Performance Study Protocol – NGPOD®

Scientific Title	Clinical investigation of the NGPOD®, a novel medical device, compared to current NHS Trust practice to confirm the correct placement of nasogastric tubes prior to the administration of liquids. The study will include checks made after the first insertion of the nasogastric tube, as well as repeat testing immediately before the administration of liquids.
Public/ Short Title	NGPOD® pH test compared to current NHS Trust practice to determine Nasogastric Tube (NGT) position.
HRA conformance	This protocol has regard for the HRA guidance and order of content, adapted for a non-randomised medical device study.
Research Reference Numbers	TBC
IRAS Number	217641
Protocol Version (Date)	V0.4 (04.06.19)
Trial Registry	Not required – not Trial – Diagnostic Device Performance Comparator Study (none randomised) ISRCTN14985496 https://doi.org/10.1186/ISRCTN14985496
Sources of monetary or material support	Sponsor funded.
Primary Sponsor	NGPOD® Global Limited.
Primary Sponsors Number	Company registration number 078794414
Manufacturer	NGPOD® Global Limited
Countries of Recruitment	England, UK
Health Condition Studied	Correct placement of Nasogastric tube (NGT) in stomach.
Interventions	This study involves the use of NGPOD®, a novel device attached to a fibre optic sensor that gives an intuitive and clear result to confirm the correct placement of a nasogastric tube in the stomach. The device measures the pH at the tip of the nasogastric tube. The study will compare the use of this device with current standard practice to determine if the device is as reliable, effective and accurate as the testing of pH aspirate with pH strips (Universal indicator paper). In addition, the study will determine if there is a **potential** reduction in practice subsequent to the study in the number of X-rays taken to check correct NG tube placement, reducing the risk to patients' of repeated exposure to X-rays. According to national guidelines the NGT is confirmed on initial insertion and before each treatment with nutrition, hydration or medication. Testing before treatment is known as "repeat testing" also known as reconfirmation testing. In this study NGPOD® results **will not** be used to confirm correct placement of the NG tube in order to start nutrition, hydration or medication. Administration of liquids through the NGT will only commence after correct placement of the NGT has been checked using clinically approved Hospital Trust guidelines.

Key Inclusion and exclusion criteria	**Inclusion** – All adults over the age of 18 who require a NGT as part of their treatment. Patients who are unable to give written or verbal consent because of their medical condition will be assessed, and their legal representative or consultee will be asked to indicate the patient's wishes regarding participation. Exclusion – All patients who have undergone oesophageal gastro-intestinal surgery within the last 3 months; all patients who have partial or total gastrectomy; patients with bleeding gastric and/or duodenal ulcers; patients with gastric cancer; those with oesophageal varices; those considered by their medical team to be inappropriate (e.g. at the end of life); patients who are un-befriended and lack the capacity to give informed consent.
Study type	A diagnostic accuracy study (non-randomised) comparing NGPOD® to the current practice of checking NGT tube placement by testing aspirate against universal indicator paper, and if this is inconclusive by chest X-ray.
Date of first enrolment	Recruitment of patients with capacity commenced 10.05.19 Enrolment of patients lacking capacity to give consent will be as soon as granted by REC and HRA.
Target Sample Size	**At each site:** 100 initial nasogastric tube insertion checks and 300 repeat nasogastric tube checks prior to nutrition, hydration or medication. Any further sites will be added by IRAS amendment.
Recruitment Status	Pending
Primary and Secondary Outcome Measures	Primary outcome measure: • 1.) To establish if NGPOD® is as reliable in establishing the position of a NGT as current methods on both initial insertion and repeat testing. Secondary outcome measures: • 2.) To find out if the use of NGPOD® will reduce the requirement for confirmatory X-rays compared to current first line testing of a pH change using aspirate and universal pH indicator paper. If the NGPOD® system is able to confirm placement more frequently than the current front-line method of aspiration, then there is an opportunity to reduce the number of patients requiring an X-ray. • 3.) To find out if the use of NGPOD® will reduce delays to patients receiving nutrition, hydration or medication compared to current testing using the aspirate and universal indicator pH paper test, and if this is inconclusive an X-ray check of tube placement. As above, in the event that the NGPOD® test is more reliable than the current front-line method of testing, then the number of patients requiring X-ray will be reduced. The normal delay between placing a tube and nutrition, hydration and/or medication being administered will also be reduced.

