitate national coordination and manage e-health development [51].

3.2 Why DTAC

The DTAC is designed to be used by healthcare organizations to assess healthcare technology or recommend it to patients. Additionally, to ensure that new digital technologies meet the minimum requirement of standards[52]. Also, the DTAC has been introduced to respond to the need for clear direction on how to build and purchase solid digital health technologies [53]. Further, DTAC aims to help developers and innovators understand what is expected for entry into the NHS and social care [52, 54].

According to Dr. D J Hamblin-Brown, DTAC will provide every involving part related to healthcare with a one-stop means to assure that the end-users within NHS and social care have the highest standards of risk management and informative governance [54].

While DTAC is not currently mandatory, the feedback from more than 800 stakeholders from the first draft on DTAC states that DTAC brings together legislation and best practice in five areas such as clinical safety, data protection, technical security, and interoperability [55].

Tim Andrews, the chief operating officer of ORCHA, came forward with a statement telling, "It's never been more vital for health professionals to know, with absolute certainty, that the apps they are using and recommending are of the required standard." [56]. Briefly, it is an organization focusing on the assessment of digital health solutions to empower healthcare professionals, service users, and developers in order to improve health outcomes [57]. Further, they have also created App Library in order to find the best quality of applications. Moreover, ORCHA's review process of health applications is based on DTAC [55]. In addition, Andrews stated that the numbers downloaded from the ORCHA App libraries had been exponentially [55].

It must be mentioned that because DTAC has launched just recently, there are very few scientific papers addressing the NHSx DTAC in the literature search.

3.3 Digital Technology Assessment Criteria - DTAC

Digital Technology Assessment Criteria - (DTAC) is intended to be standard baseline criteria to clarify how digital health and social care technologies will be assessed [52]. The reason behind this creation is the rapidly changing of the UK digital health ecosystem with patients, commissioners, and developer organizations which all have an active role in the development and use of digital solutions [52].

DTAC consists of 4 sections [52]:

- A. Company information
- B. Value proposition
- C. Technical questions
- D. Key principles for success

Sections A and B will provide the assessors the context required to understand the product and support the evidence. Naturally, these sections will only provide information and are not a part of the assessment. Hence, the reason this master thesis will only include sections C and D in our evaluation.

The assessment criteria focus on five core areas and are defined in Section C. Section D details the required key principles of Usability and Accessibility.

The assessment criteria defined in section C contains [52]:

1. **Clinical safety** - Products are assessed to ensure that baseline clinical safety measures are in place and that organizations 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 security** - 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 while staying safe and secure

The core criteria in Section C will determine the overall success of assessing a product or service. Thus, developers must provide evidence asking of the assessment criteria in order to receive great success.

Section D includes core elements that will form part of the overall review of the product or service and is a key part to ensure that the product or service is suitable for use [58]. The assessment of this section will set a compliance rating and recommend areas that the organization could improve on following the core principles [58]. This section is a score section, and the score from this will show the level of adherence to the NHS Service Standard.

In this section, the DTAC includes company information and value proposition sections for context. Each of the scored and assessed sections contains [12]:

- 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

3.4 Chapter Summary

In this chapter, we introduced NHS and NHSx, including Norwegian versions of the public organs. In order to understand how the DTAC is built, we had to state the reasons it was developed. Finally, we presented the assessment criteria the DTAC included.

Further, this master thesis will use DTAC to evaluate the COPD calculator in chapter 5, but first, we will present the customization process of the DTAC in the next chapter.

Chapter 4

Implementation of the Framework

The COPD calculator is developed by a Norwegian organization and its intended use is within Norway. This implies that the framework must adapt to standards and regulations that exist in Norway. Thus, for the criteria table to hold these standards and regulations, a customized version of the NHSx DTAC assessment criteria table[1] will therefore be proposed in this chapter.

As well as a description of the implementation process of this adjusted criteria table, a thorough discussion of which criteria to include and which to exclude will also be presented. Every criterion belonging to the NHSx DTAC table will be discussed systematically, by first presenting the ones we chose to include, and then the ones we chose to exclude. Our intended purpose is to include only criteria that yield significant outcomes to the evaluation while considering the Norwegian context.

All criteria of the DTAC table discussed in the following sections, referred to by their code, can be found in the appendix "The Digital Technology Assessment Criteria for Health and Social Care (DTAC)".

[1] The NHSx DTAC full criteria table form can be downloaded here: `https://www.nhsx.nhs.uk/key-tools-and-info/digital-technology-assessment-criteria-dtac/`

4.1 Criteria included

4.1.1 Clinical safety

C1.1, C1.1.1, and C1.1.2

C1.1, C1.1.1, and C1.1.2 are Clinical Risk Management criteria that must be an integral part of any health IT software evaluation framework. The evidence Clinical Risk Management criteria provide of clinical safety increases the integrity of healthcare applications and has the potential to increase trust among end-users. These three criteria have therefore been included as they set the standard for a healthcare application.

A standard, such as DCB0129, developed by the UK government and NHSx, has, to the extent of the author's knowledge, not yet been developed in Norway. This standard is specific for Clinical Risk Management to provide manufacturers of health IT software with evidence of the clinical safety of their products. DCB0129 is based on International Standard Organization (ISO) 14971, which is an international standard that has been used since 2007. [59] Although the Norwegian government has not created a standard like DCB0129, Norwegian developers can follow the ISO 14971, but it is not a requirement unless manufacturers and organizations want to put their product on the market. Thus, we have to customize the criteria to comply with ISO 14971 which is the globally used clinical risk management standard for medical devices.

C1.3, C1.3.1, and C1.3.2

These criteria are asking if the product falls within the UK Medical Devices Regulations (MDR) 2002. Obviously, since these regulations are for within the UK, the COPD calculator does not. However, being registered with the Medicine and Healthcare products Regulatory Agency (MHRA) and/or providing a Declaration of Conformity proves that the product has undergone the process of receiving a CE certificate [60]. These criteria were therefore included, only with the alterations needed to fit a Norwegian context.

The Norwegian regulations for medical devices are defined in the Act of 12 January 1995 no 6 on medical devices § 3 and the Regulations of 15 December 2005 no 1690 on medical Devices § 1-5. The above regulations implement the three EU directives on medical devices in one text [60]. Both the UK

MDR and the Norwegian MDR are based on the EU MDR.

The COPD calculator is classified, according to the regulations, as a *stand-alone medical device Class IIa*, as its function is to give diagnostic support. This means that it falls within the Norwegian MDR. Every medical device where Norwegian MDR is applicable, meaning devices classified as Class I, IIa, IIb, or III according to the regulations, must undergo conformity assessment from an EU notified body. They must also be issued a Certificate of Conformity, also referred to as "CE".

The criteria also ask whether the software is registered with the MHRA. The MHRA is an executive agency, sponsored by the Department of Health and Social Care, that regulates medicines, medical devices, and blood components for transfusion in the UK [61]. There exists a Norwegian version of MHRA called The Norwegian Medicines Agency (NoMA) (Norwegian: Statens legemiddelverk)[2]. As part of the Norwegian post surveillance, all Norwegian manufacturers of medical devices or medical devices for use in Norway must register in the Medical Device Database. The NoMA requires that to be registered, every medical device must have a CE-mark [60].

As Norway requires any medical device to be registered with the NoMA, it naturally follows that it is best and least time-consuming that developers should heed their criteria from the beginning of their development process of any medical software. Thus, this criterion should be included in any future Norwegian framework.

C1.4 and C1.4.1

These criteria were included as part of the evaluation to provide end-users with the transparency of the application. Stating whether the product connects to a third party, and providing the relevant clinical risk documentation if so, proves to end-users that extensive clinical risk evaluation has been taken into account and the result ensures clinical safety.

4.1.2 Data protection

Both the UK and Norway, from our perspective, have created great procedures to establish the process of compliance with data and privacy regula-

[2] `https://legemiddelverket.no/english`

tions. These requirements must be included in any framework to ensure that the product complies with General Data Protection Regulation (GDPR).

C2.1

To pass this criterion, the developer must submit evidence that they have a current registration with the Information Commissioner, the organ in the UK with authority to uphold the public's information rights and ensure data privacy for individuals[3]. As data protection and GDPR are two very important areas, such a criterion should be included in our framework. Products that have evidence of taking data protection and GDPR into consideration have the potential to gain more trust among end-users than those that do not.

Norway has an organ similar to the Information Commissioner called The Norwegian Data Protection Authority (Datatilsynet)[4]. This is an agency of the Norwegian government responsible for managing the Personal Data Act 2000, concerning privacy concerns [62]. As the COPD calculator is meant for use in Norway, the developers must follow the rules stated by The Norwegian Data Protection Authority. However, the Norwegian Data Protection Authority does not require a registration or have a registration fee. They have only a checklist of all the obligations a company has with regard to privacy regulations when personal information is collected and used. Hence, this criterion has to be customized accordingly. Providing evidence of all the obligations on the checklist will ensure that the necessary procedures regarding data protection and security have been established.

C2.3

This criterion was included to establish how the product access data and if they are doing it properly according to the GDPR. However, this criterion also needed to be altered to fit the Norwegian GDPR. Further, we chose to exclude 2.3.1 in the final criteria table (the reason for this will be explained in section 4.2), so we expect that to pass this criterion, the developers or the organizations must provide evidence that all access to any personally identifiable data or patient data that is following the GDPR.

[3]Read more on the Information Commissioner at `https://ico.org.uk/`

[4]Read more on The Norwegian Data Protection Authority at `https://www.datatilsynet.no/en/`

C2.3.2

Data Protection Impact Assessment (DPIA) is a process to help you identify and minimize the data protection risks of a project [63]. It shall also ensure that the privacy of the end-users of the product is safeguarded. This is an obligation under the privacy regulations. Also, the Norwegian Data Protection Authority requires a DPIA if the product collects and processes any sensitive personal data on a large scale. Hence, this criterion was included in our evaluation framework. Another reason for the inclusion was to ensure the end-users that data protection has been handled correctly according to the regulations.

C2.5 and C2.5.1

These criteria were included to secure transparency of the collected data to the end-users. There exists policies and obligations regarding the location of data storing and data processing for every country. However, these policies and obligations may vary between countries, and sometimes within the country itself. Following the procedures stated in these criteria ensures the end-users that the product or organization has done the necessary steps to show transparency and data integrity.

4.1.3 Technical security

C3.3

This criterion asks for a confirmation that all custom code has undergone a security review. If this requirement has been considered during development, the quality of both the code and the application will be affected positively. An important principle all developers should adhere to is producing clean and maintainable code. Code review is a crucial part of ensuring this. Thus, this criterion has been included in our evaluation framework.

C3.4

Multi-Factor Authentication (MFA) is to create a layered defense to ensure that an unauthorized person won't get access to the target, e.g. a physical location, computing device, network, or database [64]. It is more secure than traditional authentication such as username and password. Hence, this

criterion, asking whether all privileged accounts have MFA, has been included in our evaluation framework.

C3.6

Load testing means testing the performance of a software application by simulating multiple users accessing the program concurrently [65]. It determines how the software application behaves when multiple users are accessing it simultaneously. This is included in the evaluation to give the end-users confidence in the system, reliability, and performance.

4.1.4 Interoperability

Interoperability is the key to ensure that healthcare systems can communicate across platforms successfully. The UK has managed to integrate this well in their country. In comparison, Norway is only in the beginning phase [66]. The criteria belonging to this section of the NHSx DTAC table should be included in any future framework.

C4.1 and C4.1.1

Application Programming Interfaces (API) is a set of functions that allows two applications or systems to communicate with each other[67]. These two criteria concern the use of API. If the product uses API, it must be relevant to the use case for the product and must follow Open API Best practices and healthcare standards of data. These criteria were included in the final table because they serve the interoperability purpose. Additionally, if evidence of interoperability is provided according to the bullet points in the C4.1.1, this could make the product even more appealing for end-users, as it proves that the product can exchange data well with other systems.

C4.2 and C4.2.1

These criteria concern the use of NHS numbers for the identification of patient data and the use of the NHS login for verification. The NHS number and NHS login are specific to the UK. The Norwegian version of this is the social security number. Norway has established its own electronic id platform for logging into online public services, such as tax reports and patient records.

An example of an electronic id in use is BankID. This service is very well established, and one of Norway's most innovative creations.

