LungHealth: COPD Clinical and Technical Risk Analysis

Document review

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Background

LungHealth guided consultation products, including COPD have been developed in an iterative manner from its conception of the idea, through to delivery of our current products. The final product has been developed by incorporating feedback from Respiratory Consultants, GPs, Practice Nurses, Commissioners of NHS Services, and any individual involved in delivering COPD care in today's NHS. We have also had significant input from key opinion leader boards and indeed market research from patients to ensure that our guided consultation products meet with NHS as well as patient approval.

The framework for review, is already in existence in the form GOLD/NICE guidelines for COPD, the challenge was translating these evidence-based guidelines into a product that would ensure that every COPD guideline received a review, which was bespoke to them and bespoke to their disease severity i.e. to ensure that all COPD patients received a guideline level review and personalised care.

Risk analysis

LungHealth recognised that as part of the process outlined above, both a comprehensive clinical and technical risk analysis were required to be completed prior to our products being used in a live environment with patients. The risk analysis was conducted by the LungHealth (LH) clinical team, which consisted of four Consultant Chest Physicians, supported by a team of ten Respiratory Nurse Advisors from National Services for Health Improvement Ltd. (NSHI) and associated GP's with a specialist interest in COPD.

Clinical risk analysis

The risk analysis was conducted based one the following assumptions:

1. ***Patients entering the LH COPD app. have a confirmed READ code diagnosis of COPD***
2. ***Healthcare professionals using the app. where deemed competent by the practice to review COPD patients, in the absence of the LungHealth app***.
3. ***The COPD product was to be used in primary care***

Purpose

The risk assessment was performed on the software to identify areas of the programme that represented any clinical risk to the patient, which included, but was not limited to:

- Diagnostic algorithms
- Algorithmic pathways
- Automated calculations
- Disease severity classification
- Drug interventions in line with guidelines including escalation/de-escalation of treatment
- Referral pathways
- Data read in from the GP clinical system (READ codes/SNOMED codes)
- Data written back to the GP clinical system from LungHealth (patient report and QoF update (READ CODES/SnowMed codes))

Approach

- All identified clinical risks were identified and subject to both logic and algorithmic review by a minimum of two respiratory consultants for each assessment. This included testing. In addition, user acceptance testing was conducted by Respiratory Nurse Specialists

- All identified clinical risks underwent consultant testing and user acceptance testing (UAT) following programming and prior to any new deployment to ensure the integrity of the whole COPD package utilising a unit testing methodology

As part of LungHealth's 'Change Request process' the same Data Protection Impact Assessment is carried out to determine the impact of the change on GDPR.

Scope

The Risk Assessment is intended to review a number of areas of distinct risk.

These include:

- Clinical risks to the patient when undergoing a COPD consultation
- Identified levels of risks to the integrity of the LungHealth Guided Consultation package and its data

With each risk assessment describing:

- The risk location within the package
- The identification of the risk
- The level of risk posed to the patient or program integrity if the risk is not mitigated / addressed
- Detail of possible Risk Avoidance measures that have been put in place
- The detail of any risk mitigation
- The testing of avoidance / mitigation solutions

1. COPD Risk Analysis

1.1. Clinical Risk Analysis

A summary of the LungHealth COPD risk analysis is shown below, with our testing documents available for review by registered users if requested.

In addition to the risk levels indicated below LungHealth have also conducted likelihood and residual risk rating (i.e. the rating post mitigation to show that the risk is controlled), which is available to LungHealth users upon request.

Please contact info@lunghealth.co.uk if you are a registered user and would like to review any of the testing documents in relation to specific 'Risk Descriptions'

Risk Location	Risk Description	Risk Level	Avoidance Measures	Mitigation	Testing / Verification	Notes
Diagnosis	The patient being staged at an incorrect level of COPD severity	High	The COPD module calculates the GOLD staging using the input	The result is displayed on screen and is subsequently used to guide the patient's level of	Clinical Lead Testing following Risk Analysis: [T-015]	Tested 6/8/20-22/8/20 Passed [T-015]

