Requirements Specification for an Asthma & COPD Telehealth System

Version 1

18/3/2016

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Revision History

This section needs to be updated to reflect the revisions of the specification that exist when the revision was created and the reason for the revision.

Version	Date	Comments
1	18/3/2016	The initial concept for the COPD telehealthcare system

Review Panel

This section needs to contain the details of the review panel. The review panel are responsible for the content of the specification and signing the document off.

Name	Position	Signature	Date
Robert Edwards	Business	R. Edwards	26/2/2016
Casey Johnson	Software Engineer	Casey J	4/3/2016
Patrick Jones	Electronics Engineer	Patrick Jones	4/3/2016
Dr. Dave Caspian	Lead Medical Supervisor	D Caspian	8/3/2016

Distribution

This section contains the list of people the requirements specification needs to be distributed to.

Client:	NHS Trust Software Engineering Company Hardware Engineering Company
Consultants:	Software Engineers Hardware Engineers Information Security Consultant Consulting chest physician

1. INTRODUCTION

1.1. Purpose

This paper aims to specify the requirements for a |user-friendly| telehealthcare system that would enable sufferers of chronic obstructive pulmonary disease (COPD), (and their carers) to manage their own condition from home with feedback from a medical professional.

COPD is among the 10 most prevalent chronic conditions, and occupies a substantial proportion of the available health-care resources. It is similar in its symptoms to asthma - coughing, wheezing and difficulty breathing - and they share similar diagnosis and treatment methods (Shaya et al. 2008). The major difference between the 2 conditions is their prognosis: unlike asthma, COPD gets progressively worse over time, with treatments aiming to slow the decline rather than stop it. (Bellamy, 2005)

This system is intended for those patients who have been diagnosed with COPD, or who are at high risk of COPD (smokers in particular-according to Bellamy (2005)), as well as their GPs, and any surgeon or consultant physician who needs access to their data.

1.2 Business Context

An NHS Trust has sponsored the development of the telehealthcare system, in line with their aims of improved clinical outcomes and patient experience.

A number of studies have studied telehealth(care) systems, and their results present a case for meeting the intended objectives:

- “Telehealth related changes for patients with COPD… have a greater effect on pooled estimates of hospital activity [than diabetes]” (Car, Huckvale and Hermens, 2012)
- “people with little experience of technology using a new asthma telehealthcare system daily for three weeks found that 88% of them felt safer while being monitored by the system; 94% were interested in using the same system in the future.” (McLean, Protti and Sheikh, 2011).
- “Telehealth is associated with lower mortality and emergency admission rates” (Steventon et al., 2012)

1.3. Scope

The system shall require read and write access to NHS databases for long-term storage and retrieval of patient information

The system shall include a device local to the patient (most likely in their home) that will require access to the local wireless internet. There will also be an optional connection to a local computer.

The system will consist primarily of software and data on the GP side, with records of measurements taken and previous feedback kept in the GP’s database.

There should be a server/set of servers that any sufficiently authorised, interested party can connect to in order to find necessary information on the patient’s condition.

1.4. User Characteristics

The primary users of the system will be the respiratory disease patients and their GP. Other medical professionals may also need access to the data such as consulting chest physicians or

surgeons who may be performing an operation such as lung volume reduction surgery (Washko *et al.*, 2008). It is also possible that some patients will require assistance from their guardians or carers.

The patients and/or their carers would operate the system from home, with a measurement device and a connected means of transmitting and receiving information.

The incidence of COPD increases with age (Bellamy, 2005), so it can be expected that the elderly will be be the main users. They also provide bounds for inclusive design.

2. REGULATIONS AND STANDARDS

There are regulations and standards of horizontal, semi-horizontal and vertical scope that must be complied with for this system.

Horizontal

2.1. Directive 93/42/EEC - Medical Device Directive

This is the EU directive for medical devices, providing legal restraints for what can medical devices can do. It requires that medical devices are safe and perform as the manufacturer intended. It also necessitates EC examination, clinical evaluation and a declaration of conformity (including a CE mark).

2.2. The Medical Devices Regulations 2002 (Amended 2013)

The UK-specific regulations on medical devices, again legally required. This includes the need to maintain technical documents ready for inspection, and to notify the competent authority when carrying out clinical tests.