However, Norway is far behind when it comes to establishing a common solution used across the country for all patient record data. One can access one's national patient record at the public service Helsenorge[5] using the electronic id authentication system. However, there also exist regional, even local systems, for storing patient data, that are not available at Helsenorge. When it comes to interoperability the systems do not communicate with each other as each region may be using different systems, and that makes it hard for data sharing across the municipality.

We wanted to include these criteria as moving towards only having one login service is a step in the direction of nationwide interoperability.

C4.3, C4.3.1, and C4.3.2

These criteria concern the use of industry standards for read/write operations with electronic health records (EHR). They were included in the final evaluation table because the use of industry standards shows compliance with best practices. The ability to integrate with complex systems such as EHR shows that the product has interoperability. If a product has the capability for read/write operations with EHR, then the product might become more attractive to end-users.

4.1.5 Usability and accessibility

D1.1 and D1.1.1

These criteria concern the involvement of users in the development of the product under evaluation. They were included in our evaluation framework since applications and services must be easy to use and actually provide the help they are intended to do. Many products that are on the market today might not be useful to users at all; some because they are frustrating and hard to use. It is important to develop a service that can help users in their daily life. Engaging users early in the development stage will help developers understand which problems need to be solved instead of developing something that is not useful. If the developers can demonstrate that they have taken the

[5]For more information on Helsenorge, see `https://www.helsenorge.no/en/`

need of users into account when developing the product, it can help improve the product's integrity. Thus, we have considered these questions essential to any evaluation framework.

D1.2 and D1.2.1

These criteria were included because we wanted to determine if developers are creating a product that solves whole user problems or if it is clear to users how it fits into their pathway or journey. It is difficult to make products that fix whole health problems, but it may be able to improve them and to support or influence a wider solution.

D1.3 and D1.3.1

Making the service simple to use is an essential part of usability. Health is complex, therefore, we want to develop services that are easy for people to use. The intended users will have health problems, and should therefore expect such services to work as intended, without giving them additional struggles; such as getting used to complex user interfaces. Users might often be frustrated or ill and worried, and they need things to be easy and running smoothly for them. User acceptance testing is a principle to validate the usability of a product, that every project must undertake if they want to ensure that user's needs and requirements are met. Hence, these criteria, regarding user acceptance testing, have been included in the evaluation framework.

D1.4 and D1.4.1

These criteria, concerning compliance with Web Content Accessibility Guidelines (WCAG) 2.1 level AA and provision of published accessibility statements, were included because making sure that everyone can use the service is an important part of development. Developers should follow the international WCAG 2.1 level AA to ensure that their service is universally designed.

A published accessibility statement is a great information pool for end-users and stakeholders. This information gives public transparency on how well established the product is when it comes to accessibility.

If the product or service can provide evidence of what is asked for in these criteria, this could increase its popularity and gain a larger target group.

D1.5

This criterion was included in the evaluation table because it is more likely that a team with a diversity of expertise and skills will produce the best solution.

D1.6

This criterion was included in our evaluation framework because the methods chosen in the workflow can affect the quality of the product.

D1.7

This criterion, concerning continuous product development, was included in the evaluation as it is important to ensure that the organization considers user feedback and improves the product accordingly. Additionally, it is important to ensure that the product is always up to date.

D1.8

This criterion was included in the evaluation because it defines the performance of the product. It is important to show transparency of the performance of the product to the public. Doing this could gain acknowledgment and integrity towards both the product and the organization.

D1.11 and D1.12 and D1.12.1, D1.12.2

Operating a reliable service is crucial in healthcare, therefore, these criteria were included in the final evaluation framework. The public, users, and medical staff need to be able to access NHS services at all times. If a service is unavailable or slow, it could inhibit people from getting help [68].

If the product or service reports its performance to users, offer a service legal agreement, and show that they have an up-time of 99.9 percent or above, it can significantly increase the product's quality, integrity, popularity and, last but not least, gain trust among healthcare providers and end-users.

4.2 Criteria excluded

C1.2

The requirement for a Clinical Safety Officer (CSO) was not included in our evaluation as we considered it would not have much impact. We think that evidence of clinical risk management is enough evidence for receiving a great evaluation. Further, KBB Medic is in the process of getting their CE certificate, and according to that process they have to comply with ISO standards 13485, 26304, and 14971. ISO 14971 concerns clinical risk management, and it does not require appointing an executive manager solely for clinical risk management such as a CSO.

C.2.2 and C2.2.1

These criteria were excluded for the same reasons as were given above.

C2.3.1

This criterion asks for a confirmation of compliance with the annual Data Security and Protection Toolkit Assessment. The Data Security and Protection Toolkit is an online self-assessment tool that enables organizations to measure and publish their performance against the National Data Guardian's ten data security standards [69]. All organizations that have access to NHS patient data and systems must use this toolkit to assure that they are practicing good data security and that personal information is handled correctly.

This toolkit only works within England and Wales. However, it would be great if Norway could adapt such a toolkit to use within the country. In the future, when Norway has, hopefully, established an official body and standards for developers within healthcare, this should be a requirement in Norwegian standard/criteria as well. Data protection is an important topic both in Norway and the EU. Having this kind of tool to confirm that your organization complies with certain standards will simplify the process of checking data protection. It will also show that the government has a high standard regarding data security and protection for healthcare products developed in the country, and ensure users' safety first and foremost.

C2.4

Since we excluded C.2.2 and C2.2.1 (regarding DPO) from the evaluation, it naturally follows that we dismissed this criterion as well.

C3.1

Cyber Essentials Certificate is a UK Government-backed scheme that will help you to protect your organization against a whole range of the most common cyber attacks. Further, the UK has the National Cyber Security Centre, which has a guide for small to medium enterprises on how to handle cybersecurity without the certificate. There exists a Cyber Essentials Europe Certificate, which is very similar to ISO 27001, but it is not a requirement. However, this is meant for larger organizations. It is very hard to find such a certificate in the Norwegian environment. Hence, we chose to exclude this criterion.

The National Security Authority (NSM) is a professional body for preventive security and a security authority under the National Security Act. NSM shall provide information, advice, and guidance on preventive safety work[70]. They have created the so-called NSM's basic principles for ICT security. This is similar to the Cyber Essentials Certificate, except that it is not a certificate but guidance to contribute to raising security competence and the level of security in Norwegian companies both public and private[70]. NSM's basic principles for ICT security are a set of recommendations for how companies can secure their information systems.

Norway has established principles but developers are not required to follow them. If they want to keep up with the rest of the world, Norway should develop and require something equivalent to the Cyber Essentials Certificate. If they do, this criterion should be included in any future Norwegian framework.

We chose to exclude this criterion from our final criteria assessment table as KBB Medic and CodeLab did not have guidance on penetration testing or OWASP in the Norwegian development environment when they developed the COPD calculator in 2016. We chose to exclude this criterion from our final criteria assessment table as KBB Medic and CodeLab did not have guidance on penetration testing or OWASP in the Norwegian development environment when they developed the COPD calculator in 2016.

Later in 2017, Norway and the NSM have established a principle called Perform penetration tests [70]. The goal of the principle is that the company tests elements in its own defense mechanisms (technology, processes, and personnel) by simulating the goals and actions of an attacker. This principle actually links to the NCSC guidance on penetration testing, which DTAC provides as supporting information [70].

In addition, Norway published a guide on Software development with built-in privacy in 2018 [63]. Hopefully, it will help Norwegian companies to understand and comply with the requirement for built-in privacy in the privacy regulations. It has been prepared in collaboration with security experts and program developers in the private and public sectors. This guide is primarily aimed at developers, architects, project managers, testers, and privacy and security consultants who develop or contribute to the development of, software that contains personal information[63]. In this guide, they suggest the OWASP Framework, among others, to be used during the development of software that processes sensitive personal information.

The two guidance mentioned in the paragraphs above, provide great information about penetration tests and OWAS. The two guidances should be included as requirements in a future Norwegian framework.

Even though we did not include this as a criterion in our evaluation, KBB Medic can confirm that the product included OWASP. KBB Medic uses Vaadin as a framework for development. Vaadin is an open platform for building web apps in Java [37].

Vaadin does not handle all the issues regarding the WASP top ten vulnerabilities, but issues such as CSRF, XSS, or direct object references can be handed on a user interface framework level. According to COPD they do not have written input, which implies that it is secure from injection attacks. Therefore, they conclude that the COPD calculator is safe.

C3.5

The reason this criterion was left out of the evaluation, is because not all developers have advanced audit capabilities. KBB Medic is a small organization with less than ten people. They do not have this process established yet. However, since they are in process of getting the CE-mark, the monitoring procedure is now part of the Quality Management System.

Logging and protective monitoring is an important part of NCSC's ten steps to cybersecurity, and should therefore be considered. We can use logging and monitoring to identify threats and protect smartphones, tablets, laptops, and desktop PCs. The NSM basic principles are applicable for Norwegian application developers. NSM takes inspiration from NCSC and provides links to NCSC as supporting material. As a piece of advice to KBB Medic, they can follow NCSC's provided guidance for smaller companies, called "Logging made easy", to make sure that they at the very least have an effective logging system in place [71].

This criterion should be a requirement in future Norwegian assessment criteria because it is important to ensure cyber-security. This criterion can help developers detect vulnerabilities in advance and thereby identify threats before it is too late.

C4.4 and C4.4.1

The COPD-calculator is a stand-alone software. It is an online web application that is neither wearable nor a physical device. These criteria were therefore excluded.

D1.9 and D1.9.1

We excluded these criteria as we did not think that the choice of technology and tools should be evaluated and given a score. After all, it should be up to the organization to choose the technology and tools that suit them. The requirement that the product should meet with the NHS Cloud-First Strategy, is applicable in the UK because the UK Government has actually developed and implemented a public cloud that is open for all. In comparison, there is not yet a public cloud to be used within healthcare in Norway, which leaves the choice of technology to the organization. However, Norway should initialize this in order to move closer towards accessibility and interoperability.

D1.10 and D1.10.1

We left these criteria out because Norway does not have many open sources, common components, and patterns, especially in healthcare, compared with what NHS/UK Government has developed.

According to the current Norwegian government [72], one of their goals is to develop common principles for cooperation with the private sector in the field of digitization, with the view to further developing such cooperation. In addition, they want to establish national common components, especially in health care. They have already succeeded in some areas.

Another reason why we chose to exclude them, is because the COPD-calculator does not include any of these common components. It is an independent software that only deals with input data of patients that the doctor himself enters. Eventually, they want to integrate it with the Norwegian patient register and the EHR, but, to do so, the public sector should establish a guidance or a framework for private businesses that want to develop health services, on how they can collaborate more closely with the public sectors. At the very least on how they should proceed.

4.3 Final criteria table

The final assessment criteria table is presented here:

Table 4.1: Final criteria table

Code	Criterion	Requirements
C1.1	Have you undertaken Clinical Risk Management activities for this product which comply with ISO 14971?	Developers must confirm that they have undertaken Clinical Risk Management activities in compliance with ISO 14971.
C1.1.1	Detail your clinical risk management system	Developers is required to provide evidence that is compliant with ISO 14971.
C1.1.2	Supply your Clinical Safety Case Report and Hazard Log	Developers is required to submit Clinical Safety Case Report and Hazard Log.
C1.3	If your product falls within the Norwegian Medical Devices Regulations, is it registered with The Norwegian Medicines Agency (NoMA)?	Developers is required to provide evidence of a valid registration.
C1.3.1	If yes, please provide your NoMA registration number	The registration number must be valid.
C1.3.2	If the Norwegian Medical Device Regulations are applicable, please provide your Declaration of Conformity and, if applicable, certificate of conformity issued by a Notified Body	Valid documentation appropriate to the risk classification of the device must be provided.
C1.4	Do you use or connect to any third-party products?	-
C1.4.1	If yes, please attach relevant Clinical Risk Management documentation and conformity certificate	A valid conformity certificate must be provided. The Clinical Risk Management documentation must meet the requirements detailed in question C1.1.