			Spirometry data.	treatment. If the COPD diagnosis is not confirmed the program exits and refers the patient for specialist review	Standard UAT Performed during Testing Phase of Developme nt cycle: [T-003], [T-005], [T-011]	
Diagnosis	The patient being misdiagnosed, with their lung function being normal	High	The COPD module calculates uses Spirometry data to determine lung function	Patients with Normal spirometry exit the program early (COPD ShowStopper)	Clinical Lead Testing following Risk Analysis: [T-015] Standard UAT Performed during Testing Phase of Developme nt cycle: [T-003], [T-005], [T-011]	Tested 6/8/20 Passed
Diagnosis	The patient being misdiagnosed, with their lung function indicating a Restrictive lung disease, rather than COPD	High	The COPD module calculates Spirometry data to determine lung function	Patients with Restrictive lung disease exit the program early (COPD ShowStopper)	Clinical Lead Testing following Risk Analysis: [T-015] Standard UAT Performed during Testing Phase of Developme nt cycle: [T-003], [T-005], [T-011]	Tested 6/8/20 Passed
Diagnosis	The patient being misdiagnosed, with Sub-maximal spirometry, but still indicating restrictive lung disease (without previous spirometry)	High	The COPD module calculates uses Spirometry data to determine lung function	Patients with Restrictive lung disease exit the program early (COPD ShowStopper)	Clinical Lead Testing following Risk Analysis: [T-015] Standard UAT Performed during Testing Phase of Developme nt cycle:	Tested 8/8/20 Passed

					[T-003], [T-005], [T-011]	
Diagnosis	The patient being misdiagnosed, with Spirometry indicating reversibility (Asthma)	High	The COPD module calculates uses Spirometry data to determine lung function	Patients with Reversibility exit the program early (COPD ShowStopper)	Clinical Lead Testing following Risk Analysis: [T-015] Standard UAT Performed during Testing Phase of Development cycle: [T-003], [T-005], [T-011]	Tested 7/8/20 Passed
Diagnosis	The patient continuing with a COPD review, despite no spirometry on the day (as contraindicated) or possible in the future, with no confirmatory history	High	The COPD module review's the patient's breathlessness, symptoms, and clinical history. If this is deemed acceptable the clinician is then requested to indicate their assessment of the patient. If the patient has no spirometry on the first review and there is no clinical evidence of COPD, the patient exits the program	Program will exit early with no breathlessness, or if the clinician indicates no history (COPD ShowStopper)	Clinical Lead Testing following Risk Analysis: [T-015] Standard UAT Performed during Testing Phase of Development cycle: [T-003], [T-005], [T-011]	Tested 7/8/20 Passed
Diagnosis	Patient is misdiagnosed, with Spirometry contraindicated	High	The COPD module review's the patient's breathlessness. If this is deemed acceptable the clinician is then requested to indicate their assessment of the patient. If the patient	Program will exit early with no breathlessness, or if the clinician indicates no history (COPD ShowStopper)	Clinical Lead Testing following Risk Analysis: [T-015] Standard UAT Performed during Testing Phase of Development cycle:	Tested 9/9/20 Passed

			has no spirometry on the first review and there is no clinical evidence of COPD, the patient exits the program		[T-003], [T-005], [T-011]	
Exacerbation	Patient is exacerbating at time of the initial review	High	The COPD module review's the patient's symptoms and prompts the clinician with any abnormal findings that indicate a current exacerbation.	Program will exit early when there are clear symptoms, or with partial symptoms following confirmation from the clinician (COPD ShowStopper This prompt exits the review, and the operator is invited to submit the patient for an "Exacerbation" consultation if they have previously successfully completed an "Initial Review"	Clinical Lead Testing following Risk Analysis: [T-015] Standard UAT Performed during Testing Phase of Development cycle: [T-003], [T-005], [T-011]	Tested Passed 11/9/20
BMI	The patient's weight may be a contributing factor in their breathlessness	Low	The patient's BMI is calculated	The presence of a high BMI contributing to breathlessness is alerted on the software. The presence of a low BMI is also alerted with appropriate dietary alerts	Clinical Lead Testing following Risk Analysis: [T-015] Standard UAT Performed during Testing Phase of Development cycle: [T-007], [T-012], [T-003], [T-014]	BMI Passed 12/9/20
ECG	Cardiac causes have not been ruled out as a reason for the patient's breathlessness at the time of the diagnosis	Medium	The COPD module reviews the patient's ECG status at the time of diagnosis	Appropriate prompts are included in the module, with alerts are pulled through to the reports. Abnormal ECGS	Clinical Lead Testing following Risk Analysis: [T-015]	ECG alert correctly pulled through in "Diagnostic Issues" and over to the