2.3 EN ISO 9000 family - Quality management

This set of standards provides a quality management system, for ensuring that products and systems are created to a consistently high quality. Used in determining risk classification.

2.4. BS EN 62366-1:2015 - Medical devices. Application of usability engineering to medical devices

A version of ISO 9001 that is specifically tailored towards ensuring the quality of medical devices.

2.5. ISO 14971 - Application of risk management to medical devices Required by BS EN ISO 13485.

Provides risk management techniques through hazard identification and risk evaluation and control, as well as methods for monitoring the effectiveness of controls.

Semi-Horizontal

2.6. BS EN 60601-1-X family - Medical electrical equipment - General requirements for safety

A collection of standards regarding the minimum safety standards required for electrical aspects of medical equipment.

2.7. ISO/TS 13131:2014 ED1 - Health informatics. Telehealth services. Quality planning guidelines

Guidelines for telehealth services over any distances based on a ‘risk management process’. This includes guidance on quality, finances, people management, infrastructure and IT resources. Includes the normative reference to ISO 31000:2009 Risk Management - Principles and Guidelines.

Vertical

2.8. BS EN ISO 23747:2015 - Anaesthetic and respiratory equipment — Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans

A standard on how Peak Expiratory Flow meters, which measure one correlate of COPD, should be taken, in order to maintain consistent with other measures and be safe. It provides 26 waveforms against which a measuring device can be tested to determine whether it is suitable.

2.9. BS EN ISO 26782:2009 - Anaesthetic and respiratory equipment. Spirometers intended for the measurement of time forced expired volumes in humans

A standard giving requirements for accuracy, repeatability, electrical safety etc for spirometers that are used for forced expired volumes - the maximum volume of air a patient can forcefully breathe out (with possible additional constraints, such as the length of time this is measured). FEV_1 for example, a common indicator of COPD, is the amount of air forcefully expelled in 1 second.

3. FUNCTIONAL PROPERTIES

Functional Performance for patient

3.1. Setup

- The device shall have a **means for users to perform basic calibration** (to ensure that results are reliable)
- The inlet shall have a means for **connecting to a new mouthpiece** (to ensure hygiene with a new disposable or cleaned mouthpiece)

3.2. Data collection

3.2.1. Measurement Process

- The device shall have a means of **measuring and digitally encoding air inflow volume** (this is the main metric to be analysed)
    - The device shall have an inlet allowing sufficient airflow as required by BS EN ISO 26782 and BS EN ISO 23747 (minimises poor airflow as a confounding factor)
    - The device's mouthpiece shall minimises air leaks around the sides (as above)
- The device shall have a means of determining time passed to a precision better than or equal to 0.001s (necessary for time-based expired volume, as in BS EN ISO 26782)
- The device shall **inform the user of any method errors both audibly and visually** (need to know what they are doing wrong to improve; users may be deaf/blind)
- The device shall have a **means for retaking a measurement** (they may have taken one in error/may not have put in full effort, as required, and want to try again)
- The device shall have a means **for the patient to indicate they have finished their measurements** (should make the user feel in control; mitigates unwanted data sending)

3.2.2. Numerical Input

(See interface)

3.2.3. Comments

- The device shall have a **means for recording the patient's spoken comments for up to 2 minutes** (this may be the most natural way for the patient to interact; they may be blind, and so have difficulty with manual entry)
- The device shall have a means for **attempting the comment further times** (the patient may think of a better wording of a comment, make a mistake, or have background audio while recording their first comment)
- The device shall have a **means for canceling a recorded comment** (the patient may decide against leaving extra information after initially recording one)
- The device should have a **means for adding text-based comments** (the patient may prefer text comments to spoken ones; they may be deaf and/or have difficulty speaking clearly)

3.3. Finish

3.3.1. Local data processing

- The device shall be capable of determining at least the following incorrect measurement procedures as described by Bellamy (2005, p.11) (they are common mistakes and have simple, detectable patterns, so they should be prevented from being recorded)
    - Coughing during exhalation
    - Slow start to forced exhalation
    - Extra breath taken during manoeuvre
    - Early stoppage of manoeuvre
- The device should have an **override for autodetected errors** (it is possible that the device's error-checking may generate false positives, which the patient should be able to ignore)
- The device shall have a means of **displaying basic results information** (it is important for the patient to receive immediate feedback on their performance)
- The device shall be able to **determine Forced Expiratory Volume** (for immediate feedback)
- The device shall be able to **determine Forced Vital Capacity** (for immediate feedback)
- The device should be able to **determine Peak Expiratory Flow** (for immediate feedback, but less important as a measure)