C2.1	Does your product process any personal information?	Developers are required to submit evidence that complies with the checklist provided by The Norwegian Data Protection Authority.
C2.3	Does your product have access to any personally identifiable data or NNIN?	
C2.3.2	Attach the Data Protection Impact Assessment (DPIA) relating to the product.	Developer must provide a DPIA that is compliant with the requirements set out under the General Data Protection Regulations.
C2.5	Confirm where you store and process data (including any third party products your product uses)	Just a confirmation to either: Norway only — In EU — Outside of EU
C2.5.1	If you process store or process data outside of Norway, please name the country and set out how the arrangements are compliant with current legislation	Developer must demonstrate that the country in which data is processed or stored is compliant with current legislation or the organization's policy (should this differ).
C3.3	Confirm whether all custom code had a security review.	Developer must confirm that an internal or an external custom code security review has been undertaken.
C3.4	Confirm whether all privileged accounts have appropriate Multi-Factor Authentication (MFA)?	The developer must confirm yes/no. If yes all privileged accounts must have MFA.
C3.6	Confirm whether the product has been load tested	The developer must confirm yes that load testing has been performed.

C4.1	Does your product expose any Application Programme Interfaces (API) or integration channels for other consumers?	Developers are required to demonstrate that they have APIs that are relevant to the use case for the product.
C4.1.1	If yes, please provide detail and evidence: • The API's (e.g. what they connect to) • Set out the healthcare standards of data interoperability eg. Health Level Seven International (HL7) / Fast Healthcare Interoperability Resources (FHIR) • Confirm that they follow Government Digital Services Open API Best Practice • Confirm they are documented and freely available • Third parties have reasonable access to connect If no, please set out why your product does not have APIs.	Developers must provide evidence according to the bullet points.
C4.2	Do you use the Norwegian national identification number (NNIN) to identify patient record data?	Developers must confirm that if a product uses a Norwegian NIN to identify a patient record.

C4.2.1	If yes, please confirm whether it uses Digital Identification Certificate (eg. BankID) Login to establish a user's verified NNIN number. If no, please set out the rationale, how your product established the NNIN number, and the associated security measures in place. If a product does not use Digital Identification Certificate (eg. BankID) log in to establish a verified NNIN number then a legitimate rationale should be set out and the security and appropriateness of the methodology should be considered.	Provide the evidence according to the questions.
C4.3	Does your product have the capability for read/write operations with electronic health records (EHRs) using industry standards for secure interoperability (e.g. OAuth 2.0, TLS 1.2)	Developers must confirm that the product has the capability to read/write into EHR using industry standards for secure interoperability.
C4.3.1	If yes, please detail the standard	
C4.3.2	If no, please state the reasons and mitigations, methodology, and security measures.	
D1.1	Understand users and their needs in the context of health and social care Do you engage users in the development of the product?	Developers must demonstrate that user need has been taken into account through user research, search data, analytics, or other data to understand the problem.

D1.1.1	If yes or working towards it, how frequently do you consider user needs in your product development and what methods do you use to engage users and understand their needs?	
D1.2	Work towards solving a whole problem for users Are all key user journeys mapped to ensure that the whole user problem is solved or it is clear to users how it fits into their pathway or journey?	Developers must attach supporting information showing that the product solves a whole user problem or that it is clear to users how it fits into their pathway or journey.
D1.2.1	If yes or working towards it, please attach the user journeys and/or how the product fits into a user pathway or journey	Provide information according to the questions.
D1.3	**Make the service simple to use** Do you undertake user acceptance testing to validate the usability of the system?	Developers must attach supporting information showing user acceptance testing to validate the usability of the product.
D1.3.1	If yes or working towards it, please attach information that demonstrates that user acceptance testing is in place to validate usability.	
D1.4	**Make sure everyone can use the service** Are you international Web Content Accessibility Guidelines (WCAG) 2.1 level AA compliant?	Developers must provide evidence for WCAG 2.1 level AA compliance.

D1.5	**Create a team that includes multi-disciplinary skills and perspectives** Does your team contain multidisciplinary skills?	Developers must confirm that they have a multi-disciplinary team.
D1.6	**Use agile ways of working** Do you use agile ways of working to deliver your product?	Developers must confirm if they use agile ways of working.
D1.7	**Iterate and improve frequently** Do you continuously develop your product?	Developers must confirm that they continually develop their product.
D1.8	**Define what success looks like and be open about how your service is performing** Do you have a benefits case that includes your objectives and the benefits you will be measuring and have metrics that you are tracking?	Developers must confirm that the benefits case includes objectives and metrics that can be tracked.
D1.11	**Operate a reliable service** Do you provide a Service Level Agreement to all customers purchasing the product?	Developers must confirm the offer of a service level agreement, reporting on performance, and having an uptime of 99.9% or above.
D1.12	Do you report to customers on your performance with respect to support, system performance (response times), and availability (uptime) at a frequency required by your customers?	
D1.12.1	Attach a copy of the information provided to customers	

D1.12.2	Provide your average service availability for the past 12 months, as a percentage to two decimal places	

4.4 Summary

Studying the framework, we learned that the NHSx DTAC focuses on many lacking areas. Earlier we learned that interoperability and scalability were aspects that a CDSS should be evaluated. NHSx DTAC has shown that the two have been taken into consideration. DTAC offers one whole section to interoperability that is intertwined with scalability. In the Introduction chapter we stated that many comprehensive frameworks only limit their work to the quality of care improvement and costs reduction [5]. The NHSx DTAC proved that there exist many more aspects to be evaluated that are equally important. DTAC provides an evaluation in clinical management risk to ensure that organizations have made sure their product or service is safe for end-users. In health care especially, is clinical risk management one of the top priorities. Further, the security sections set a high standard for health care services. That is how it should be because of personal information. Another area that DTAC provides, is the consideration of software architecture. They are considering the development phase, and, last but not least, the usability and accessibility aspects. What is shown here is very accurate to the conclusion of the extra curriculum where we conducted a review that NHSx DTAC is obviously a comprehensive framework [8].

Moving on to the comparison of UK advanced health IT with the Norwegian health IT. We state the obvious fact that the UK has progressed much further than Norway in the digitalisation of the health care sector. From our comparison, Norway lacks standards to create interoperability nationwide.

Chapter 5

Assessment of the COPD calculator

This chapter presents the assessment of the COPD calculator by applying the customized version of the NHSx DTAC Framework. We will present the answer and evidence provided by the developers of the COPD calculator or KBB Medic, to the question asked of the criterion.

The scoring criteria for the assessment of the COPD calculator are:

- 1 point - If all requirements are fulfilled
- 0.5 points - If some are fulfilled
- 0 points - If none is fulfilled

There is an exception to the Usability and Accessibility criteria section. Every criterion will have a weighted score and scoring criteria attached to the table.

Requirements will not be shown, but the full requirements list can be found in the appendix A.1.

5.1 Assessment of the Clinical safety category

The purpose of this category this section is to establish that the product is clinically safe to use. Next, we present the criteria table in this category. Then, an evaluation will be presented.

Table 5.1: Criteria table for Clinical safety

Code	Criterion
C1.1	Have you undertaken Clinical Risk Management activities for this product that comply with ISO 14971?
C1.1.1	Detail your clinical risk management system .
C1.1.2	Supply your Clinical Safety Case Report and Hazard Log
C1.3	If your product falls within the Norwegian Medical Devices Regulations, is it registered with The Norwegian Medicines Agency (NoMA)?
C1.3.1	If yes, please provide your NoMA registration number
C1.3.2	If the Norwegian Medical Device Regulations are applicable, please provide your Declaration of Conformity and, if applicable, certificate of conformity issued by a Notified Body
C1.4	Do you use or connect to any third-party products?
C1.4.1	If yes, please attach relevant Clinical Risk Management documentation and conformity certificate

5.1.1 C1.1, C1.1.1, and C1.1.2

Yes.

They have undertaken Clinical Risk Management activities in compliance

with ISO 14971.

Currently, KBB Medic is in the process of getting a CE certificate for their products including the COPD calculator. One of the many standards they must comply with is clinical risk management, ISO 14971. Although the DCB0129 is Britain's standard for the development and maintenance of health IT systems, it is based on ISO 14971 and we will conclude that their clinical risk management complies with DCB0129.

The evidence of clinical risk management can be found in the appendix C.3.

5.1.2 C1.3, C.1.3.1 and C1.3.2

No.

The COPD calculator is not registered with the NoMA but falls within the Norwegian Medical Devices Regulations.

As for C1.3.2, there is no evidence available at the moment, because KBB Medic is in the process of CE-marking. When KBB Medic and the COPD calculator receive the CE certification, the product will comply with essential requirements and standards and will be able to register with the No

5.1.3 C1.4 and C1.4.1

No.

The COPD calculator does not use or connect to any third-party products. Since the product does not involve any third party, we can continue to C2.

5.2 Assessment of the Data protection category

This category is to establish that your product collects, stores, and uses data(including personally identifiable data) compliantly. Next, we present the criteria table in this category. Then, an evaluation will be presented.

Table 5.2: Criteria table for Data Protection

Code	Criterion
C2.1	Does your product process any personal information?
C2.3	Does your product have access to any personally identifiable data or NNIN?
C2.3.2	Attach the Data Protection Impact Assessment (DPIA) relating to the product.
C2.5	Confirm where you store and process data (including any third party products your product uses)
C2.5.1	If you process store or process data outside of Norway, please name the country and set out how the arrangements are compliant with current legislation

5.2.1 C2.1

Yes.

According to the Norwegian information commissioner, any product that processes sensitive information must follow a checklist established by the organization. Hence, the COPD calculator must follow the checklist. KBB Medic has evidence that the checklist has been followed to secure the General Data Protection Regulation (GDPR).

The evidence can be found in the appendix C.3 under subsection C.3.

5.2.2 C2.3

No.

The COPD calculator does not have access to any personally identifiable data or the Norwegian Patient Register.

It must be mentioned that they want to be able in the future, to integrate with the public sector. That depends on when Norway has managed to establish a great common foundation for the Norwegian Patient Register/Journal. As of today, there exist too many platforms concerning Patient Register.

5.2.3 C2.3.2

Attached.

Because KBB Medic the holder of COPD is such a small company they have decided to not have a DPIA. I can attach the evidence of that.

KBB Medic, the holder of the product COPD calculator state the fact that they are a small company and decided to not include a DPIA. The statement can be found in the appendix C.3.

5.2.4 2.5 and C2.5.1

Norway.

It has already been stated that the COPD calculator is meant for use in Norway only, which is only logical that data is stored in Norway.

KBB Medic and CodeLab state that data is stored on a Linux server located in a dedicated computer room in Oslo at ServeTheWorld[1]. The server is of the SuperMicro type, runs almost the latest version of Debian Linux 10.9[2] and has these files in local ext4 file system. No cloud storage or foreign storage of data.

5.3 Assessment of the Technical Security category

The purpose of this category this section is to establish that the product meets industry best practice security standards and that the product is stable. Next, we present the criteria table in this category. Then, an evaluation will be presented.

Table 5.3: Criteria table for Technical Security

Code	Criterion

[1]More on ServeTheWorld can be read here: `https://servetheworld.net/no-no/`

[2]Read more: `https://en.wikipedia.org/wiki/Debian_version_history#Debian_10_(Buster)`

C3.3	Confirm whether all custom code had a security review.
C3.4	Confirm whether all privileged accounts have appropriate Multi-Factor Authentication (MFA)?
C3.6	Confirm whether the product has been load tested

5.3.1 C3.3

Yes, partly.

Further, we used the guidance on producing clean code and maintainable code, provided by National Cyber Security Centre (NCSC) [73]. NCSC also provided a self-assessment list to assess your own practices. This list contains just an overview of what a good code practice is. Further, we used this list as a base and provided one point to each row in the list. It is possible to receive 6 points in total. Their code received 3.5 points. The evidence of the self-assessment being conducted can be found in the appendix C.3.1.

KBB Medic and CodeLab stated that they did not have any form for internal or external code review, which is not great. Even though, they did score just a little bit above average on the self-assessment on producing clean code and maintainable code. There was a lack of code review, peer review, and testing. This should be established as soon as possible.

5.3.2 C3.4

No.

According to CodeLab, the current version of the COPD calculator has no Multi-factor authentication. As of now, the service is open and free for use on their website[3]. It is intended with user log-in on this website, but this is under development. The developers want to implement a BankID solution for registration and only username/password for the log-in functionality on the service.

[3]See: `www.medguideline.com`

The BankID solution is a personal electronic identification that is used for online identification and signature [74]. The solution has been developed since 2000 to be a common infrastructure for Norwegian citizens [74]. BankID is used by every bank in Norway and can be used by all organizations and enterprises. The solution satisfies the highest security level, at level 4 according to the Norwegian framework called "Framework for authentication and non-repudiation in electronic communication with and in the public sector" [75].