Signature Page

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the MHRA Medical Devices Regulations 2002, GCP guidelines, the Sponsor's SOPs, and other regulatory requirements as amended.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:
Signature: Date:
……/……/……

……
Name (please print): Mr Stephen Thorpe

……
Position: Chief Executive Officer, NGPOD® Global Limited.

Chief Investigator:
Signature: Date:
……/……/……

……
Name: (please print): Tracy Earley

……
Position: Consultant Nurse – Nutrition, Lancashire Teaching Hospitals NHS Foundation Trust.

Statistician:
Signature: Date:
……/……/……

……
Name: (please print):

……
Position: Qualified Statistician at JB Medical Ltd
Qualifications:

Study Summary

Study Title	Clinical investigation of a NGPOD®, a novel medical device, compared to current NHS Trust practice to confirm the correct placement of nasogastric tubes prior to the administration of nutrition, hydration and/or medication. The study will include checks made after the first insertion of the nasogastric tube, as well as repeat testing immediately before the administration of liquids.	
Internal ref. no. (or short title)	NGPOD® pH test compared to current NHS Trust practice to determine Nasogastric Tube (NGT) position.	
Clinical Phase	NA – Diagnostic medical device study.	
Study Design	Diagnostic Accuracy Study (Performance Comparator Study).	
Study Participants	All adults over the age of 18 who require a NGT as part of their treatment. See exclusion criteria.	
Target Sample Size	**At each site:** 100 initial nasogastric tube insertion checks and 300 repeat nasogastric tube checks prior to nutrition, hydration or medication. Any further sites will be added by IRAS amendment.	
Participant duration (timings approximate)	**Initial insertion of NGT:** 1 hour 5 minutes at patient bedside, for initial insertion of NGT (including consent, tube insertion and testing by two methods): • Verbal consent or consultee consent for NGT 10mins. • Written consent or consultee consent for NGPOD® 10mins • Insertion of NGT 20 minutes • NGPOD® test 5 minutes • Confirmation of NGT placement using aspirate and universal indicator paper 20minutes. • If aspirate unsuccessful in confirmation of correct placement then follow-up X-ray either in patient bed area or in radiology department. Time depends on hospital schedules. **Repeat check of NGT position:** • NGPOD test 5 minutes • Confirmation by aspirate and universal indicator paper 20 minutes	
Follow up duration	No follow up is required.	
Planned Study Period	1 year	
	Objectives	**Outcome Measures**
Primary	1.) To establish if NGPOD® is as reliable in establishing the position of a NGT as current methods on both initial insertion and repeat testing.	1.) If the NGPOD® is demonstrated to be as reliable as the current methods of checking NGT placement, by aspirating stomach content and testing with universal indicator paper, it will: reduce the time to test; eliminate the need to aspirate; eliminate the need to use confirmatory chest X-rays if inconclusive aspirate and pH test. This

		will reduce time and cost to check NGT placement, and aim to make administration of nutrition, hydration and/or medication by NGT a safer procedure.
Secondary	2.) To find out if the use of NGPOD® will reduce the requirement for confirmatory X-rays. 3.) To find out if the use of NGPOD® will reduce delays to patients receiving nutrition, hydration or medication compared to current testing.	2.) If the NGPOD® system is able to confirm placement more frequently than the current front-line method of aspiration, then there is a potential reduction in the number of patients requiring an X-ray. This would save time, cost and the risks associated with exposure to ionizing radiation. 3.) In the event the NGPOD® test is more reliable than the current front-line method of testing, then the number of patients requiring X-ray will be reduced. The time taken for X-ray confirmation can be 20 mins to 2 days, depending on work flow in Radiography. Therefore nutrition, hydration and/or medication through the NGT may be delayed. This means less than optimal patient care, and has the potential to delay recovery. 4.) Recording PPI dose, time and route of administration will demonstrate if NGPOD® has improved sensitivity compared to aspiration of stomach content and testing with universal indicator paper.
Investigational Medical Device	NGPOD® plus NGPOD® sensor	
Device Usage	The NGPOD® system consists of a single use fibre optic sensor (NGPOD® sensor) and a small handheld light source and detector (NGPOD®). The fibre optic sensor is fully inserted down a placed NGT. The sensor is then connected to the handheld NGPOD® and a test button is pressed. The NGPOD® returns a Green tick or a Red cross based on the pH level at the tip of the sensor. The sensor can then be removed from the NGT and discarded.	