				are alerted through to the report.	Standard UAT Performed during Testing Phase of Development cycle: [T-007], [T-012],	patient report ECG prompt according to NICE guidance: Pass Tested BC Passed 14/8/2020
CXR	Other respiratory causes have not been ruled out as a reason for the patient's breathlessness at the time of the diagnosis	Medium	The COPD module reviews the patient's Chest X-Ray status at the time of diagnosis	Appropriate prompts are included in the module, with alerts are pulled through to the reports. Abnormal CXRs are alerted through to the report	Clinical Lead Testing following Risk Analysis: [T-015] Standard UAT Performed during Testing Phase of Development cycle: [T-007], [T-012],	CXR prompt according to NICE guidance: Pass Tested Passed 14/8/2020
Pulmonary Rehab Referral	Pulmonary rehab is an outpatient-based programme which aims to improve the function of people with long term respiratory disease, particularly COPD. The programme is provided by a multidisciplinary team of health care professionals in a hospital or community setting. It is vital that eligible patients be referred following a COPD review	Medium	The COPD module review's the patient's lung function to determine if the patient is eligible for PR referral	Appropriate prompts are included in the module, with the referral status pulled through to the reports	Clinical Lead Testing following Risk Analysis: [T-015] Standard UAT Performed during Testing Phase of Development cycle: [T-009]	Patient had not previously attended for pulmonary rehabilitation. Software correctly prompts operator whether patient should be referred, and information box displayed: Pass mMRC score 1; no pulmonary rehab referral prompt appears: PASS Tested Passed 14/8/2020

Oxygen Saturation	The patient might be suffering from Hypoxia (where the body or a region of the body is deprived of adequate oxygen supply at the tissue level)	High	The COPD module review's the patient's oxygen saturation level, and will display an alert should the patient be deemed to be hypoxic	Appropriate prompts are included in the module for an expected action to be taken by the clinician in the event that the patient is hypoxic. All data is pulled through to the patient reports. The presence of hypoxia and normal/disproportionate spirometry is also alerted	Clinical Lead Testing following Risk Analysis: [T-015] Standard UAT Performed during Testing Phase of Development cycle: [T-007]	Tested on 2 domains: <u>Mod COPD:</u> Hypoxia alert and pull through into report for investigation: PASS <u>Severe COPD:</u> Oxygen clinic prompt working: PASS Tested Passed 15/8/2020
Blood Pressure	The patient might be suffering from high or low blood pressure	High	The COPD module reviews the patient's Blood Pressure level, and will display an alert should the patient be deemed to have high or low bloody pressure	Appropriate prompts are included in the module for an expected action to be taken by the clinician in the event that the patient has high or low blood pressure. All data is pulled through to the patient reports	Clinical Lead Testing following Risk Analysis: [T-015] Standard UAT Performed during Testing Phase of Development cycle: [T-008], [T-013]	Calculation working correctly Tested Passed 14/8/2020
Pulse	Detection of Tachy -bradycardia. This abnormal heart rhythm problem is often seen in people who have been diagnosed with atrial fibrillation.	High	The COPD module reviews the patient's Pulse, and will display an alert should the patient be deemed to have a high or low pulse	Appropriate prompts are included in the module for an expected action to be taken by the clinician in the event that the patient has high or low pulse. All data is pulled through to the patient reports	Clinical Lead Testing following Risk Analysis: [T-015] Standard UAT Performed during Testing Phase of Development cycle:	Calculation working correctly Tested Passed 14/8/2020 Tested Passed 6/8/20

					[T-001], [T-007], [T-012]	
End of life referral	The patient's wishes and appropriate referrals are required when their COPD severity becomes very severe		The COPD module reviews the patient's FEV1 reading, with additional questions posed, and community referrals made	Appropriate prompts are included in the module for an expected action to be taken by the clinician in the event that the patient has severe COPD/previous NIV use. The end of life wishes, and referrals are pulled through to the patient reports	Clinical Lead Testing following Risk Analysis: [T-015] Standard UAT Performed during Testing Phase of Development cycle: [T-007]	This was correctly triggered when FEV1 dropped to "Very severe" threshold but not above (FEV1 29% predicted). Tested 14/8/2020 Passed
Smoking / Smoking Cessation Referral	Smoking is considered a primary cause of COPD within the patient population, therefore smoking cessation referrals are considered to be vital is slowing the rate of deterioration in COPD patients		The COPD module reviews the patient's smoking status – with the pack years calculated. The package prompts the clinician with further questions and a request to refer the patient to a smoking cessation course if they are considered to be smokers	Appropriate prompts are included in the module for an expected action to be taken by the clinician in the event that the patient is a current smoker. He patient's wishes and referrals are pulled through to the patient reports. An information box containing the key principles of smoking cessation. Furthermore, those patients with a minimal/no smoking history are highlighted as being atypical for a diagnosis of COPD	Clinical Lead Testing following Risk Analysis: [T-015] Standard UAT Performed during Testing Phase of Development cycle: [T-007], [T-006]	Pack year calculated correctly and patient current smoker: smoking cessation referral triggered: PASS 4 pack year history: THIS WAS ALERTED (Pass): less than 5 pack year alert triggered Tested Passed 14/8/2020
Age	The COPD package is designed for adults over the age of 18 only		Patients under 18 cannot be registered on the software		Clinical Lead Testing following Risk Analysis: [T-015]	TESTED 20/8/2020 Passed Have to be 18 to be registered on the software