This solution qualifies as multi-factor authentication and when successfully implemented, the COPD calculator will pass this criterion.

5.3.3 C3.6

Yes.

The evidence of the test created for load testing is visible in the figure 5.1

```
package no.codelab.kbb;

import java.io.BufferedReader;
import java.io.IOException;
import java.io.InputStream;
import java.io.InputStreamReader;
import java.net.URL;


public class Test implements Runnable {

        private static final int NUM_ITERATIONS = 5000;
        private static final int SLEEP_MILLIS   = 10;

        private int num = 0;
        private static int fails = 0;

        public static void main(String[] args) {

                long start = System.currentTimeMillis();

                for(int i = 0; i< NUM_ITERATIONS; i++) {
                        Thread t = new Thread(new Test(i));
                        t.start();

                        try {
                                Thread.sleep(SLEEP_MILLIS);
                        } catch (InterruptedException e) {
                                // TODO Auto-generated catch block
                                e.printStackTrace();
                        }
                }

                long elapsed = System.currentTimeMillis() - start;
                int  numPerSec = (int) ( (NUM_ITERATIONS * 1000) / elapsed);

                System.out.println("");
                System.out.println("**** Finished: used " + (elapsed / 1000) + "sec. " + numPerSec + " Per seccond. " + fails +" failed of " + NUM_ITERATIONS + " ****");
        }

        public Test(int n) {
                num = n;
        }

        @Override
        public void run() {
                URL url;
            InputStream is = null;
            BufferedReader br;
            String line;

            try {
                url = new URL("http://localhost:8080/calculator/no");
                is = url.openStream();  // throws an IOException
                br = new BufferedReader(new InputStreamReader(is));

                while ((line = br.readLine()) != null) {
                        //if(num == 9000)
                                //System.out.println(line);
                }
            } catch (Exception e) {
                fails++;
                System.out.println("*** FAIL: " + num);
            } finally {
                try {
                    if (is != null) is.close();
                } catch (IOException ioe) {
                         System.out.println("*** EX3: " + num);
                }
            }
        }
}
```

Figure 5.1: A code snippet of load testing

5.4 Assessment of the interoperability

The purpose of this category is to establish how well the product exchanges data with other systems. Next, we present the criteria table in this category. Then, an evaluation will be presented.

Table 5.4: Criteria table for Interoperability

Code	Criterion
C4.1	Does your product expose any Application Programme Interfaces (API) or integration channels for other consumers?
C4.1.1	If yes, please provide detail and evidence: • The API's (e.g. what they connect to) • Set out the healthcare standards of data interoperability eg. Health Level Seven International (HL7) / Fast Healthcare Interoperability Resources (FHIR) • Confirm that they follow Government Digital Services Open API Best Practice • Confirm they are documented and freely available • Third parties have reasonable access to connect If no, please set out why your product does not have APIs.
C4.2	Do you use the Norwegian national identification number (NNIN) to identify patient record data?
C4.2.1	If yes, please confirm whether it uses Digital Identification Certificate (eg. BankID) Login to establish a user's verified NNIN number. If no, please set out the rationale, how your product established the NNIN number, and the associated security measures in place. If a product does not use Digital Identification Certificate (eg. BankID) log in to establish a verified NNIN number then a legitimate rationale should be set out and the security and appropriateness of the methodology should be considered.
C4.3	Does your product have the capability for read/write operations with electronic health records (EHRs) using industry standards for secure interoperability (e.g. OAuth 2.0, TLS 1.2)
C4.3.1	If yes, please detail the standard
C4.3.2	If no, please state the reasons and mitigations, methodology, and security measures.

5.4.1 C4.1 and C4.1.1

No.

The product does not expose any Application Programme Interfaces (API) or integration channels for other consumers. The COPD calculator classifies as a standalone application. In addition, the knowledge base for the COPD calculator is based on the medical guidelines related to COPD. These are hardcoded into the application because the data is of a different format and cannot be integrated into the calculator. Further, the product does not integrate with the patient register nor public system such as FHIR/HL7.

5.4.2 C4.2 and C4.2.1

No, because the product doesn't identify patient record data.

5.4.3 C4.3, C4.3.1, and C4.3.2

No.

The reason why this product does not have the capability to read/write with electronic health records is that the process is very complicated and comprehensive. This product is meant for use in Norway first and foremost. The Norwegian health care system does not seem to have interoperability. Hospitals, practices, and other health care facilities, all use different systems/software that do not communicate across platforms. Further, there exist many EHRs in Norway that is used by different facilities. Thus, the reason why their product does not read/write to EHR.

The COPD calculator's mitigation is to show a journal summary of diagnosis, chosen treatments, and recommendations that the physician can copy and paste into the desired EHR.

5.5 Assessment of the usability and accessibility

The purpose of this category is to establish that the product has followed best practices. Next, we present the criteria table in this category. Then, an evaluation will be presented.

Table 5.5: Criteria table for Usability and accessibility

Code	Criterion	Scoring criteria
D1.1	Understand users and their needs in the context of health and social care Do you engage users in the development of the product?	Developers must demonstrate that user need has been taken into account through user research, search data, analytics, or other data to understand the problem. If fulfilled they should be rewarded with 10%. .
D1.1.1	If yes or working towards it, how frequently do you consider user needs in your product development and what methods do you use to engage users and understand their needs?	If the developer selects working towards it and/or can only partially evidence the requirement, for example, user need has only partially been considered or it is not considered on an ongoing basis they should be awarded 5%. If the developer selects no to this question or cannot provide evidence that user need has been considered they should be awarded 0%
D1.2	Work towards solving a whole problem for users Are all key user journeys mapped to ensure that the whole user problem is solved or it is clear to users how it fits into their pathway or journey?	Developers must attach supporting information showing that the product solves a whole user problem or that it is clear to users how it fits into their pathway or journey. If fulfilled they should be rewarded with 10%.

D1.2.1	If yes or working towards it, please attach the user journeys and/or how the product fits into a user pathway or journey	If the developer selects working towards it and can provide evidence that goes some way to explaining how the whole user problem is solved or only partially explains how the product fits a user journey they should be awarded 5%. If the developer selects no to this question or cannot provide evidence that shows the user journey or how the product fits into the pathway or journeys they should be awarded 0%. .
D1.3	**Make the service simple to use** Do you undertake user acceptance testing to validate the usability of the system?	Developers must attach supporting information showing user acceptance testing to validate the usability of the product. If fulfilled they should be rewarded with 10%.
D1.3.1	If yes or working towards it, please attach information that demonstrates that user acceptance testing is in place to validate usability.	If the developer selects working towards it and can provide evidence that goes some way to demonstrate that user acceptance testing is being used to validate the usability of the system they should be awarded 5%. If the developer selects no to this question or cannot provide evidence that shows user acceptance testing to validate the usability of the system they should be awarded 0%.

D1.4	**Make sure everyone can use the service** Are you international Web Content Accessibility Guidelines (WCAG) 2.1 level AA compliant?	Developers should be awarded 20% for WCAG 2.1 level AA compliance. Developers should be awarded 5% for working towards it. If the developer selects no to this question they should be awarded 0%.
C1.4.1	If yes, please attach relevant Clinical Risk Management documentation and conformity certificate	
D1.5	**Create a team that includes multi-disciplinary skills and perspectives** Does your team contain multidisciplinary skills?	Developers should be awarded 2.5% for confirming they have a multi-disciplinary team. If the developer selects working towards it or no to this question they should be awarded 0%.
D1.6	**Use agile ways of working** Do you use agile ways of working to deliver your product?	Developers should be awarded 2.5% if they confirm they use agile ways of working. If the developer selects working towards it or no to this question they should be awarded 0%.
D1.7	**Iterate and improve frequently** Do you continuously develop your product?	Developers should be awarded 5% if they confirm they continually develop their product. If the developer selects working towards it or no to this question they should be awarded 0%.

D1.8	**Define what success looks like and be open about how your service is performing** Do you have a benefits case that includes your objectives and the benefits you will be measuring and have metrics that you are tracking?	Developers should be awarded 10% for confirming that the benefits case includes objectives and metrics that can be tracked. If the developer selects working towards it or no to this question they should be awarded 0%.
D1.11	**Operate a reliable service** Do you provide a Service Level Agreement to all customers purchasing the product?	Developers should be awarded 10% offering a service level agreement, reporting on performance, and having an uptime of 99.9% or above.
D1.12	Do you report to customers on your performance with respect to support, system performance (response times), and availability (uptime) at a frequency required by your customers?	If the developer does not provide a service level agreement and/or reporting on the performance they should be awarded but has an uptime of 99.9% or above they should be awarded 5%.
D1.12.1	Attach a copy of the information provided to customers	If the developer has an uptime of 99% or above they should be awarded 2.5%.
D1.12.2	Provide your average service availability for the past 12 months, as a percentage to two decimal places	If the developer has an uptime of less than 99% they should be awarded 0%.

5.5.1 D1.1 and D1.1.1

Working towards it.

According to KBB Medic and CodeLab, during the development phase of

the COPD calculator, they visited several practices where the amount of clinician's attendance was significant. In the meeting sessions, they received feedback from clinicians. Unfortunately, they do that have the data log on these sessions.

Two members of the team are lunge specialists and are a major part of the development process. Further, the clinicians will be using the COPD calculator. KBB Medic and CodeLab also mentioned that the tool was presented to many interesting parts and colleagues during the development process and post-production. They received a great amount of feedback, which they have adjusted accordingly.

After production in 2016, the COPD calculator is still receiving feedback and is considering every feedback. A method they use to still engage users and understand their needs is a feedback/review form.

Their process in understanding the users and their needs is very iterative. It is a great way to engage users in the development process and to use the information to improve the service.

Feedback from the clinicians will be attached to support the understanding of the user's needs. The evidence can be found in the appendix C.3.

5.5.2 D1.2 and D1.2.1

Yes.

According to KBB Medic and CodeLab, this is the user journeys:

1. Collection of the necessary information.
2. Diagnosis,
3. Medical guidance according to diagnosis,
4. Journal summary with recommendations
5. References,
6. Follow-up

CodeLab and KBB Medic have put in a lot of effort to provide a solution that was demanded by the COPD health community in Norway. Based on the feedback, which can be found in the appendix, it seemed like this CDS

tool granted many wishes for clinicians. It eased the workflow for clinicians and provided the clinicians with a more effective session with patients.

From an end-user perspective, the CDS tool in the form of a web application does have a great navigation flow. It is very simple to use and intuitive and does not need any text input. The input of data is based on a button click. This functionality can potentially help reduce medical errors, and the worst-case diagnosis errors.

D1.3 and D1.3.1

Yes, to some extent.

KBB Medic and CodeLab stated that when there is an occasion for major updates, the CDS tool is always tested by Bjarte or Bernt before production, which are the two lung specialists on their team. They are considered super-users. Further, they are working towards a formal procedure to make sure that every product must pass automated testing before being deployed.

From the end-user perspective, navigating through the system is very easy. The design of the web application is very comfortable to look at. There are 12 questions to be answered, the overview of these questions is displayed in a position on the web application that is very visible. Every question expects an answer and won't give the end-user any diagnosis until every question is answered.

Since the web application is only meant for doctors, we can consider the COPD calculator to be universally designed in this particular case.

D1.4 and D1.4.1

Yes.

KBB Medic and CodeLab used the Vaadin platform during the development of the COPD calculator. The Vaadin framework considers WCAG to a certain extent, but it is up to the developers to make sure that the product follows the guidelines.

Further, one of the employees at CodeLab provided evidence of the service being compliant with WCAG. The URL was checked against two different accessibility validation tools. The first was the usage of a chrome extension

while having a session on the COPD calculator open. The result is presented in the figure 5.2.

Next, the employee used a web accessibility evaluation tool provided by w3.org[4]. The URL of the COPD calculator was run on the web accessibility evaluation website[5].