Funding

FUNDER	**FINANCIAL AND NON FINANCIAL SUPPORT GIVEN**
NGPOD® Global Ltd	NA

Key Study Contacts

Chief Investigator	Tracy Earley Consultant Nurse in Nutrition Lancashire Teaching Hospitals NHS Foundation Trust, Royal Preston Hospital Sharoe Green Lane Fulwood Preston PR2 9HT Phone: 01772 523 057 E mail: tracy.earley@lthtr.nhs.uk
Principal Investigator	To be appointed – will be the main investigator at other sites.
Study Co-ordinator	Rosemary Howell – NGPOD® Global Ltd.
Primary Sponsor	Mr Stephen Thorpe, CEO, NGPOD®Global Limited, I – TAC, BIO 17 Keckwick Lane Daresbury Laboratory Sci – Tech Daresbury Cheshire WA4 4AD Phone: 07500 047 676 E mail: sthorpe@ngpodglobal.com
Device Manufacturer	Mr Stephen Thorpe, CEO, NG Pod Global Limited, I – TAC, BIO 17 Keckwick Lane Daresbury Laboratory Sci – Tech Daresbury Cheshire WA4 4AD Phone: 07500 047 676 E mail: sthorpe@ngpodglobal.com
Funder(s)	NGPOD® Global Limited.
Clinical Trials Unit	NA Centre for Health Research and Innovation NIHR Lancashire Clinical Research Facility Lancashire Teaching Hospitals NHS Foundation Trust
Key Protocol Contributors	Tracy Earley, Adam Partington, Rosemary Howell, Paul Brown
Statistician	Provided JB Medical Ltd.
Trials pharmacist	NA
Committees	No formal committees. Study co-ordination team – Tracy Earley, Paul Brown, Rosemary Howell

Role of Study Sponsors and Funder

NGPOD® Global is both the sponsor and sole funder of this clinical study.

Research Title: Clinical investigation of a NGPOD®, a novel medical device, compared to current NHS Trust practice to confirm the correct placement of nasogastric tubes prior to the administration of nutrition, hydration and/or medication.

The study will include checks made after the first insertion of the nasogastric tube, as well as repeat testing immediately before the administration of liquids.

Chief Investigator: Tracy Earley Consultant Nurse - Nutrition

Contracting Organisation: Lancashire Teaching Hospitals NHS Foundation Trust (LTHTR).

Lancashire Teaching Hospitals NHS Foundation Trust has been subcontracted to conduct the clinical study by NGPOD® Global Limited.

Legal liability in respect of the device is provided by NGPOD® Global Limited Ltd.

Lancashire Teaching Hospitals NHS Foundation Trust is subcontracted by NGPOD® Global Limited Ltd to design, conduct, analyse outcome measures and write up the results of the study.

The study was designed by Tracy Earley, Paul Brown, (Lancashire Teaching Hospitals NHS Foundation Trust), statistician at JB Medical Ltd, Adam Partington and Rosemary Howell (NGPOD® Global Limited). Rosemary Howell is providing interim management services as contractor to NGPOD® Global Ltd for the duration of the study.

Tracy Earley and Paul Brown are responsible for the conduct of the study.

NGPOD® Global Limited Ltd as the device manufacturer is responsible for supply, operation, training and on-going support of the medical device for the duration of the study. NGPOD® Global Limited Ltd is the named manufacturer in respect of conformity to MHRA requirements for the provision and use of non-CE marked devices and for fulfilment of adverse event reporting responsibilities.

During this study, results obtained using NGPOD® will **not** be used to confirm the correct placement of the nasogastric tube. Correct nasogastric tube placement will be confirmed by the current methods of a pH change with universal indicator paper, and if this is inconclusive chest X-ray.

Protocol Contributors

This protocol was developed by Tracy Earley, Paul Brown, Adam Partington and Rosemary Howell. Statistical requirements were detailed by statistician at JB Medical Ltd. Peer review and comment was provided Alison Young, Consultant Nurse, Nutrition.