Breathlessness	The patient could be misdiagnosed if a sudden onset of breathlessness is not investigated	High	An alert appears on screen at the time of the duration being entered	Appropriate prompts are included in the module for an expected action to be taken by the clinician in the event that the patient has a sudden onset if breathlessness. The alert and recorded action is pulled through to the patient reports.	Clinical Lead Testing following Risk Analysis: [T-015] Standard UAT Performed during Testing Phase of Development cycle: [T-001], [T-007], [T-012]	TESTED Passed 14/8/2020 Correctly pulled through to report
Cough	Misattribution of cause of cough i.e., wrong diagnosis	High	An alert appears on screen at the time of the duration being entered	Appropriate prompts are included in the module for an expected action to be taken by the clinician in the event that the cough is atypical. The alert and recorded action is pulled through to the patient reports	Clinical Lead Testing following Risk Analysis: [T-015] Standard UAT Performed during Testing Phase of Development cycle: [T-013]	New onset cough tested and working appropriately Tested Passed 15/8/20
Sputum	Missing alterative diagnosis such as an exacerbation or bronchiectasis could be missed	Low	Alerts for Consideration for other causes of sputum production	Appropriate prompts are included in the module for an expected action to be taken by the clinician in the event that bronchiectasis is suspected. The alert and recorded action is pulled through to the patient reports	Clinical Lead Testing following Risk Analysis: [T-015] Standard UAT Performed during Testing Phase of Development cycle: [T-013], [T-001], [T-007], [T-012]	Tested Passed 14/8/20 Alerts working. Included in the report
Haemoptysis	Missing alterative diagnosis if haemoptysis is ignored	High	Alert for further investigation e.g., CXR	Program will exit early if haemoptysis is recorded (COPD ShowStopper)	Clinical Lead Testing following Risk Analysis: [T-015] Standard UAT	Alerts working. Included in the report Tested Passed 14/8/20

					Performed during Testing Phase of Developme nt cycle: [T-013]	
Chest pain	Missing alterative diagnosis if new chest pain is ignored	High	Alert for further investigation e.g., CXR, ECG	Program will exit early when chest pain is recorded (COPD ShowStopper)	Clinical Lead Testing following Risk Analysis: [T-015] Standard UAT Performed during Testing Phase of Developme nt cycle: [T-013]	Tested Passed 14/8/20 Alerts working. Included in the report
mMRC	Necessary for phenotyping. An incorrect mMRC could lead to a wrong classification of severity	Medium	Some suggestive alerts exist if the level of mMRC seems to be inconsistent with the reported level of breathlessnes s.		Clinical Lead Testing following Risk Analysis: [T-015] Standard UAT Performed during Testing Phase of Developme nt cycle: [T-013]	Tested Passed 15/8/20 Programme will not proceed unless entered
CAT	Useful for phenotyping. An incorrect CAT could lead to a wrong classification of severity	Medium			Clinical Lead Testing following Risk Analysis: [T-015] Standard UAT Performed during Testing Phase of Developme nt cycle:	Tested Passed 15/08/20
Ankle oedema	May indicate Cor Pulmonale or left sided heart failure	High	Clinical Examination advised within the programme where appropriate.	Appropriate prompts are included in the module, with alerts are pulled through to the reports	Clinical Lead Testing following Risk Analysis: [T-015]	Tested Passed 14/8/20 Alert identified and pulled over into