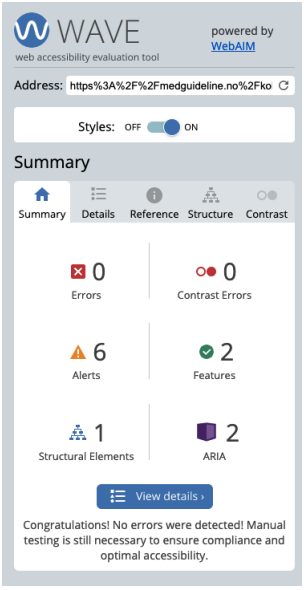

Figure 5.2: The result from validating the accessibility with the chrome extension tool

[4]This the list of web accessibility evaluation tool:`https://www.w3.org/WAI/ER/tools/`
[5]`https://www.webaccessibility.com/`

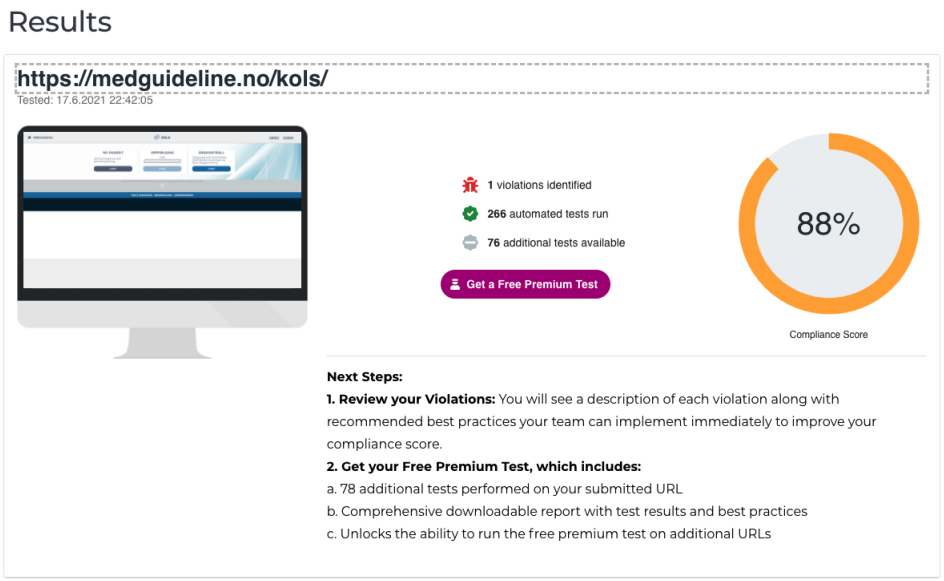

Figure 5.3: The result of running COPD calculator URL on a web accessibility evaluation website

The product does not have a published accessibility statement.

5.5.3 D1.5

Yes.

CodeLab and KBB Medic is a small team with a great variation of skills. It is a variation of developers with a long work experience and experts in lunge conditions.

5.5.4 D1.6

Yes.

The organization's workflow is based on an Agile manifesto. They consider MVP first and foremost.

5.5.5 D1.7

No.

According to CodeLab they do not iterate and improve their product frequently. The product is not being continuously developed either. It is only being updated when there is an update on the guidelines, etc. The product is often in the production state for longer periods at the time.

5.5.6 D1.8

Yes.

These are the statement of the success provided by KBB Medic and CodeLab.

- Success 1: Used by clinicians in general practice with good feedback. High success rate.
- Success 2: Paying clinicians in general practice and hospitals. No. We are not there yet.

5.5.7 D1.11

As stated earlier, the service is free for use at the moment. There are no paying customers/users.

5.5.8 D1.12, D1.12.1, and D1.12.2

No.

KBB Medic and CodeLab usually reply within a couple of hours or within the day. 99% (24-7) is their average uptime of the service.

5.6 Evaluation results

In this section, we will present the results from applying the customized version of NHSx DTAC to evaluate the COPD calculator.

5.6.1 The results regarding assessment criteria in section C

Table 5.6: Score results of the evaluation in section C

Category	Code	Score
Clinical safety	C1.1 C1.1.1 C1.1.2	1
Clinical safety	C1.3 C1.3.1 C1.3.2	0
Clinical safety	C1.4 C1.4.1	0.5
Data protection	C2.1	1
Data protection	C2.3	-
Data protection	C2.3.2	0
Data protection	C2.5 C2.5.1	1
Technical Security	C3.3	0.5
Technical Security	C3.4	0.5
Technical Security	C3.6	0.5
Interoperability	C4.1 C4.1.1	1
Interoperability	C4.2 C4.2.1	0.5
Interoperability	C4.3 C4.3.1 C4.3.2	0.5
Total score:		7/12

5.6.2 The results regarding the scoring section D

Table 5.7: Score results from section D - Usability and Accessibility section

Code	Score

D1.1 D1.1.1	5 %
D1.2 D1.2.1	10%
D1.3 D1.3.1	5%
D1.4 D1.4.1	20%
D1.5	2.5%
D1.6	2.5 %
D1.7	0 %
D1.8	10%
D1.11 D1.12 D1.12.1 D1.12.2	5%
Total:	$60/85 \approx 70.5882\%$

5.6.3 Evaluation Summary

The results from the evaluations serve as useful indicators for whether how well the calculator score.

The evidence provided by the developers of the COPD calculator resulted in a total score of 6.5 out of 12 in section C, which is equivalent to approximately 58.3333%. The other result from evaluating section D showed that the overall review of the product or service is at 70.5882%.

Clinical safety and technical security were the categories the COPD calculator received the lowest points.

In summary, the overall success of assessment according to criteria in section C was expected to be greater than 58.3333%. This suggests that there are numerous improvements to be made in the COPD calculator.

5.7 Chapter Summary

In this chapter, we described the process and results of two evaluation sessions by applying the customized version of the NHSx DTAC. The first session included the evaluation of core assessment criteria such as clinical safety, data protection, technical security, and interoperability. The second included evaluation of Usability and Accessibility. We evaluated these criteria with the consideration of the Norwegian context.

During the evaluation, we discussed the evidence provided by the developers of the COPD calculator, which led to potential improvements or future inclusion of the evidence.

In the next chapter, we will discuss whether the research questions have been answered and addressed.

Chapter 6

Discussion

This chapter will present and discuss the results achieved. We will answer and reflect upon the research questions while state the contribution to the research field and limitations of the results.

6.1 Answers to the research questions

RQ 1: What does the literature research tell about the need for good frameworks to evaluate eHealth applications in general, and CDS systems in particular?

The answer to this research question is mainly presented in section 1.1 and chapter 2. During the literature research, we discovered the challenges to develop an excellent framework to evaluate complex systems such as eHealth and CDS. eHealth systems usually include many phases during their life cycle. This indicates the many aspects to the architect of such systems, which an evaluation framework must consider.

Considering the CDS systems, in particular, we discovered that current evaluations conducted on CDS systems have mainly been focused on the improvement at the point of care, impact on the clinician and cost reductions, rather than on outcomes or structures. In addition, during a review conducted in the extra-curriculum [8], we identified lacking areas in the existing framework such as interoperability, data security, and privacy. Therefore, a comprehensive framework must have a broad perspective and not only care

improvement and the financial aspect. Such a framework has the potential to better the development and implementation of a CDS.

RQ 2: How can the general UK NHSx DTAC framework be customized to be suitable for evaluating a particular national CDS application?

The answer to this research question is mainly presented in chapter 4, where we proposed a customized version of the NHSx DTAC Framework to fit the context of the country where the CDS application applies. We achieved this by discussing inclusion and exclusion criteria, taking into account that the criteria asked of NHSx DTAC Framework is more advanced than what Norway has yet to implement.

During the process of including assessment criteria, we discovered that several assessment criteria did not suit the Norwegian context obviously because the criteria often refer to the UK. Thus, we substituted the reference of country name with Norway. Further, we found substituting materials in Norwegian that is equivalent to what the criteria are asking.

Moreover, we also discovered that several criteria refer to standards that only UK has developed to fit their healthcare system. Even so, the possibility to find anything related or equivalent to in Norway, is slight. Although, we could find evidence of regulations that refers Norwegian developers or stakeholders within healthcare to follow the European standards and regulations. Again, we substituted the materials with our findings to fit the Norwegian context.

RQ 3: By using our customized version of NHSx DTAC (from RQ2) to evaluate the COPD calculator, how well does the COPD calculator score?

In the section 5.6 in chapter 5, we present the results from evaluating the COPD calculator by applying the customized version of NHSx DTAC. The answer to this research question can be divided into two parts. The first is the results from the criteria section C, including clinical safety, data protection, technical security, and interoperability. The second part is the results from section D regarding usability and accessibility.

We found in chapter 5 that the results achieved from the first part of the evaluation were expected to be better. Receiving only 58.3333% on an essential criteria section indicates that the COPD calculator must make some

improvements. Although, we have to consider that the Norwegian developers did not have standards or guidelines in developing healthcare applications/systems during the development of the COPD calculator. Thus, they might not understand the expectations for entry into Norwegian healthcare. Hence, the results could serve as a guide for further improvements to the COPD calculator.

The second part of the evaluation concerns the usability and accessibility aspect of the COPD calculator. The results achieved were significantly better than expected, with a percentage of 70. The results indicate the effort of making the COPD calculator simple and easy to use. Even so, they can achieve better results with improvements.

In general, the results from the evaluation of the COPD calculator were considered successful. It is natural to interpret that results above 50% are a success. In the two evaluation sessions, both results were above 50%.

RQ 4: How suitable is NHSx DTAC as a framework for evaluating a CDS tool like the COPD calculator?

We stated in RQ1 that a framework for evaluating a CDS needs to focus on structure and outcome. Further, the framework must have a broad perspective and focus more on the lacking areas identified in the extracurriculum. The answer to this research question has been provided and presented through RQ2 and RQ3.

During the customization process, we identified every criterion in the framework and discovered that these assessment criteria addressed more or less the issues stated in RQ1. Thus, the NHSx DTAC focuses more holistically on healthcare services. Hence, the aspects considered and provided by the NHSx DTAC can be applied to any health-related product. Also, the assessment criteria address the success described by Douthit et al. [41] in section 2.4.

The results indicated that a CDS tool like the COPD calculator needed a framework such as DTAC to understand what is expected of an application/system in healthcare.

6.2 Research contributions

The choice of using the recently launched NHSx DTAC as a framework is hopefully a contribution to the research field. Our purpose was to provide evidence of framework usage in a qualitative study.

Through customization, we provide evidence that the NHSx DTAC could adjust to fit a specific context.

Further, we addressed the issue of the lack of a comprehensive framework to evaluate CDS systems. Through evaluation, we provided evidence of the comprehensiveness of the framework, thus being customized, the NHSx DTAC still had many critical criteria included.

6.3 Reflections and limitations

Reflection over the NHSx DTAC

The NHSx DTAC consists of assessment criteria that addressed many issues from the literature research. As expected, the framework provides the evaluation on other aspects than just the clinical. Through evaluation, it proved that any healthcare services must hold a high standard to enter the market.

Although the framework provided us with essential criteria, we missed more concrete questions asked of the criteria. Significantly, section D included questions that seemed broad. It could be difficult for developers to understand the meaning of the question. Even though the framework provided supporting information, some of the supporting material could lead to more confusion.

Reflection over the COPD calculator

The usage of the COPD calculator provided a great example of how such a clinical decision support tool/system could be effective in healthcare. The calculator provided functionalities that could potentially ease the workflow.

From another perspective, even though the results achieved from the evaluation process were considered successful, we are glad that there are still improvements for the COPD calculator to address. Ergo, they can improve their product to be as much quality as possible to apply for the CE-mark.

Also, we have to consider that developers of the COPD calculator did not have Norwegian standards or guidelines to follow during the development in 2014. Even so, they managed to receive successful results from the evaluation.

Limitations

Limitations to this study are mainly towards the framework and the COPD calculator. As for the framework, the downfall was the limitation to the UK only. The NHSx DTAC has the potential to be an international baseline for developing healthcare applications/systems.

The limitation to the COPD calculator is the underdevelopment of guidelines and standards for stakeholders in health-related applications/systems/services.

Chapter 7

Conclusion

Through a customization process of the NHSx DTAC Framework, we evaluated a Norwegian CDS tool and received a successful result. Further, we have presented evidence for the comprehensiveness of NHSx DTAC and that it has the ability to be applied to any healthcare-related applications/system because of the many aspects it considers.

The evaluation also yields further improvements for the COPD calculator, which was our intended purpose. KBB Medic and CodeLab yearned for information on how their product could be ready for CE-mark.