The scope and content of the study was developed Tracy Earley and Adam Partington, with latter input from Rosemary Howell. The final design was agreed with Stephen Thorpe, Adam Partington and Rosemary Howell on behalf of NGPOD® Global Limited Ltd and Tracy Earley and Paul Brown at Lancashire Teaching Hospital NHS Foundation Trust.

Version 0.1 of the protocol was peer reviewed by Ms Alison Young, Consultant Nurse in Nutrition at Royal Liverpool and Broadgreen University Hospital NHS Trust, Department of Gastroenterology. The protocol has been adapted by comments from Alison Young.

Role of Study Management Committees/Groups and Individuals

This is a diagnostic comparator study of a class I medical device, it does not involve randomisation of patients to control groups. The device is classified as having a low level of risk. All clinical diagnoses will be made solely using the existing local protocols to check NG tube placement. It has been agreed that a trial steering committee is not required for its safe and ethical conduct.

The study co-ordination team of Tracy Earley, Paul Brown, and Rosemary Howell will review the study weekly by phone or e mail with a more detailed review every month. The monthly meeting may be by phone, e mail or face to face.

The Chief Investigator will be responsible for the day-to-day conduct and management of the study along with an assigned manufacturers study representative (Rosemary Howell) for NGPOD® Global Limited Ltd.

Lancashire Teaching Hospitals NHS Foundation Trust Chief Investigator will provide routine oversight of the conduct and management of the study, with the NGPOD® Global Limited Ltd CEO providing oversight of the manufacturers role.

Key Words

NGPOD® Fibre-Optic Feeding Tube Position Confirmation Device; NGPOD® device; NGPOD® Sensor; NGPOD® Global Limited; Clinical Nutrition; nasogastric tube placement; chest X-ray; pH aspirate; Diagnostic Accuracy Study; Performance Comparator Study; enteral feeding; parenteral feeding.

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List of Abbreviations

NGT	Nasogastric tube
CXR	Chest X-ray
CRN	Clinical Research Network
DMC	Data Monitoring Committee
NIHR	National Institute for Health Research
CI	Chief Investigator
PI	Principal Investigator
CRF	Case Report Form
PIS	Patient Information Sheet
SOP	Standard Operating Procedure
LTHR	Lancashire Teaching Hospitals NHS Foundation Trust
NHS	National Health Service
CEO	Chief Executive Officer
Ltd	Limited company
REC	Research Ethics Committee
Hrs	hours
Mins	minutes

1 Background

Use of misplaced nasogastric tubes (NGT) was first recognised as a patient safety issue by the National Patient Safety Agency (NPSA) in 2005[1] and three further alerts were issued by the NPSA and NHS England between 2011 and 2013. Introducing fluids or medication into the respiratory tract or pleura through a misplaced NGT is considered a "Never Event" by NHS England. Never Events" are considered preventable but the current methods for determining correct placement of NGT are open to clinical interpretation.

The existing NPSA safety guideline recommends testing the pH of NGT aspirate. Feeding is considered safe if a pH of 5.5 or lower has been observed; otherwise chest X-rays are recommended [2].

Most NGTs placed in the UK are inserted "blind" i.e. the inserting method does not use a form of visualisation to establish that they are in the correct position prior to use.

Current NPSA guidelines recommend that pH testing of aspirate obtained from the NGT is the first-line method of confirmation. This can be a difficult procedure with success in obtaining aspirate ranging from 55%[4] to 80% of cases[3]. Where aspirate is obtained, a variety of human factors can affect the accuracy of the interpretation of the result. Inability to obtain aspirate combined with interpretation and human factors often results in patients being sent for X-ray to determine NGT position. An NHSI Level 2 Alert July 2016 identified misinterpretation of X-ray as the root cause of 45% of NGT related "Never Events" in the preceding 12 months.

The administration of nutrition, hydration and medications via NGT is a commonplace and a vital part of the treatment of many conditions experienced by both adults and children. Approximately 1 million NGTs are used in the UK NHS each year. The use of a misplaced NGT is associated with significant increase in morbidity and mortality and is currently classified as a "Never Event" by NHS England.