			The COPD module reviews the patient's Clinical Examination status at the time of diagnosis		Standard UAT Performed during Testing Phase of Developme nt cycle: [T-013]	clinical examination
Past Medical History	Useful for management	Low	Alert at time of management decisions	Past medical history is carried through to the patient reports. This highlights any previous cardiac issues and links it to breathlessness hence improving diagnostic accuracy	Clinical Lead Testing following Risk Analysis: [T-015] Standard UAT Performed during Testing Phase of Developme nt cycle: [T-007]	Tested Passed 15/8/20 Alerts working. Included in the report
Allergies	Important in management if significant allergy Risk of anaphylaxis and death	High	Programme asks these are recorded. N.B also asked check GP system	Allergies are then carried to the medication review screen, and patient reports	Clinical Lead Testing following Risk Analysis: [T-015] Standard UAT Performed during Testing Phase of Developme nt cycle: [T-004], [T-008]	Tested Working Penicillin allergy/other allergies all tested Tested Passed 20/8/20 Passed
Recording COPD exacerbation related events	Necessary for phenotyping (Gold classification)	High	Programme asks these are recorded. i.e., antibiotic courses oral steroid courses AED attendance Admissions N.B also asked check GP system	Classification appears at the start of the patient reports	Clinical Lead Testing following Risk Analysis: [T-015]	Tested Passed 14/8/20 Prompts working Phenotyping working
Clinical Examination	A Clinical Examination should be	High	The COPD module reviews the	Appropriate prompts are included in the	Clinical Lead Testing following	Tested Working

	performed on all patients at the time of the COPD diagnosis, or where the patient's presentation warrants further examination. Not performing the Clinical Examination where appropriate could result in misdiagnosis.		patient's Clinical Examination status at the time of diagnosis. If the patient's presentation warrants a new Clinical Examination, then this is recommended on the day of the review	module, with alerts are pulled through to the reports. The recommendation for the clinical exam are followed up on subsequent visits	Risk Analysis: Clinical Lead Testing following Risk Analysis: [T-015] Standard UAT Performed during Testing Phase of Development cycle: [T-006]. [T-014]	All alerts correctly identified and pulled over to the report Tested Passed 20/8/20
Alpha 1 anti-trypsin	Missing deficiency	Low	Alert present in high-risk group	Alerts and current Alpha 1 anti-trypsin status are pulled through to the patient reports	Clinical Lead Testing following Risk Analysis: [T-015] Standard UAT Performed during Testing Phase of Development cycle:	Age related alert in the report Tested Passed
Inhaler technique	Poor Inhaler technique from the patient will result in ineffective therapy.	Medium	Alert to check, correct or change where appropriate	Alerts and current inhaler technique are pulled through to the patient reports	Clinical Lead Testing following Risk Analysis: [T-015] Standard UAT Performed during Testing Phase of Development cycle: [T-004], [T-008]	Tested Passed 22/8/20 Alerts working Included in report Tested Passed 20/8/20
Prescribing	Ineffective therapy Or contraindicated therapy	Medium	Prompt to guideline therapy Duplication not permitted Separate prescribing on the GP or other systems	Alerts working and are pulled through to the patient report	Clinical Lead Testing following Risk Analysis: [T-015] Standard UAT	Tested Passed 22/8/20

			is where changes happen		Performed during Testing Phase of Developme nt cycle: [T-007]	
Concordance	Poor concordance to prescribed medication from the patient will result in ineffective therapy.	Medium	Prompt to check, ratify from other systems and patient education	Prompts working correctly	Clinical Lead Testing following Risk Analysis: [T-015] Standard UAT Performed during Testing Phase of Developme nt cycle: [T-007]	Tested Passed 22/8/20
Personal action plan	If omitted, ineffective exacerbation management	Medium	Prompt to complete action plan on the day. Or amend the action plan if the current plan is deemed inappropriate. This includes rescue pack for severe patients. Only advanced planning on ceiling of care invited	Action plan details are pulled through to the reports and are available to be taken away by the patient on the day	Clinical Lead Testing following Risk Analysis: [T-015] Standard UAT Performed during Testing Phase of Developme nt cycle: [T-007]	Tested Passed 22/8/ (Including rescue pack)
Oxygen Clinic Referral	Worse outcome in selected patients if not referred for oxygen clinic referral	High	Prompt to refer eligible patients during the review	Referral details pulled through to the patient report. In subsequent reviews the results of the referral are discussed with the patient	Clinical Lead Testing following Risk Analysis: [T-015] Standard UAT Performed during Testing Phase of Developme nt cycle: [T-007]	Prompt to refer Tested Passed 15/8/20
Vaccination	Risk of more severe exacerbations/pne umonia/influenza	Medium	Patient vaccination records are recorded	Vaccination and possible referral details pulled	Clinical Lead Testing following	Prompt to refer Tested