Appendices

A.1 Final Assessment Criteria Table

This appendix present a table of the final assessment criteria that will be used to evaluate the COPD-calculator.

Table 1: Final criteria table

Code	Criteria	Requirements
C1.1	Have you undertaken Clinical Risk Management activities for this product which comply with ISO 14971?	Developers must confirm that they have undertaken Clinical Risk Management activities in compliance with ISO 14971.
C1.1.1	Detail your clinical risk management system	Developers is required to provide evidence that is compliant with ISO 14971.
C1.1.2	Supply your Clinical Safety Case Report and Hazard Log	Developers is required to submit Clinical Safety Case Report and Hazard Log.
C1.3	If your product falls within the Norwegian Medical Devices Regulations, is it registered with the The Norwegian Medicines Agency (NoMA)?	Developers is required to provide evidence of a valid registration.
C1.3.1	If yes, please provide your NoMA registration number	The registration number must be valid.
C1.3.2	If the Norwegian Medical Device Regulations are applicable, please provide your Declaration of Conformity and, if applicable, certificate of conformity issued by a Notified Body	Valid documentation appropriate to the risk classification of the device must be provided.
C1.4	Do you use or connect to any third party products?	-
C1.4.1	If yes, please attach relevant Clinical Risk Management documentation and conformity certificate	A valid conformity certificate must be provided. The Clinical Risk Management documentation must meet the requirements detailed in question C1.1.

C2.1	Does your product process any personal information?	Developers are required to submit evidence that complies with the checklist provided by The Norwegian Data protection Authority.
C2.3.2	Attach the Data Protection Impact Assessment (DPIA) relating to the product.	Developer must provide a DPIA that is compliant with the requirements set out under the General Data Protection Regulations.
C2.5	Confirm where you store and process data (including any third party products your product uses)	Just a confirmation to either: UK only — In EU — Outside of EU
C2.5.1	If you process store or process data outside of the UK, please name the country and set out how the arrangements are compliant with current legislation	Developer must demonstrate that the country in which data is processed or stored is compliant with current legislation or the organisation's policy (should this differ).
C3.3	Confirm whether all custom code had a security review.	Developer must confirm that an internal or an external custom code security review has been undertaken.
C3.4	Confirm whether all privileged accounts have appropriate Multi-Factor Authentication (MFA)?	The developer must confirm yes/no. If yes all privileged accounts must have MFA.
C3.6	Confirm whether the product has been load tested	The developer must confirm yes that load testing has been performed.
C4.1	Does your product expose any Application Programme Interfaces (API) or integration channels for other consumers?	Developers are required to demonstrate that hey have API's that are relevant to the use case for the product.

C4.1.1	If yes, please provide detail and evidence: • The API's (e.g. what they connect to) • Set out the healthcare standards of data interoperability eg. Health Level Seven International (HL7) / Fast Healthcare Interoperability Resources (FHIR) • Confirm that they follow Government Digital Services Open API Best Practice • Confirm they are documented and freely available • Third parties have reasonable access to connect If no, please set out why your product does not have APIs.	Developers must provide evidence according to the bullet points.
C4.2	Do you use Norwegian national identification number (NNIN) to identify patient record data?	Developers must confirm that if a product uses an Norwegian NIN to identify a patient record.

C4.2.1	If yes, please confirm whether it uses Digital Identification Certificate (eg. BankID) Login to establish a user's verified NNIN number. If no, please set out the rationale, how your product established NNIN number and the associated security measures in place. If a product does not use Digital Identification Certificate (eg. BankID) Login to establish a verified NNIN number then a legitimate rationale should be set out and the security and appropriateness of the methodology should be considered.	Provide the evidence according to the questions.
C4.3	Does your product have the capability for read/write operations with electronic health records (EHRs) using industry standards for secure interoperability (e.g. OAuth 2.0, TLS 1.2)	Developers must confirm that the product has the capability to read/write into EHR using industry standards for secure interoperability.
C4.3.1	If yes, please detail the standard	
C4.3.2	If no, please state the reasons and mitigations, methodology and security measures.	
D1.1	Understand users and their needs in context of health and social care Do you engage users in the development of the product?	Developers must demonstrate that user need has been taken in account through user research, search data, analytics or other data to understand the problem.

D1.1.1	If yes or working towards it, how frequently do you consider user needs in your product development and what methods do you use to engage users and understand their needs?	
D1.2	Work towards solving a whole problem for users Are all key user journeys mapped to ensure that the whole user problem is solved or it is clear to users how it fits into their pathway or journey?	Developers must attach supporting information showing that the product solves a whole user problem or that it is clear to users how it fits into their pathway or journey.
D1.2.1	If yes or working towards it, please attach the user journeys and/or how the product fits into a user pathway or journey	Provide information according to the questions.
D1.3	**Make the service simple to use** Do you undertake user acceptance testing to validate usability of the system?	Developers must attach supporting information showing user acceptance testing to validate usability of the product.
D1.3.1	If yes or working towards it, please attach information that demonstrates that user acceptance testing is in place to validate usability.	
D1.4	**Make sure everyone can use the service** Are you international Web Content Accessibility Guidelines (WCAG) 2.1 level AA compliant?	Developers must provide evidence for WCAG 2.1 level AA compliance.

D1.5	**Create a team that includes multi-disciplinary skills and perspectives** Does your team contain multidisciplinary skills?	Developers must confirm that they have a multi-disciplinary team.
D1.6	**Use agile ways of working** Do you use agile ways of working to deliver your product?	Developers must confirm if they use agile ways of working.
D1.7	**Iterate and improve frequently** Do you continuously develop your product?	Developers must confirm that they continually develop their product.
D1.8	**Define what success looks like and be open about how your service is performing** Do you have a benefits case that includes your objectives and the benefits you will be measuring and have metrics that you are tracking?	Developers must confirm that the benefit case includes objectives and metrics that can be tracked.
D1.11	**Operate a reliable service** Do you provide a Service Level Agreement to all customers purchasing the product?	Developers must confirm the offer of a service level agreement, reporting on performance and having an uptime of 99.9% or above.
D1.12	Do you report to customers on your performance with respect to support, system performance (response times) and availability (uptime) at a frequency required by your customers?	
D1.12.1	Attach a copy of the information provided to customers	

D1.12.2	Provide your average service availability for the past 12 months, as a percentage to two decimal places	

B.2 The Digital Technology Assessment Criteria (DTAC)

The Digital Technology Assessment Criteria for Health and Social Care (DTAC)

Table of contents

The assessment criteria is made up of five core components. Sections A and B will provide the assessors the context required to understand your product and support your evidence. The core assessment criteria is defined in section C1-C4. Section D details the key Usability and Accessibility principles required. Further frequently asked questions are available at the end of the document.

The core criteria in Section C will determine the overall success of the assessment of your product or service. The accompanying score provided from Section D will show the level of adherence to the NHS Service Standard.

A. Company information - Non-assessed section

Information about your organisation and contact details.

Code	Question	Options
A1	Provide the name of your company	Free text
A2	Provide the name of your product	Free text
A3	Provide the type of product	App | Wearable | Software as a Service (SaaS) | Other
A4	Provide the name and job title of the individual who will be the key contact at your organisation	Free text
A5	Provide the key contact's email address	Free text
A6	Provide the key contact's phone number	Free text
A7	Provide the registered address of your company	Free text

A8	In which country is your organisation registered?	Free text
A9	If you have a Companies House registration in the UK please provide your number	Free text
A10	If applicable, when was your last assessment from the Care Quality Commission (CQC)?	Date | Not applicable
A11	If applicable, provide your latest CQC report.	Provided

B. Value proposition - Non-assessed section

Please set out the context of the clinical, economic or behavioural benefits of your product to support the review of your technology. This criteria will not be scored but will provide the context of the product undergoing assessment.

Where possible, please provide details relating to the specific technology and not generally to your organisation.

Code	Question	Options	Supporting information
B1	Who is this product intended to be used for?	Patients | Diagnostics | Clinical Support | Infrastructure | Workforce | Other	
B2	Provide a clear description of what the product is designed to do and of how it is expected to be used	Free text	This question is a context question and therefore a high-level summary is required.
B3	Describe clearly the intended or proven benefits for users and confirm if / how the benefits have been validated	Free text	This question is a context question and therefore a high-level summary is required. If your product has had an evaluation or undergone clinical trials include this information.

B4	Please attach one or more user journeys which were used in the development of this product Where possible please also provide your data flows	Provided | Not available	This question is a context question, and it is expected that existing documentation will be provided. GOV.UK provides guidance on how to make a user journey map and what should be included. Data flows enable the assessor to understand how data moves through a product. This may be included within a Data Protection Impact Assessment. If this is the case, please provide as a separate attachment for ease of review.

C. Technical questions - Assessed sections

C1 - Clinical safety

Establishing that your product is clinically safe to use.

You must provide responses and documentation relating to the specific technology product that is subject to assessment.

The DCB0129 standard applies to organisations that are responsible for the development and maintenance of health IT systems. A health IT system is defined as “product used to provide electronic information for health and social care purposes”. DTAC is designed as the assessment criteria for digital health technologies and C1 Clinical Safety Criteria is intended to be applied to all assessments. If a developer considers that the C1 Clinical Safety is not applicable to the product being assessed, rationale must be submitted exceptionally detailing why DCB0129 does not apply.

The DCB0160 standard applies to the organisation in which the health IT is deployed or used. It is a requirement of the standard (2.5.1) that in the procurement of health IT systems the organisation must ensure that the manufacturer and health IT system complies with DCB0129. The organisation must do so in accordance with the requirements and obligations set out in the DCB0160 standard. This includes personnel having the knowledge, experience and competences appropriate to undertaking the clinical risk management tasks assigned to them and organisations should ensure that this is the case when assessing this section of the DTAC.

If the Clinical Safety Officer or any other individual has concerns relating to safety of a medical device including software and apps, this should be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting system: Report a problem with a medicine or medical device - GOV.UK (www.gov.uk).

Code	Question	Options	Supporting information	Scoring criteria
C1.1	Have you undertaken Clinical Risk Management activities for this product which comply with DCB0129?	Yes | No	The DCB0129 standard applies to organisations that are responsible for the development and maintenance of health IT systems. A health IT system is defined as '"product used to provide electronic information for health and social care purposes".	To pass, the developer is required to confirm that they have undertaken Clinical Risk Management activities in compliance with DCB0129.
C1.1.1	Please detail your clinical risk management system	Provided | No evidence available	DCB0129 sets out the activities that must and should be undertaken for health IT systems. An example clinical risk management system template can be downloaded from the NHS Digital website.	To pass, the developer is required to evidence that a clinical risk management system is in place and that it is compliant with the requirements set out in DCB0129. This should include: ● The clinical risk management governance arrangements that are in place ● The clinical risk management activities ● Clinical safety competence and training ● Audits

C1.1.2	Please supply your Clinical Safety Case Report and Hazard Log	Provided | No evidence available	Specifically, your DTAC submission should include: ● A summary of the product and its intended use ● A summary of clinical risk management activities ● A summary of hazards identified which you have been unable to mitigate to as low as it is reasonably practicable ● The clear identification of hazards which will require user or commissioner action to reach acceptable mitigation (for example, training and business process change) It should not include the hazard log in the body of the document - this should be supplied separately. Example Clinical Safety Case Report and Hazard Log templates can be downloaded from the NHS Digital website.	To pass, the developer is required to submit the Clinical Safety Case Report and Hazard Log that is compliant with the requirements set out in DCB0129. This should be commensurate with the scale and clinical functionality of the product and address the clinical risk management activities specified with the standard. The Clinical Safety Case Report should present the arguments and supporting evidence that provides a compelling, comprehensible and valid case that a system is safe for a given application in a given environment at the defined point in the products lifecycle. It should provide the reader with a summary of all the relevant knowledge that has been acquired relating to the clinical risks associated with the product at that point in the life cycle: ● A clear and concise record of the process that has been applied to determine the clinical safety of the product ● A summary of the outcomes of the assessment procedures applied ● A clear listing of any residual clinical risks that have been identified and the related operational constraints and limitations that are applicable ● A clear listing of any hazards and associated clinical risks that have

				been transferred, together with any declared risk control measures, that are to be addressed as part of the clinical risk management process in the organisation where the product is being deployed ● A listing of outstanding test issues / defects associated with the product which may have a clinical safety impact. The Hazard Log should record and communicate the on-going identification and resolution of hazards associated with the product. All foreseeable hazards should be identified, and the risk of such hazards should be reduced to acceptable levels. A summary should also be provided to the assessor of identified hazards that the developer has been unable to mitigate to as low as it is reasonably practicable. It should also clearly identify the hazards which will require user or commissioner action to reach acceptable mitigation.