Significant contributing factors to these Never Events are;

- **Inability to utilise bedside testing:** The recommended 1st line test method of pH testing aspirate from a NGT due to the difficulty in obtaining the aspirate leading to the requirement for X-ray.

- **Misinterpretation of X-ray:** This was identified as the root cause of 45% of Never Events in the year to the end March 2016[5]. X-rays are also expensive, time consuming as well as potentially harmful to patients who have repeated exposure.

The difficulty and delay caused by the above two methods also means that nutrition, hydration and medication are often delayed contributing to slower recovery or deterioration in a patient's condition.

There are also significant human factors that come into play if aspirate is obtained, for example having visual acuity to interpret the result of a pH test successfully. Visual interpretation depends on suitable lighting conditions, which may be low at night time, as well as a heavily coloured aspirate making colour comparison difficult or impossible.

NGPOD® has been designed to help the correct location of the NGT in the stomach. It does not require material to be aspirated from the stomach and has the following benefits for the patient, clinician and NHS:

Improved patient experience

- Reduction in the number of never events
- Reduction in X- Ray exposure
- Reduction in delay of nutrition, hydration, medication

Improved clinician experience

- Removal of interpretation
- Reduction in exposure to bodily fluids
- Improvement in time and efficiency

Benefits for the NHS

- Reduction in cost associated with X-rays (at the time of writing £70 - £100)
- Reduction in overall length of stay
- Reduction in readmissions to reconfirm NGT placement (if patient is being cared for outside secondary care).

1.1 NGPOD® Device description and application

Full instructions for use will be provided to all NHS staff participating in the clinical study. Training in the use of NGPOD® will be given before the start of the study.

The NGPOD® is a device to assist in position confirmation of a NG tube and consists of a re-usable, portable handheld detection device and a single use fibre-optic Sensor tipped with a pH indicator.

It has been designed to be an alternative to conventional feeding tube position confirmation tests, delivering a visual indication of the pH environment of the NG tube tip. The result is a YES/NO indication reducing the risk of clinical interpretation error.

The Sensor attaches to the NGPOD® to supply visible spectrum light energy for the software-controlled detection of the colour change in the pH indicator in an acidic environment.

The NGPOD® and Sensor can only be used together and are intended to aid in the correct placement of NG tubes by detecting the pH value through the colour change in the pH indicator.

It is important to ensure the correct size Sensor is used for the NG tube. The Sensor packaging clearly indicates the length and size of NG tube with which it is compatible.

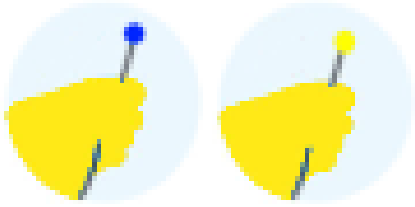
As the consequences of feeding tube misplacement can be very serious, the quick, clear indication delivered by the NGPOD® can facilitate safer and more efficient NG placement in the clinical environment.

This device is fully compliant with NPSA (National Patient Safety Agency) feeding tube positioning confirmation guidelines.

1.2 Intended Use

NGPOD® is intended to be used by persons who are trained in its use, for patients requiring enteral nutrition/medication via an NG tubes in the hospital or homecare environment. The NGPOD® is designed to be used with the specific Sensor referred to in the Sensor description section of this document.

Before use, on visual inspection of the sensor tip should be blue. If the tip of the sensor is yellow, it must not be used.



Use **Don't Use**

The tip of the sensor must not be touched before inserting into the NG tube as it will potentially contaminate the reagent.

1.3 NGPOD® features

Figure 1. NGPOD® features.

	Feature	Description
1.	Self-test cap	Protects internal mechanisms. Remove cap to insert sensor into the NGPOD™.
2.	Lock/Unlock markings	To guide the locking and unlocking of the cap to NGPOD™.
3.	Green Tick and Red Cross pH status indicators	Displays test result: Green indicates pH reference in range Red indicates pH reference out of range
4.	Ph Test button	Press to start pH test
5.	LED indicator light	Flashing amber light indicates NGPOD™ is in a ready state for pH testing.
6.	Tether	Attaches the NGPOD™ cap to the body
7.	Power on/off button	Powers the NGPOD™ on and off.