3.3.2. Data transfer

- The device shall be able to **connect to WiFi directly** (this enables regular use without other devices required)
- The device shall be able to **connect to the internet via USB to a computer** (this enables use for those without WiFi, those who want to record data, and an option for text input)
- The device shall be able to send recorded data to:
    - System servers???
    - NHS database (long-term storage and available for consultant/surgeon)
    - GP local database (the data needs to be sent for GP feedback)
- The device should be capable of encrypting any data it sends (information security)
- The GP subsystem and storage servers should be capable of decrypting any data they receive (return from secure form to usable form)
- The data shall be sent via the TLS protocol using version 1.2 or later (information security)
- The device shall be able to queue recorded data to send when later connected to the internet (the internet may be down when the patient takes measurements, they should not have to retake valid measurements when the internet returns)
- The device shall **indicate how many recorded sessions are queued** to be sent (0 to N) (the patient needs to know whether or not their data has been sent)

3.4. Receiving Feedback

(see Interface)

Functional Performance for GP

3.5. Analysis

- The system shall perform analysis of the data on arrival into subsystem (this allows for immediate prioritisation)
- The system shall **prioritise cases into 'Urgent', 'High Priority' and 'Routine'** using criteria set by the GP (the patient may need to be attended to in the near future)

3.6. Alerts

- The system shall **alert the GP** of ‘Urgent’ cases immediately (in a worst case scenario)
- The system shall alert the GP of ‘High Priority’ cases at the end of the day (avoids interrupting their other appointments)
- The system shall prepare the ‘Routine cases’ to be analysed and fed back on at a set point each month (minimise time and mental effort taken for GPs compared to normal appointments)

3.7. Feedback

- The system shall provide means for the **GP to record feedback in audio and text formats** (feedback for users with any sensory ability level)
- The system should provide means for the GP to attach images for display (may be able to provide other information not easily conveyed verbally)

4. PHYSICAL PROPERTIES

- The device shall be airtight between the air inlet and the measurement point (the results will be distorted if air can leak in/out)
- The device shall be **easy to hold** down to 1st percentile elderly (65+) female hand size and strength (as many users as possible should be able to use the product)
- The device shall be held together in a way that makes it difficult for users to take it apart (this reduces the probability of exposing any electronic hazards)
- The device shall withstand the chemicals it is likely to come into contact with

5. INTERFACE REQUIREMENTS

Patient-side

5.1. Feedback/Displays

- The device should be independently operable by patients with impaired visual or auditory function
- The system should provide a **help function** useable at any stage of operation

5.1.1. Audio & Visual

- The device shall have the **means to inform the user of incorrect measurement method** used (Bellamy, 2005, p.17)
- The device shall have the means to **audibly and visually alert the user of feedback from the GP**
- The device shall have the means of **audibly and visually conveying the result of the input data**
- The device shall have a means of **displaying how many of the required measurements have been taken** (typically taken 3 times - the best 2 of which should be consistent) (the patient may forget how many they have taken/are left to take, particularly if they retake some)
- The device shall have the **means of alerting** the patient that the GP has sent them feedback
- The device shall have the means to **display visual and audio feedback** from the GP

5.1.2. Audio Only

- The device shall provide means for the user to listen to **feedback via headphones** (they may not want to disturb others, and headphones may be easier to hear over background noise)
- The volume be of a sufficient volume and clarity for patients with typical presbycusis (age-related hearing loss) to be able to understand what is said in a normal operating environment. (blind users may also have lost some of their hearing ability)

5.1.3. Visual Only

- The system should have a means of **displaying the exhalation trace** (it may be interesting for advanced users to see the graph of their expiration, but it is not necessary)
- The system shall have the means of alerting the patient of GP feedback via email

5.2. Controls

- The device shall have the **means to input numerical data** when prompted (this will be useful if other measurements need to be taken relating to COPD, e.g. SpO_2 from blood oximetry)