C1.2	Please provide the name of your Clinical Safety Officer (CSO), their profession and registration details	Free Text	The CSO must: ● Be a suitably qualified and experienced clinician ● Hold a current registration with an appropriate professional body relevant to their training and experience ● Be knowledgeable in risk management and its application to clinical domains ● Be suitably trained and qualified in risk management or have an understanding in principles of risk and safety as applied to Health IT ● Have completed appropriate training The work of the CSO can be undertaken by an outsourced third party.	To pass, the developer must have a named CSO which can be through an outsourced arrangement. They must be a suitably qualified and experienced clinician and hold a current registration with an appropriate professional body relevant to their training and experience.

C1.3	If your product falls within the UK Medical Devices Regulations 2002, is it registered with the Medicines and Healthcare products Regulatory Agency (MHRA)?	Yes | No | Not applicable	If this question is not applicable, because your product does not fall within the UK Medical Devices Regulations 2002, continue to question C1.4. If No, but the product falls within the UK Medical Devices Regulations 2002, continue to question C.1.3.2. The MHRA provides guidance on medical devices to place them on the market in Great Britain and Northern Ireland, regulatory requirements for all medical devices to be placed on the UK market, conformity assessment and the UK Conformity Assessed (UKCA) mark, classification of stand-alone medical device software (including apps) and how to tell if your product falls within the UK Medical Devices Regulations 2002.	To pass, if the product falls within the UK Medical Device Regulations 2002 and is required to be registered with the MHRA, the product must have a valid registration. It is currently possible that products do fall within the UK Medical Devices Regulations 2002 but are not yet required to be registered with the MHRA.
C1.3.1	If yes, please provide your MHRA registration number	Free text		To pass, the registration number must be valid.

C1.3.2	If the UK Medical Device Regulations 2002 are applicable, please provide your Declaration of Conformity and, if applicable, certificate of conformity issued by a Notified Body / UK Approved Body	Provided | No evidence available	Medical device manufacturers must ensure that their device complies with the relevant Essential Requirements of the legislation and draw up a Declaration of Conformity to declare this. Class I devices with a measuring function and devices in Class IIa, IIb and III must undergo conformity assessment from an EU Notified Body or UK Approved Body which has been designated for medical devices, and be issued a certificate of conformity (commonly referred to as a "CE certificate" or "UKCA certificate").	To pass, valid documentation appropriate to the risk classification of the device must be provided.
C1.4	Do you use or connect to any third-party products?	Yes I No	If no, continue to section C2. DCB0129 contains the requirements in relation to third party products.	
C1.4.1	If yes, please attach relevant Clinical Risk Management documentation and conformity certificate	Provided | No evidence available		To pass, a valid conformity certificate must be provided. The Clinical Risk Management documentation must meet the requirements detailed in question C1.1.

C2 - Data protection

Establishing that your product collects, stores and uses data (including personally identifiable data) compliantly.

This section applies to the majority of digital health technology products however there may be some products that do not process any NHS held patient data or any identifiable data. If this is the case, the Data Protection Officer, or other suitably authorised individual should authorise this data protection section being omitted from the assessment.

Code	Question	Options	Supporting information	Scoring criteria
C2.1	If you are required to register with the Information Commissioner, please attach evidence of a current registration. If you are not required to register, please attach a completed self-assessment showing the outcome from the Information Commissioner and your responses which support this determination.	Provided | Not provided	There are some instances where organisations are not required to register with the Information Commissioner. This includes where no personal information is being processed. The Information Commissioner has a registration self-assessment tool to support this decision making.	To pass, the developer is required to submit evidence that they have a current registration with the Information Commissioner. This can be validated against the Information Commissioner's Register of Fee Payers. Alternatively, if the developer confirms they are not registered with the Information Commissioner because they are not required to do so, then a self-assessment from the Information Commissioner's self-assessment tool should be attached which aligns to the product.

C2.2	Do you have a nominated Data Protection Officer (DPO)?	Yes | No | We do not need one	Not all organisations are required to have a Data Protection Officer (DPO). This is determined by the type of organisation and core activities. The most common reason for organisations providing digital health technologies to have a DPO is due to the core activities involving processing health data (being a special category). The Information Commissioner has a self-assessment tool to determine whether you must appoint a DPO.	
C2.2.1	If you are required to have a nominated Data Protection Officer, please provide their name. If you are not required to have a DPO please attach a completed self-assessment showing the outcome from the Information Commissioner and your responses which support this determination.	Free text | Provided		To pass, the developer is required to confirm they have a DPO in place where this is mandated. Where a DPO one is in place if it is not required by the Information Commissioner then this will also constitute a pass. Alternatively, if the developer confirms they do not have a DPO because they are not required to do so, then a self-assessment from the Information Commissioners self-assessment tool should be attached which confirms this and aligns to the product.

C2.3	Does your product have access to any personally identifiable data or NHS held patient data?	Yes | No	The UK General Data Protection Regulation (GDPR) applies to the processing of personal data. If no, continue to question C2.4	
C2.3.1	Please confirm you are compliant (having standards met or exceeded status) with the annual Data Security and Protection Toolkit Assessment. If you have not completed the current year's assessment and the deadline has not yet passed, please confirm that you intend to complete this ahead of the deadline and that there are no material changes from your previous years submission that would affect your compliance.	Confirmed | Unable to confirm	The Data Security and Protection Toolkit allows organisations to measure performance against the National Data Guardian's 10 data security standards.	To pass, the developer must confirm that they are compliant with the Data Security and Protection Toolkit Assessment. This should be validated against the Data Security and Protection Toolkit database and achieve Standards Met or Exceeded status. Dependent on the date of the assessment versus the opening of the annual assessment period, it may be that a developer has not yet completed the toolkit. The developer is asked to confirm that they will complete the assessment and that they will maintain their compliance versus the previous year.

C2.3.2	Please attach the Data Protection Impact Assessment (DPIA) relating to the product.	Provided | Not provided	DPIA's are a key part of the accountability obligations under the UK GDPR, and when done properly help organisations assess and demonstrate how they comply with data protection obligations. The Information Commissioner has provided guidance on how to complete a DPIA and a sample DPIA template.	To pass, the developer must provide a DPIA that is compliant with the requirements set out under the General Data Protection Regulations. It should ensure that risks to the rights and freedoms of natural persons are managed to an acceptable level. The DPIA should: ● Establish the context; taking into account the nature, scope, context and purposes and processing and the sources of the risk ● Assess the risks; considering the particular likelihood and severity of high risks ● Treat the risks; through mitigation and ensuring the protection of personal data and demonstrating compliance with the GDPR It should include: ● A description of the envisaged processing operations and the purposes of the processing ● An assessment of the necessity and proportionality of the processing ● An assessment of the risks to the rights and freedoms of data subjects ● The measures envisaged to address the risks and to demonstrate compliance with the GDPR

C2.4	Please confirm your risk assessments and mitigations / access controls / system level security policies have been signed-off by your Data Protection Officer (if one is in place) or an accountable officer where exempt in question C2.2.	Confirm | Cannot confirm		To pass, the developer must confirm that their Data Protection Officer or accountable officer has signed-off the risk assessments and mitigations / access controls and system level security policies.
C2.5	Please confirm where you store and process data (including any third-party products your product uses)	UK only | In EU | Outside of EU	Individual organisations within the Health and Social Care system are accountable for the risk-based decisions that they must take.	Individual organisations within the Health and Social Care system are accountable for the risk-based decisions that they must take. Due consideration should be taken where data is processed outside of the UK. Please note: It is a contractual requirement under the new GP IT Futures (GPITF) framework as it was in the GP System of Choice (GPSoC) framework, to host all data in England.

C2.5.1	If you process store or process data outside of the UK, please name the country and set out how the arrangements are compliant with current legislation	Free text	From 1 January 2021, the UK GDPR applies in the UK in place of the "EU GDPR'. The UK GDPR will carry across much of the existing EU GDPR legislation. The Department for Digital, Culture, Media & Sport has published two Keeling Schedules which show the changes to the Data Protection Act 2019 and EU GDPR. The Information Commissioner has published guidance on international data transfers after the UK exit from the EU Implementation Period.	Individual organisations within the Health and Social Care system are accountable for the risk-based decisions that they must take. Due consideration should be taken where data is processed outside of the UK and should only be hosted within the European Economic Area (EEA) or a country deemed as adequate by the European Commission. To pass, the developer must demonstrate that the country in which data is processed or stored is compliant with current legislation or the organisation's policy (should this differ).

C3 - Technical security

Establishing that your product meets industry best practice security standards and that the product is stable.

Dependent on the digital health technology being procured, it is recommended that appropriate contractual arrangements are put in place for problem identification and resolution, incident management and response planning and disaster recovery.

Please provide details relating to the specific technology and not generally to your organisation.

Code	Question	Options	Supporting information	Scoring criteria
C3.1	Please attach your Cyber Essentials Certificate	Provided | No evidence available	Cyber Essentials helps organisations guard against the most common cyber threats. The National Cyber Security Centre (NCSC) have published cyber security guidance for small to medium enterprises (SME's).	To pass, developers must have a valid Cyber Essentials certificate. Certification lasts for a period of 12 months so the certificate should be within date. This should be validated against the IASME database. NHS organisations are required to have Cyber Essentials in place (and is now incorporated into the NHS Digital Data Security and Protection Toolkit (DSPT) for NHS Trusts and Foundation Trusts in 2021-22 assessments) and to mitigate risk within the supply chain, suppliers should hold Cyber Essentials.

C3.2	Please provide the summary report of an external penetration test of the product that included Open Web Application Security Project (OWASP) Top 10 vulnerabilities from within the previous 12-month period.	Provided | No evidence available	The NCSC provides guidance on penetration testing. The OWASP Foundation provides guidance on the OWASP top 10 vulnerabilities.	To pass, the developer must evidence that the product has undergone an external penetration test that included the OWASP top 10 vulnerabilities. The penetration testing / summary report must demonstrate there are no vulnerabilities that score 7.0 or above using the Common Vulnerability Scoring System (CVSS).
C3.3	Please confirm whether all custom code had a security review.	Yes - Internal code review | Yes - External code review | No | No because there is no custom code	The NCSC provides guidance on producing clean and maintainable code.	To pass, the developer must confirm that an internal or an external custom code security review has been undertaken. An external review is preferable; however an internal code review would meet the baseline requirement.
C3.4	Please confirm whether all privileged accounts have appropriate Multi-Factor Authentication (MFA)?	Yes | No	The NCSC provides guidance on Multi-Factor Authentication.	To pass, the developer must confirm yes that all privileged accounts have MFA.

C3.5	Please confirm whether logging and reporting requirements have been clearly defined.	Yes | No	The NCSC provides guidance on logging and protective monitoring. To confirm yes to this question, logging (e.g., audit trails of all access) must be in place. It is acknowledged that not all developers will have advanced audit capabilities.	To pass, the developer must confirm yes that logging and reporting requirements have been clearly defined.
C3.6	Please confirm whether the product has been load tested	Yes | No	Load testing should be performed.	To pass, the developer must confirm yes that load testing has been performed.

C4 - Interoperability criteria

Establishing how well your product exchanges data with other systems.

To provide a seamless care journey, it is important that relevant technologies in the health and social care system are interoperable, in terms of hardware, software and the data contained within. For example, it is important that data from a patient's ambulatory blood glucose monitor can be downloaded onto an appropriate clinical system without being restricted to one type. Those technologies that need to interface within clinical record systems must also be interoperable. Application Programme Interfaces (APIs) should follow the Government Digital Services Open API Best Practices, be documented and freely available and third parties should have reasonable access in order to integrate technologies.

Good interoperability reduces expenditure, complexity and delivery times on local system integration projects by standardising technology and interface specifications and simplifying integration. It allows it to be replicated and scaled up and opens the market for innovation by defining the standards to develop upfront.