Table 1. NGPOD® features and description

1.4 Sensor features

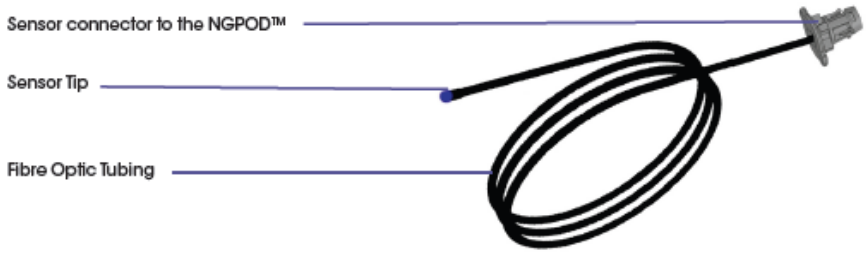


Figure 2. NGPOD® sensor.

Sensors are available in varying lengths: 75 cm, 92 cm and 125 cm.

Sensor length will be dependent on the nasogastric tube that the sensor will be inserted into.

Sensor packaging lists compatible nasogastric tubes.

1.5 Frequency of NPOD® and sensor testing

Local NHS Hospital guidance will indicate the frequency and circumstances of pH checks which can include:

- Following initial insertion
- Before adminstering nutrition and/or hydration
- Before administering medication
- Once daily check if on continuous feeds
- Following episodes of vomiting, retching or coughing.

If NGPOD® testing is inconclusive then the clinical staff may order a chest X-ray to check the correct placement of the NGT.

Illustrations of chest X-ray for correct and incorrect NGT placement.

Anatomical features of chest X-ray

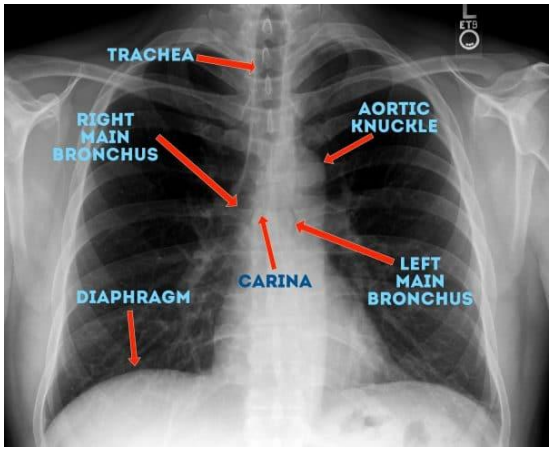


Figure 3. Anatomical features of chest X-ray.

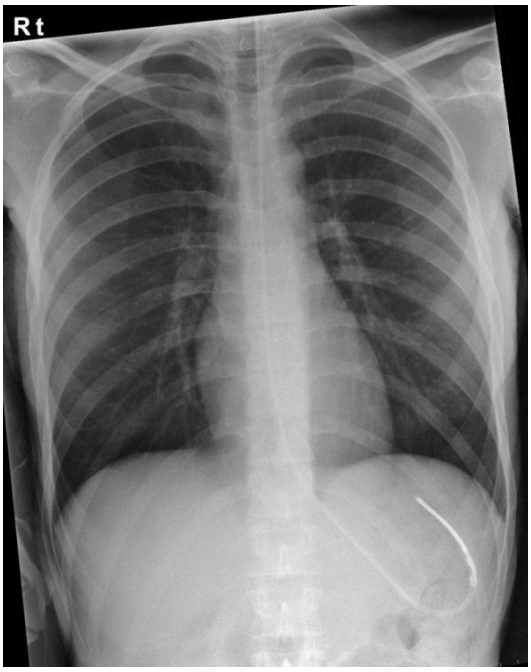


Figure 4.

CXR demonstrating correct placement of NGT in stomach.