GP-Side

- All interaction shall be done via a computer and inputs into it (keyboard, mouse, microphone etc)

6. ENVIRONMENTAL CONDITIONS

Use

6.1. Noise and Lighting

- The device shall function normally in normal workplace/domestic lighting and noise environments (this is where the device will be used and so must be fully functional here)
    - Illuminance of 20-500 lux (normal range from BS EN 12464-1:2011)
    - Light flicker of 100-120Hz (as with fluorescent lights)
    - Background noise up to 80dB (the lower exposure action value set by HSE)

6.2. Wind

- The device shall function normally in environments with air velocity below 0.9ms^{-1} (this is above the upper limit for sedentary activity as indicated in Annex G of EN ISO 7730:2015
- The device should function normally in environments with air velocity below 10ms^{-1} (there is no reason the device should not be operable in winds, but this is not necessary)

6.3. Humidity and Temperature

- The device shall function normally in environments with up to 100% relative humidity
- The device shall function normally in temperatures between -10℃ and 70℃

Transportation

- The device shall be packaged to reduce the transmission of vibration to acceptable levels (so that the performance of the device is not affected)

7. MAINTENANCE

7.1. Power

- The device should be powerable through a choice of battery or cable
- Any battery in the device should not need recharging too regularly (more than once per 2 uses)

7.2. Mouthpiece

- There should be an option of a cleanable, reusable mouthpiece or of multiple disposable mouthpieces
- The disposable mouthpiece shall be storable in large quantities for a at least a year without degrading
- The disposable mouthpieces should be cheaply available
- The reusable mouthpieces should be cleanable with

7.3. Calibration

- The device shall enable the user to perform basic calibration
- The device should be professionally checked every year by a certified professional

8. DISPOSAL

8.1. Mouthpiece

- The disposable mouthpiece should be recyclable

8.2. Electronics

- The electronics should be separable from the body of the device to be disposed in an environmentally friendly way

9. SCHEDULE

Requirements document	-	18/03/2016
Design document	-	20/05/2016
First prototype	-	30/06/2016
First round of testing	-	14/07/2016
Second prototype	-	14/08/2016
Second round of testing	-	30/08/2016
Final design	-	30/09/2016
Ship	-	01/12/2016

10. VALIDATION

- The prototypes shall be user tested to sensory-normal, blind and deaf patients, each of various ages, in the full range of stated environmental conditions, with a focus on:
    - Interface (how easily they can extract and provide the necessary information)
    - Physical design (the strength and dexterity required to operate the device)
    - Functional design (how much information they require to go through each process)
    - Task analysis - a hierarchical and cognitive task analyses shall be undertaken for each individual and for all participants combined
- The device shall be theoretically tested against the percentiles given in Smith, Norris and Peebles (2000)
- The data security shall be stress tested for:
    - The standalone device
    - Mac, Windows and Linux
    - Routers with different security levels (WEP, WPA2 etc)
- The device shall be checked for conformity to regulations and standards, including being sent to the necessary bodies.

11. MANUFACTURABILITY

- The device should use off-the-shelf or cheaply manufactured parts where possible

12. DISTRIBUTION AND STORAGE REQUIREMENTS

- The device shall be storable where the battery charges (if this option is chosen)

13. INSTALLATION

13.1. Customer-side

- The device shall be connected to available WiFi if desired (one option to send/receive data)
- The user's authentication details shall be set up (needed to access data)
- The customer shall be given the option of email feedback and/or device feedback (one may fit better into daily schedule)
- The device shall have the capability to receive and install firmware updates (later improvements to function and bug fixes)

13.2. GP

- The system shall include sensible default criteria for the 3 priority levels
- The GP should determine the criteria for each priority level for each patient
- The system shall include sensible default settings for the measurements to be taken
- The GP shall determine what measurements the patient shall take each time (depends on the severity of COPD)
- The GP shall determine how often measurements are taken (as above)

14. TRAINING OF PERSONNEL

- All versions of training information shall include a quick reference, all steps required, and safety information

14.1. Customer

- The customer shall have access to physical and digital (including audio/video) versions of training information
- The customer shall have the system demonstrated to them by their GP

14.2. GP and Medical Staff

- GPs and medical staff shall have access to physical and digital (including audio) versions of information
- GPs will have the system demonstrated to them by people who have already trained to use the software