This section should be tailored to the specific use case of the product and the needs of the buyer however it should reflect the standards used within the NHS and social care and direction of travel.

Please provide details relating to the specific technology and not generally to your organisation.

Code	Question	Options	Supporting information	Scoring criteria
C4.1	Does your product expose any Application Programme Interfaces (API) or integration channels for other consumers?	Yes | No	The NHS website developer portal provides guidance on APIs and the NHS. Government Digital Services provide guidance on Open API best practice.	To pass, developers must demonstrate that they have API's that are relevant to the use case for the product, follow Government Digital Services Open API Best Practice, are documented and freely available and that third parties have reasonable access to connect. APIs should adopt generally accepted standards of data interoperability for the NHS or social care dependent on the use case for the product. If the product does not have API's and there is a legitimate rationale for this considering the use case of the product then the buyer can accept this rationale.

C4.1.1	If yes, please provide detail and evidence: ● The API's (e.g., what they connect to) set out the healthcare standards of data interoperability e.g., Health Level Seven International (HL7) / Fast Healthcare Interoperability Resources (FHIR) ● Confirm that they follow Government Digital Services Open API Best Practice ● Confirm they are documented and freely available ● Third parties have reasonable access to connect If no, please set out why your product does not have APIs.	Free text		

C4.2	Do you use NHS number to identify patient record data?	Yes | No | No because product does not identify patient record data	NHS Digital provides guidance on NHS Login for partners and developers.	To pass, developers should confirm that if a product uses an NHS number to identify a patient record, that it uses NHS Login. NHS Digital provides a list of all current digital health and social care services that integrate with NHS Login. If a product does not use NHS Login to establish a verified NHS number, then a legitimate rationale should be set out and the security and appropriateness of the methodology should be considered.
C4.2.1	If yes, please confirm whether it uses NHS Login to establish a user's verified NHS number. If no, please set out the rationale, how your product established NHS number and the associated security measures in place.	Free text		
C4.3	Does your product have the capability for read/write operations with electronic health records (EHRs) using industry standards for secure interoperability (e.g. OAuth 2.0, TLS 1.2)	Yes | No | No because the product does not read/ write into EHRs		To pass, developers should confirm that the product has the capability to read/write into EHRs using industry standards for secure interoperability. If a product does not use industry standards, then a legitimate rationale should be set out and the security, usability and appropriateness of the methodology should be considered.

C4.3.1	If yes, please detail the standard	Free text		
C4.3.2	If no, please state the reasons and mitigations, methodology and security measures.	Free text		
C4.4	Is your product a wearable or device, or does it integrate with them?	Yes | No	If no, continue to section D.	To pass, the developer must evidence compliance with ISO/IEEE 10073
C4.4.1	If yes, provide evidence of how it complies with ISO/IEEE 11073 Personal Health Data (PHD) Standards.	Provided | No evidence available	Access the ISO Standard. This is a paid-for document.	

D. Key principles for success

The core elements defined in this section will form part of the overall review of the product or service and is a key part to ensuring that the product or service is suitable for use. The assessment will set a compliance rating and where a product or developer is not compliant highlight areas that the organisation could improve on with regards to following the core principles.

This section will be scored in relation to the NHS service standard. This will not contribute to the overall Assessment Criteria as set out in Section C.

D1 - Usability and accessibility - scored section

Establishing that your product has followed best practice.

Please note that not all sections of the NHS Service Standard are included where they are assessed elsewhere within DTAC, for example clinical safety.

Code	Question	Options	Supporting information	Weighted score	Scoring criteria
D1.1	**Understand users and their needs in context of health and social care** Do you engage users in the development of the product?	Yes | No | Working towards it	NHS Service Standard Point 1	10%	Developers should be awarded 10% if they demonstrate that user need has been taken in account through user research, search data, analytics or other data to understand the problem.

D1.1.1	If yes or working towards it, how frequently do you consider user needs in your product development and what methods do you use to engage users and understand their needs?	Free text			The submission should confirm that the developer has considered, and tested user needs with appropriate stakeholders (stakeholders will differ depending on the product) and that as the product continues to iterate user engagement has continued. If the developer selects working towards it and/or can only partially evidence the requirement, for example user need has only partially been considered or it is not considered on an ongoing basis they should be awarded 5%. If the developer selects no to this question or cannot provide evidence that user need has been considered, they should be awarded 0%.

D1.2	**Work towards solving a whole problem for users** Are all key user journeys mapped to ensure that the whole user problem is solved, or it is clear to users how it fits into their pathway or journey?	Yes | No | Working towards it	NHS Service Standard Point 2 and Point 3 are often dealt with by teams together.	10%	Developers should be awarded 10% if they attach supporting information showing that the product solves a whole user problem or that it is clear to users how it fits into their pathway or journey. If the developer selects working towards it and can provide evidence that goes some way to explaining how the whole user problem is solved or only partially explains how the product fits a user journey, they should be awarded 5%. If the developer selects no to this question or cannot provide evidence that shows the user journey or how the product fits into the pathway or journeys, they should be awarded 0%.
D1.2.1	If yes or working towards it, please attach the user journeys and/or how the product fits into a user pathway or journey	Provided | No evidence available			

D1.3	**Make the service simple to use** Do you undertake user acceptance testing to validate usability of the system?	Yes | No | Working towards it	NHS Service Standard Point 4	10%	Developers should be awarded 10% if they attach supporting information showing user acceptance testing to validate usability of the product. If the developer selects working towards it and can provide evidence that goes some way to demonstrate that user acceptance testing is being used to validate usability of the system, they should be awarded 5%. If the developer selects no to this question or cannot provide evidence that shows user acceptance testing to validate usability of the system, they should be awarded 0%.
D1.3.1	If yes or working towards it, please attach information that demonstrates that user acceptance testing is in place to validate usability.	Provided | No evidence available			
D1.4	**Make sure everyone can use the service** Are you international Web Content Accessibility Guidelines (WCAG) 2.1 level AA compliant?	Yes | No | Working towards it	NHS Service Standard Point 5 The Service Manual provides information on WCAG 2.1 level AA.	20%	Developers should be awarded 20% for WCAG 2.1 level AA compliance. Developers should be awarded 5% for working towards it. If the developer selects no to this question, they should be awarded 0%.

D1.4.1	Provide a link to your published accessibility statement.	Free text	The Government Digital Service provides guidance on accessibility and accessibility statements, including a sample template.	10%	Developers should be awarded 10% for a published accessibility statement that includes the information below: ● Whether the website or app is 'fully', 'partially' or 'not' compliant with accessibility standards ● If it is not fully compliant, which parts do not currently meet accessibility standards and why ● How people can get alternatives to content that is not accessible to them ● How to contact you to report accessibility problems and a link to the website that they can use if they are not happy with your response If an accessibility statement is not included or it does not contain the required information listed above the developer should be awarded 0%.
D1.5	**Create a team that includes multi-disciplinary skills and perspectives** Does your team contain multidisciplinary skills?	Yes | No | Working towards it	NHS Service Standard Point 6	2.5%	Developers should be awarded 2.5% for confirming they have a multi-disciplinary team. If the developer selects working towards it or no to this question, they should be awarded 0%.

D1.6	**Use agile ways of working** Do you use agile ways of working to deliver your product?	Yes | No | Working towards it	NHS Service Standard Point 7	2.5%	Developers should be awarded 2.5 % if they confirm they use agile ways of working. If the developer selects working towards it or no to this question, they should be awarded 0%.
D1.7	**Iterate and improve frequently** Do you continuously develop your product?	Yes | No | Working towards it	NHS Service Standard Point 8	5%	Developers should be awarded 5% if they confirm they continually develop their product. If the developer selects working towards it or no to this question, they should be awarded 0%.
D1.8	**Define what success looks like and be open about how your service is performing** Do you have a benefits case that includes your objectives and the benefits you will be measuring and have metrics that you are tracking?	Yes | No| Working towards it	NHS Service Standard Point 10	10%	Developers should be awarded 10% for confirming that the benefit case includes objectives and metrics that can be tracked. If the developer selects working towards it or no to this question, they should be awarded 0%.

D1.9	**Choose the right tools and technology** Does this product meet with NHS Cloud First Strategy?	Yes | No | No because it is not applicable	NHS Service Standard Point 11 NHS Internet First Policy.	5%	Developers should be awarded 5% for confirming the product meets cloud first and / or internet first. If the developer selects working towards it or no to this question, they should be awarded 0%.
D1.9.1	Does this product meet the NHS Internet First Policy?	Yes | No | No because it is not applicable			
D1.10	**Use and contribute to open standards, common components and patterns** Are common components and patterns in use?	Yes | No | Working towards it	NHS Service Standard Point 13	5%	Developers should be awarded 5% for confirming common components and patterns are used. If the developer selects working towards it or no to this question, they should be awarded 0%.
D1.10.1	If yes, which common components and patterns have been used?	Free text			

D1.11	**Operate a reliable service** Do you provide a Service Level Agreement to all customers purchasing the product?	Yes | No	NHS Service Standard Point 14	10%	Developers should be awarded 10% offering a service level agreement, reporting on performance and having an uptime of 99.9% or above. If the developer does not provide a service level agreement and / or reporting on performance, they should be awarded but has an uptime of 99.9% or above they should be awarded 5%. If the developer has an uptime of 99% or above, they should be awarded 2.5%. If the developer has an uptime of less than 99%, they should be awarded 0%.
D1.12	Do you report to customers on your performance with respect to support, system performance (response times) and availability (uptime) at a frequency required by your customers?	Yes | No			
D1.12.1	Please attach a copy of the information provided to customers	Provided | No evidence available			
D1.12.2	Please provide your average service availability for the past 12 months, as a percentage to two decimal places	Free text			

Supporting documentation

Please ensure that when providing evidence, documents are clearly labelled with the name of your company, the question number and the date of submission.

Possible documents to be provided are:

- A11 - CQC Report
- B4 - User journeys and data flows
- C1.1.1 - Clinical Risk Management System
- C1.1.2 - Clinical Safety Case Report
- C1.1.2 - Hazard Log
- C1.3.2 - UK Medical Device Regulations 2002 Declaration of Conformity and if applicable Certificate of Conformity
- C1.4.1 - Clinical Risk Management documentation and Conformity certificate for third party suppliers
- C2.1 - Information Commissioner's registration or completed Self-assessment Outcome Tool
- C2.2.1 Completed Information Commissioner's Self-Assessment Outcome Tool
- C2.3.2 - Data Protection Impact Assessment (DPIA)
- C3.1 - Cyber Essentials Certification
- C3.2 - External Penetration Test Summary Report
- C4.4.1 - If a wearable, evidence of how the product complies with ISO/IEEE 11073 Personal Health Data (PHD) Standards
- D1.2.1 - User Journeys and/or how the product fits into a user pathway or journey
- D1.3.1 - Supporting information showing user acceptance testing to validate usability
- D1.13.2 - Customer Performance Report

C.3 Evidence provided by developers during evaluation

This Appendix contains documents related to the evaluation process. These documents are evidence provided by the developers in order to achieve points by fulfilling the criteria. Because the file size of pdf documents are too large, the documents can the found in link: `https://drive.google.com/drive/folders/1hpssgp1ZkHdYzeBG4iFvdU3LUCGIQVBc?usp=sharing`.

C.3.1 The self assessment criteria related to C2.5

Table 2: Self-assessment of a good code practice

BAD	GOOD	Comments	Score
No software architecture has been established and differing coding standards are used throughout the code base.	Coding standards are enforced by automated coding and style checking tools such as 'linting'.	-	1
Code commits cannot be attributed to a specific developer.	Code is stored in a version control system that has strong authentication controls regulating who can review and accept code changes.	-	1
Code commits are irregular, resulting in the changes being large and impractical to review.	There is a well thought out software architecture documented and the file and folder naming convention is self-explanatory, leading to logical code layout.	-	1

Code commit descriptions are confusing.	All developers create small, clear and well commented code commits on a regular basis. These are peer reviewed by other team members.	Code commit descriptions are very well described. Because there was only one developer on this project, it did not have a peer review.	0.5
Code review is either non existent or ad-hoc.	New developers who do not conform to good practices have their code rejected.	Because there is only one developer on this team, there is no code review.	0
Tests or specifications are missing.	Code is written with testing or correctness checking in mind.	There are no tests for the calculator at the moment.	0
-	-	-	**Total score: 3.5**

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