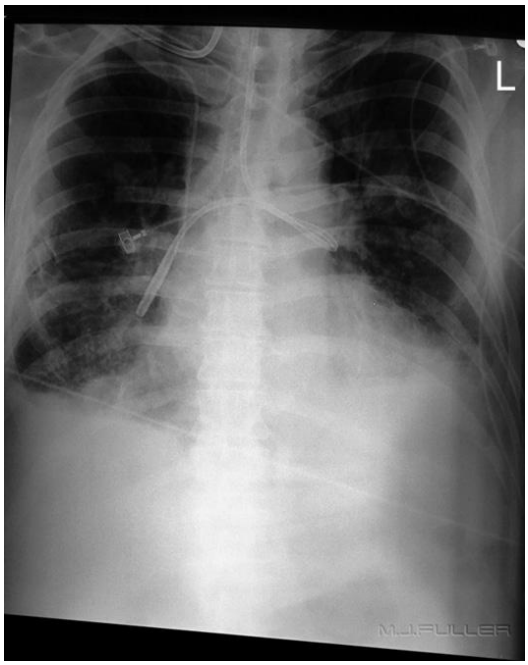


Figure 5.

CXR demonstrating incorrect placement of NGT in right main bronchus.

1.6 Regulatory status of NGPOD®

The device has had a previous CE mark (Class 1 Sterile Device), but the product was not launched in the UK.

The device requires recertification after a change in the company's structure and minor modifications to the design of the device. The previous version of the device received a CE mark on the 11th April 2015 (certificate number LRQ 4009279). Since that date the device has been modified and a further CE mark application made.

CE mark, for the modified device was granted on 21st March 2019, certificate number LRQ 00002239B

NGPOD® Global started recruitment as soon as HRA and REC approval was granted on Friday 10th May 2019. Recruitment selected patients with the capacity to give informed consent.

2 Rationale

The study aims to compare a new fibreoptic device, NGPOD® which gives an unambiguous result of the pH of the environment at the tip of the NGT. The study will compare use of the device with current standard practice to determine if the device is at least as reliable as testing of pH aspirate. The study will also investigate if NGPOD® is able to determine NGT placement in the stomach more often which would reduce the requirement for chest X-rays. Frequent

exposure to ionizing radiation is considered harmful, so exposure is actively reduced in the NHS.

In many patients it can be difficult or impossible to withdraw sufficient aspirate to perform confirmatory pH testing. The lumen volume of a 12 French gauge NGT is approximately 3.5mls, so in excess of 3.5mls of stomach aspirate is required to perform current confirmatory procedures.

Should the NGPOD® system perform as expected, its use should reduce the need for X-rays thus decrease the risk to patients and cost to the NHS. Risks will be further reduced by replacing the need to interpret the results of pH aspirate testing with a clear YES/NO indicator that the pH is either above or below pH 5.5 which is the recommended level for ascertaining the position of a NGT. This will provide a significant increase in patient safety.

For many patients where it is difficult and time consuming to withdraw sufficient aspirate to test using universal pH paper, the procedure is uncomfortable, distressing, the administration of liquids and medication can be delayed for hours, and ultimately return to health may be delayed because of inadequate nutrition. Where multiple X-rays need to be taken to confirm NGT position there is a consequent increased exposure to ionizing radiation.

This research study of NGPOD® aims to determine if use will improve the quality and outcome of a currently performed procedure reducing the need to X-ray and delay the administration of liquids.

This study may also ultimately help more patients to be successfully cared for in the community, and reduce the need to admit to hospital for a chest X-ray. This should be more preferable for patients and again help to reduce cost.

This study will gather data when the NG tube is inserted (known as initial insertion), and when the position of the NG tube is checked prior to administration of liquids, (known as repeat testing).

The repeat testing cohort is further subdivided in to those who are on continuous enteral nutrition, and those who are on bolus nutrition.

2.1 Defining selection criteria:

After the “initial insertion” of the NG tube and “repeat testing” to confirm NG tube position, there are two patient groups where it is important to gather product performance data from:

1. Patients on cyclical or bolus feeding
2. Patients on continuous 24 hour feeding

Patients who are being cyclically or bolus fed tend to be on the general hospital wards.

Patients who are on continuous 24 hour feeding are cared for in Intensive Care.

2.2 Reasons for gathering data on patients fed over two time periods

2.2.1 1. Patients on cyclical or bolus nasogastric feeding - Hospital wards

A very small number of patients who need to be fed by nasogastric tube being cared for on the hospital wards may have the capacity to give informed consent. However, the majority will be diagnosed as having suffered a stroke or with dementia, and although conscious may have fluctuating capacity to give consent.

The impairing condition in this cohort is dysphagia.