			during the review, with alerts recommending referral for vaccination if not up to date	through to the patient report.	Risk Analysis: [T-015] Standard UAT Performed during Testing Phase of Development cycle: [T-007]	Passed 16/8/20
Disease Classification Gold NICE	Wrong management if incorrect	High	Classification allocated on verified collect data	Working Carries to the report	Clinical Lead Testing following Risk Analysis: [T-015] Standard UAT Performed during Testing Phase of Development cycle: [T-005]	TESTED Passed 14/8-22/8
Alert	Bronchiectasis is a long-term condition where the airways of the lungs become abnormally widened, leading to a build-up of excess mucus that can make the lungs more vulnerable to infection	Medium	Bronchiectasis can mimic COPD in terms of spirometry so distinction by clinical history is key	Appropriate prompts are included in the module for an expected action to be taken by the clinician in the event that bronchiectasis is suspected. The alert and recorded action is pulled through to the patient reports	Clinical Lead Testing following Risk Analysis: [T-015] Standard UAT Performed during Testing Phase of Development cycle: [T-007]	Tested Passed 15/8/20 16/8/20
Not a Smoker	Low Pack year history may indicate that the patient does not have COPD, which should be investigated by the clinician.	High	COPD is seldom found in never smokers and not to recognise this results in misdiagnosis.	Appropriate prompts are included in the module for an expected action to be taken by the clinician in the event that a low pack year number is recorded. The alert and recorded action is pulled	Clinical Lead Testing following Risk Analysis: [T-015] Standard UAT Performed during Testing Phase of Development cycle:	Tested Passed 15/8/20 Never smoked (Bronchiectasis 1)

				through to the patient reports	[T-001], [T-007], [T-012]	

1.2. IT Integrity Data Risk Analysis

This section outlines the identified levels of risks to the integrity of the LungHealth Guided Consultation package and its data - and the measures that have been put in place to avoid and/or mitigate such risks

1.2.1. Data Processing or Handling

The identified levels of risk as a result of system, communication and application errors or failures that may result in data being corrupted or lost - and the measures that have been put in place to avoid and/or mitigate such risks

Risk Location	Risk Description	Risk Level	Avoidance Measures	Mitigation
System	System Crash or local failure resulting in an unhandled error within the software	High	If an unhandled error occurs during a Guided Consultation the User is presented with an error screen with an option to attempt to reload the page	The error screen contains information explaining that the error has been logged, with information on how they may contact technical support and expected response times if the error persists. In addition, the Contact screen contains the same information The Patient record is maintained with the review left open for 24 hours. Following this, a new review must be started.
System	Complete System Crash or local failure resulting in an inability to complete the current review	High		If the error screen is displayed, this contains information explaining that the error has been logged, with information on how a User can contact LungHealth technical support and expected response times. In addition, the Contact screen contains the same information If a complete failure results in the User losing complete access to the LungHealth Consultation software; the Patient record is also maintained with the review left open for 24 hours. Following this, a new review must be started.
Hardware Failure	A hardware error at the data centre	High	The LungHealth Guided Consultation is a web-based	All server data (including patient data) is backed up by AIMES, the

	resulting in a loss of patient data		application hosted within the HSCN network, via our ISO 27001 certified hosting partner, AIMES Ltd. (https://aimes.uk/p-accreditation/) AIMES Organisation Code: 8J121 Onsite and offsite web server backups are performed nightly	LungHealth hosting supplier every 24 hours A continuity plan is in place with actions detailed in a Disaster Recovery plan in the result of any software downtime or data loss. The Disaster Recovery plan is tested annually.
Incorrect Patient Details	The wrong patient might be transferred to LungHealth	High	When integrating with external clinical systems LungHealth inverts the flow of control to the external Clinical System, where the Current Patient that is loaded within the clinical system is provided to LungHealth, rather than the LungHealth Guided Consultation software searching for a specific patient	
Patient Mismatch	The wrong patient might be matched at LungHealth	High	All patient matches must match by NHS Number, which acts as a unique identifier across all NHS systems	
Patient Medications	Miss-entry of patient's current prescription	High	The LungHealth software communicates with the local clinical system to pull down the patient's most recent demographics. An alert appears on the current medication screen advising the clinician to check the patient's prescription with the patient's clinical record and the patient themselves	Alerts exist to check for inconsistencies and unusual / not recommended drug combinations. Such alerts are carried through to the reports if not addressed.
Patient Data Processing Error	Previous historic patient data may be over-written when performing new reviews or viewing patient's	High	- Patient data is timestamped - Historic data (such as patient reviews) cannot be overwritten or re-opened for edit	IT Partnership working with EMIS / SystmOne to ensure data integrity during patient record writeback

1.2.2. Data Validation Control Risks

The identified levels of risk that may result in the input of poor or incomplete data - and the measures that have been put in place to avoid and/or mitigate such risks