15. SAFETY

- The system shall conform with all safety standards and regulations mentioned (unless there is conflict, where more specific standards and regulations take precedence)
- Risk analyses shall be performed for each user, task and environment combination

16. COST

- The system shall aim to achieve the highest Quality Adjusted Life Years (QALY) to cost ratio
- The device
- The system shall be designed to remain functional after 10 years of use
- The possibility of downloadable firmware upgrades would reduce the need for physical replacement when improvements are required

17. DOCUMENTATION

A number of documents are needed for internal processes, external auditing and end user help. These include:

- risk analyses
- quality plans
- the design history file
- test and validation criteria
- manufacturing instructions
- installation instructions
- user instructions
- training manuals
- maintenance instructions
- any additional technical documents required to demonstrate conformity

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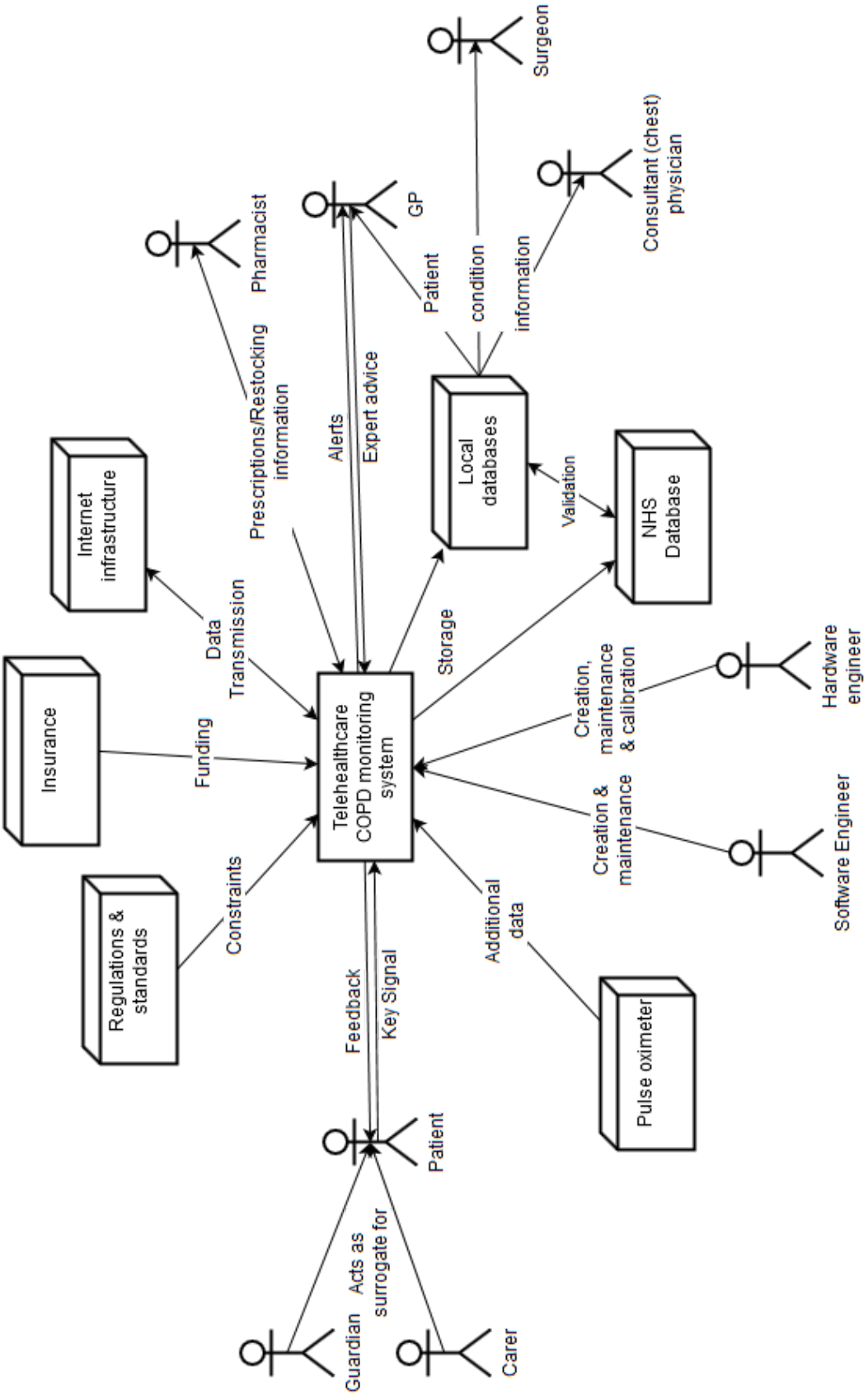
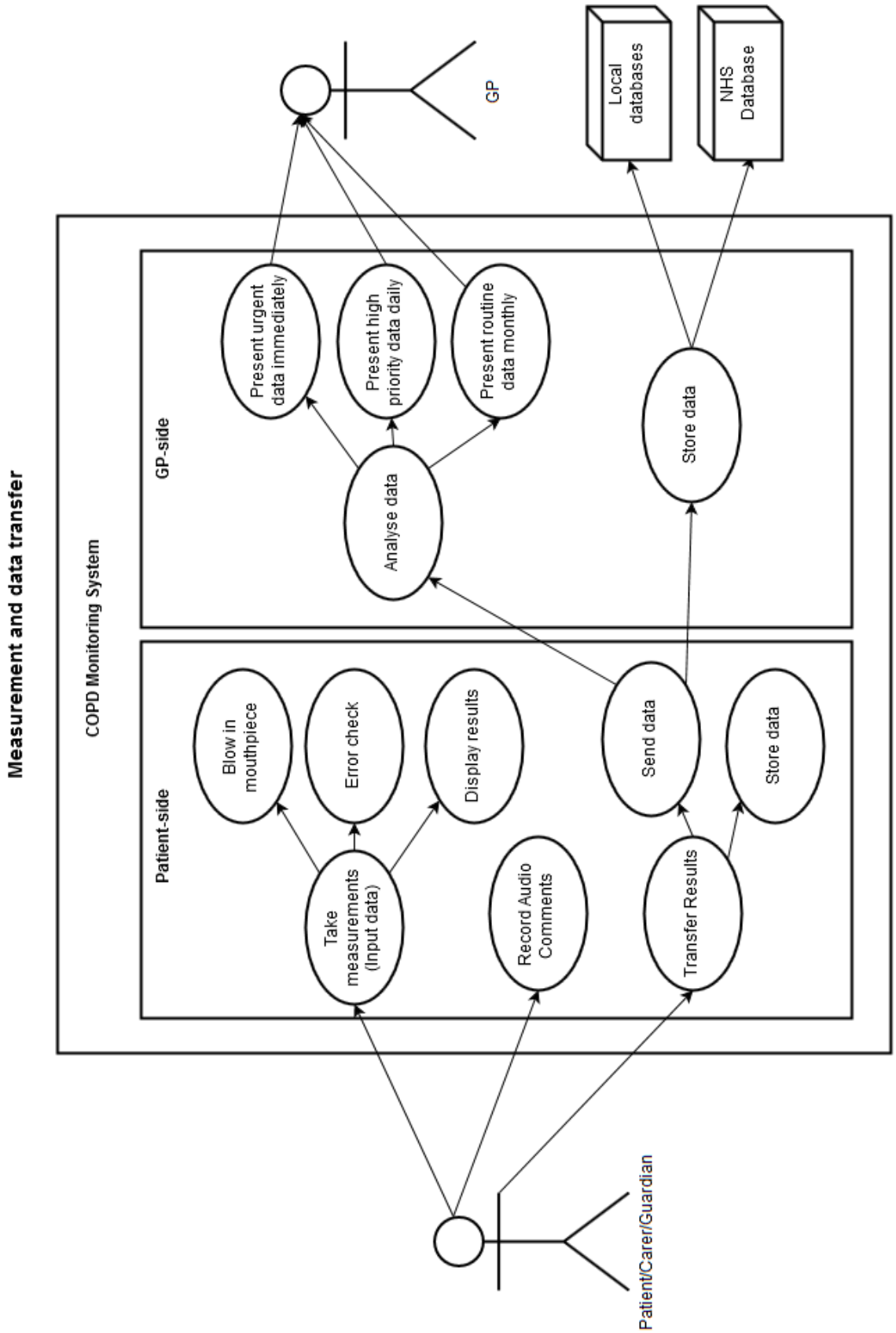
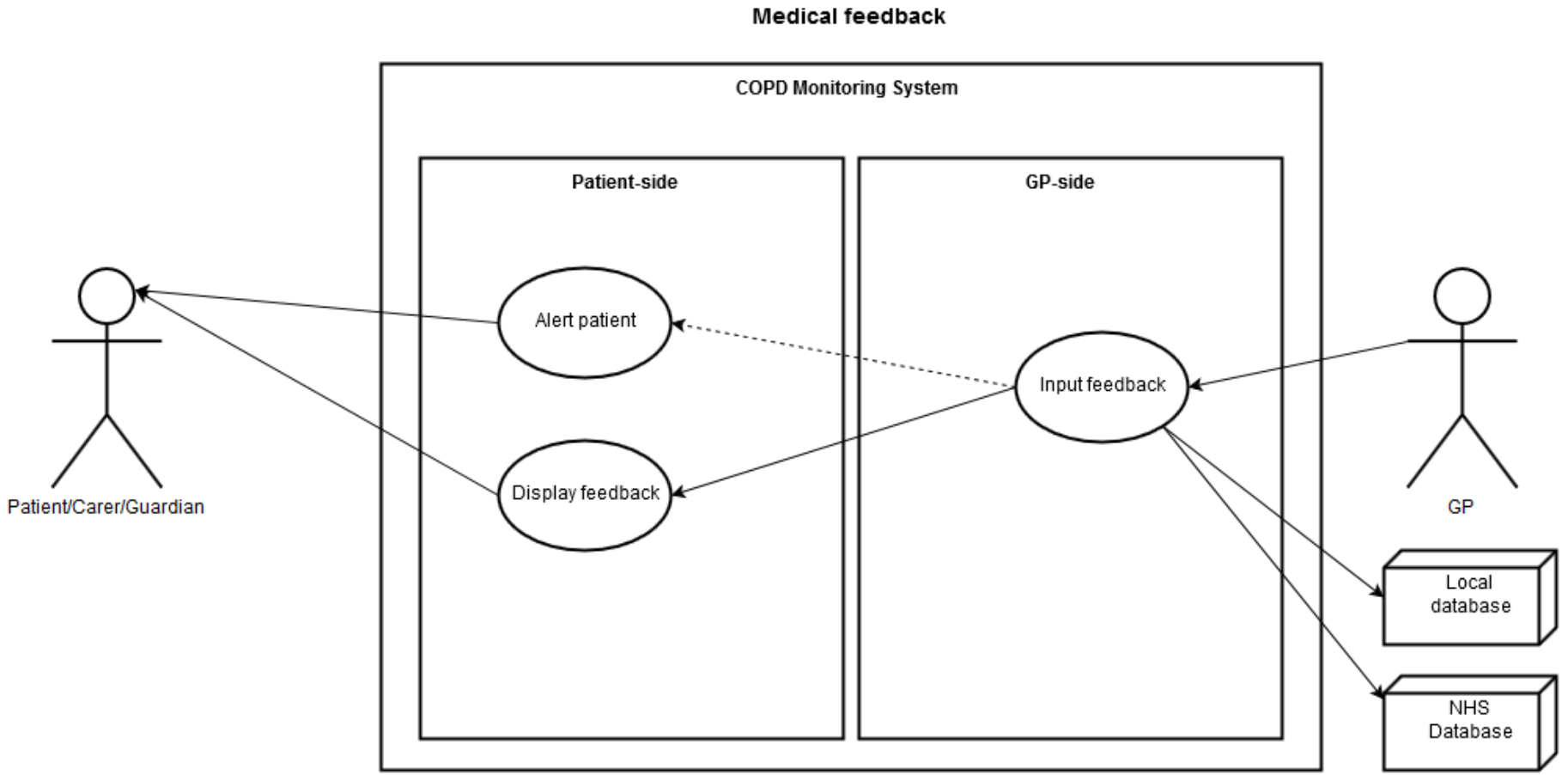
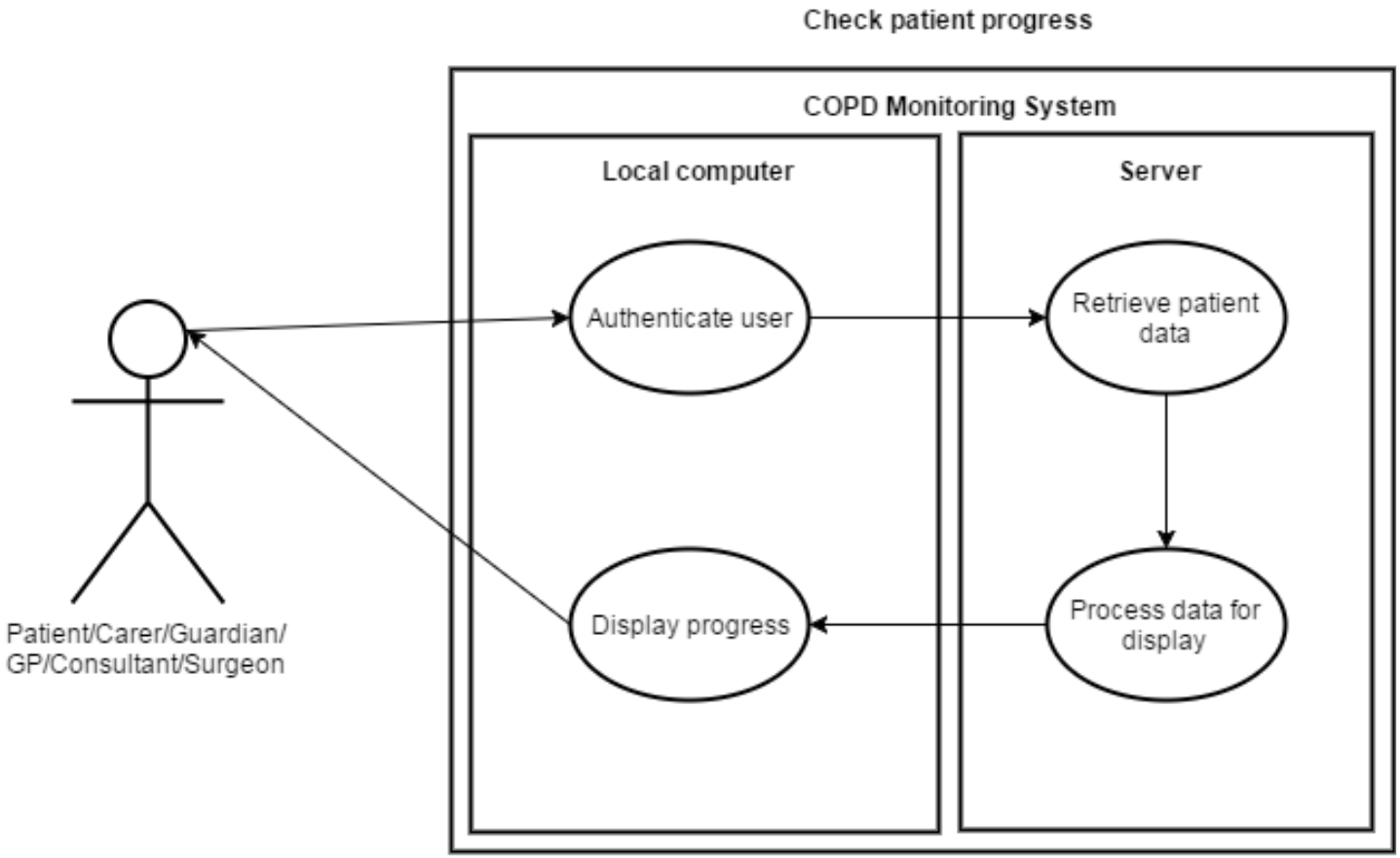
APPENDIX A: Stakeholder diagram



Appendix B: Use case diagrams




Medical feedback
COPD Monitoring System
Patient-side
GP-side
Alert patient
Display feedback
Input feedback
Patient/Carer/Guardian
GP
Local database
NHS Database


Check patient progress
COPD Monitoring System
Local computer
Server
Authenticate user
Retrieve patient data
Display progress
Process data for display
Patient/Carer/Guardian/
GP/Consultant/Surgeon

Appendix C: work domain analysis