Risk Location	Risk Description	Risk Level	Avoidance Measures	Mitigation	Testing / Verification	Notes
Diagnosis	The patient being staged at an incorrect level of COPD severity or completely misdiagnosed through the input of poor or incomplete Spirometry data	High	Input validation for Spirometry is in place for: • Height • FEV1 • FVC	A regular data analysis is performed on historic data to check the validity of Spirometry data	Clinical Lead Testing following Risk Analysis: [T-015] Standard UAT Performed during Testing Phase of Development cycle: [T-003], [T-014]	TESTED 14/8/2020 Passed
BMI	Incorrect BMI through incorrect data entry	Low	Input validation is in place for: • Height • Weight	A regular data analysis is performed on historic data to	Clinical Lead Testing following Risk Analysis: [T-015]	Tested (14/8/2020)

				check the validity of data	Standard UAT Performed during Testing Phase of Development cycle: [T-003], [T-014]	
Smoking	Incorrect pack years calculated	Low	Input validation is in place for: • Smoking years • Cigarettes per day	A regular data analysis is performed on historic data to check the validity of data	Clinical Lead Testing following Risk Analysis: [T-015] Standard UAT Performed during Testing Phase of Development cycle: [T-006], [T-007]	Pack year calculated correctly and patient current smoker: smoking cessation referral triggered: PASS 4 pack year history: THIS WAS ALERTED (Pass): less than 5 pack year alert triggered Tested (14/8/2020)
Oxygen Saturation	Patient inputs incorrect oxygen saturation. Inputs words or puts in a value greater than 100%	High	Input validation is in place for: • Oxygen saturation	A regular data analysis is performed on historic data to check the validity of data	Clinical Lead Testing following Risk Analysis: [T-015] Standard UAT Performed during Testing Phase of Development cycle: [T-008]	Tested on 2 domains: Mod COPD: Hypoxia alert and pull through into report for investigation: PASS Severe COPD: Oxygen clinic prompt working: PASS Tested BC 14/8/2020 Tested BC 14/8/2020
Blood Pressure	The patient inputs the wrong blood pressure. Inputs words or mixes the diastolic and systolic values around	High	Input validation is in place for: • Diastolic Blood Pressure • Systolic Blood Pressure	A regular data analysis is performed on historic data to check the validity of data	Clinical Lead Testing following Risk Analysis: [T-015] Standard UAT Performed during Testing Phase of Development cycle: [T-008]	Blood pressure calculation working correctly Tested BC 15/8/2020
mMRC	Necessary for phenotyping. An incorrect mMRC could lead to a wrong classification of severity	Medium	Necessary field. Programme will not proceed unless entered. Some suggestive alerts exist if the level of mMRC seems to eb inconsistent with the reported level of breathlessness. Clinician chooses from predefined values to improve data quality	A regular data analysis is performed on historic data to check the validity of data	Clinical Lead Testing following Risk Analysis: [T-015] Standard UAT Performed during Testing Phase of Development cycle: [T-013]	PASS Tested (14/8/2020)
CAT	The clinician may input a value that is	Medium	Input validation exists: • CAT Score	A regular data analysis is performed	Clinical Lead Testing following Risk Analysis:	**Tested PASS 6/8/20**

	not in the usual CAT score range			on historic data to check the validity of data	[T-015] Standard UAT Performed during Testing Phase of Development cycle: [T-013]	
Pulse	The clinician may input a value that one would consider too high for any pulse value. Or input words.	**High**	Input validation is in place for: • Pulse	A regular data analysis is performed on historic data to check the validity of data	Clinical Lead Testing following Risk Analysis: [T-015]	**Tested PASS 6/8/20**

1.2.3. System Updates / Data Changes

The identified levels of risk as a result of system changes or system updates

Risk Location	Risk Description	Risk Level	Avoidance Measures	Mitigation
Process	System errors introduced due to unplanned system or data updates performed by the developer	High	Change request process is in place with a 2-step sign-off process is in place for all system changes	System data backups are performed nightly to roll back any erroneous changes Onsite and offsite web server backups are performed nightly, performed by AIMES UK
Process	System errors introduced due to planned system or data updates performed by the developer	High	Multi-phased Test process is in place, which requires a clinical lead, and a separate clinical tester to test each change within a planned change	System data backup is performed nightly to roll-back any erroneous changes Onsite and offsite web server backups are performed nightly, performed by AIMES UK
Process	Clinical errors introduced following a planned system or data update	High	A specification is developed and signed off by the clinical lead before any planned development.	Following development changes, the testing documentation and process flows are updated and signed off by the clinical lead following clinical updates

1.2.4. System Data & Security Risks

The identified levels of risk as a result of malicious actions

In addition to the specific avoidance and mitigation measures listed below, LungHealth also routinely maintains the following commitments:

- LungHealth Ltd maintains a commitment to the NHS Data Security and Protection Toolkit and the standards maintained within it
  - Organisation Code: 8K653
- LungHealth Ltd has Cyber Essentials accreditation
  - ASME-CE-019796
- LungHealth undertakes a regular PEN test, performed by BSI Group [R10]

- LungHealth maintains a commitment to training all people within the organisation with access to personal data with appropriate data security and protection, and cyber security, training every year
    - LungHealth employees are granted continuous access to the e-LfH training database for all its training requirements.

Risk Location	Risk Description	Risk Level	Avoidance Measures	Mitigation
Access	Loss or editing of data due to unauthorised access	High	User access is controlled by access roles within the application. User Role access is tested as part of LungHealth's annual PEN Test, performed by BSI Group Healthcare professionals using the app. are deemed competent by the practice to review COPD patients, and understand that in the event of failure that they can revert to a paper / manual process in the absence of LungHealth All LungHealth staff complete mandatory data security training as part of their GDPR training suite.	Onsite and offsite web server backups are performed nightly. Server Backups are performed by AIMES UK. A continuity plan is in place with actions detailed in a Disaster Recovery plan in the result of any software downtime or data loss. The Disaster Recovery plan is tested annually.
Availability	Loss of access due malicious actions	High	LungHealth undertakes an annual PEN test of its Guided Consultation software to ensure it is protected and not susceptible to common security vulnerabilities, such as described in the top ten Open Web Application Security Project (OWASP) vulnerabilities. LungHealth's annual PEN Test is performed by BSI Group Healthcare professionals using the app. are deemed competent by the practice to review COPD patients, and understand that in the event of failure that they can revert to a paper / manual process in the absence of LungHealth Within LungHealth's server: All traffic passing through LungHealth Ltd. firewalls – whether internally from one network to another or externally to and from the Internet – is monitored. However only critical, error and warnings are logged (i.e., all traffic that is denied access). A Network monitoring tool is used to analyse traffic on LungHealth Ltd. systems. This provides LungHealth Ltd. system administrators with data about current levels of network utilisation, which can assist with diagnosing network problems and may provide information about potential security problems.	A continuity plan is in place to respond to threats to data security, including significant data breaches or near misses, and it is tested once a year as a minimum. LungHealth's business continuity plan covers both data and cyber security. Onsite and offsite web server backups are performed nightly. Server Backups are performed by AIMES UK. A continuity plan is in place with actions detailed in a Disaster Recovery plan in the result of any software downtime or data loss. The Disaster Recovery plan is tested annually.

LungHealth maintain the following documents, and SOPs which relate to our overall risk assessment and these documents are available to LungHealth users upon request.

Please contact info@lunghealth.co.uk if you are a registered user and would like to review any of the documents highlighted below.

#	Document Descriptor	Document Title
R1	Data Protection Impact Assessment - LungHealth	2020-08-19 Data Protection Impact Assessment - LungHealth v1.docx
R2	Change Request SOP	2020-08-14 - Change Request SOP process - v1.1.docx
R3	Bug Reporting SOP	2020-08-12 - Bug Reporting SOP process - v1.docx
R4	Testing Specification LungHealth Template Document	2020-08 - Testing Specification LungHealth Template 08-20.docx
R5	Technical Specification LungHealth Template Document	2020-08 - Technical Specification LungHealth Template 08-20
R6	LungHealth Disaster Recovery & IT Continuity SOP Document	LungHealth Disaster Recovery & IT Continuity SOP v1.docx
R7	LungHealth Data Quality Management Policy - v2.0 November 2020 Document	LungHealth Data Quality Management Policy - v2.0 November 2020.docx
R8	Technical support SOP process Document	2019-09-04 - Technical support SOP process - v3.docx
R9	LungHealth Guided Consultation Server Overview Document	LungHealth Guided Consultation Server Overview v1.docx
R10	PEN Testing Report, BSI	CSIRUKPRJ-1181-RPT-01 LungHealth Limited Summary of Findings v1.0.xlsx CSIRUKPRJ-1181-RPT-01 LungHealth Limited Web Application Test Report v1.0.pdf
R11	LungHealth Software Architecture Document	LungHealth Software Architecture Overview v1.docx

Summary

LungHealth are committed to ensuring that our product development is clinically led. Our products are robustly tested through both a formal risk assessment process and robust testing process by experts in the respiratory field prior to deployment.

LungHealth continuously refine our products based on user feedback and changes to NHS requirements in relation to the management of patients with COPD.