Nasogastric feeding of this group of patients will be administered as either a cyclical period (over 12 – 20 hours) or a bolus over a 24 hour period. Nasogastric tube placement will be checked before any liquid is administered through the nasogastric tube.

As these patients are being bolus or cyclically fed, there may be a small residual volume in the stomach. Providing it is possible to aspirate sufficient gastric content, staff perform the test with pH indicator strips. Where aspiration is difficult the patient will need to have a chest Xray to confirm the NG tube is in the correct position prior to the next feed.

2.2.2 2. Patients on continuous 24 hour feeding – Intensive Care Department

Patients in ICU are fed over 24 hours with a very short pause in feeding to re-test the tube position. Testing to determine the correct position of the tube is once a day.

Patients are generally unconscious, and again the impairing condition is dysphagia caused by unconsciousness.

Aspiration and pH test of gastric content
These patients are fed by nasogastric tube over a long period, generally 24 hours. The feed is administered very slowly to enable to stomach to absorb the feed, and promote better glycaemic control and oxygenation in septic patients , so there is very little gastric residual volume. The normal practice of aspirating gastric content and testing the aspirate with pH indicator strips is problematic, because there is very little residual volume to aspirate. If aspiration of gastric content is not possible a clinical override assessment will take place to determine if the nasogastric tube is in the correct position.

From anecdotal discussions with ICU clinicians they can find assessment of NG tube position a cause for concern, because if the pH aspirate test fails, there is no other quantitative bedside test to determine NG tube position. There is a reluctance to progress to chest Xray due to the exposure to ionizing radiation. Alternative methods such as the clinical override mechanism which uses clinical assessment is in line with NPSA 2016 guidelines, and in Lancashire Teaching Hospital NHS Foundation Trust, is only performed in ICU where the ratio of experienced staff to patients is high. In other hospitals this clinical override assessment, after the inability to test using the pH aspirate test, is performed by on general wards by senior nurses or junior medical staff.

2.3 Effect of medication on gastric pH

In addition, patients in Intensive Care are given administered a wide range of medication to treat their underlying condition and maintain their sedation. It is important for this clinical trial to gather performance data when patients are receiving medication which may affect the pH of gastric content. Very little data exists on how medication affects the pH of the stomach (other than acid suppression medication), so it is not possible to obtain this from drug information sheets or other clinical evidence.

2.4 Benefit of NGPOD test greatest in this group of patients

If NGPOD is able to achieve a rapid result when there is insufficient aspirate to perform a pH test, it will increase the safety of feed administration, helping to confirm position more reliably and detect never events of a lung placed tube. It will also reduce the need for chest Xray and exposure to ionizing radiation.

NGPOD has the opportunity to offer the greatest benefit to this cohort of patients in terms of patient safety and staff reassurance. It is vital the performance of the device can be studied in the Intensive Care Unit.

3 Objectives and Outcome Measures/Endpoints

3.1 Primary outcome measure:

- 1.) To establish if NGPOD® is as reliable in establishing the position of a NGT as current methods on both initial insertion and repeat testing.

3.2 Secondary outcome measures:

- 2.) To find out if the use of NGPOD® will reduce the requirement for confirmatory X-rays compared to current first line testing of a pH change using aspirate and universal pH indicator paper. If the NGPOD® system is able to confirm placement more frequently than the current front-line method of aspiration, then there is an opportunity to reduce the number of patients requiring an X-ray.

3.) If the NGPOD® test is more reliable than the current front-line method of testing, then the number of patients requiring X-ray will be reduced, the time taken for X-ray confirmation can be 20 mins to 2 days, depending on work flow in Radiography. Therefore nutrition, hydration and/or medication through the NGT may be delayed. This means less than optimal patient care, and has the potential to delay recovery.

4.) Recording PPI dose, time and route of administration will demonstrate if NGPOD® has greater sensitivity compared to aspiration of stomach content and testing with universal indicator paper.

4 Study Design

This is a diagnostic accuracy study (sensitivity and specificity) of the performance of NGPOD® in comparison to current protocols for checking the placement of NG tubes in people who require nasogastric nutrition hydration and medication in secondary care.

The study will test if NGPOD® is quicker, easier and has equivalent and superior accuracy to current NGT check procedures.

5 Study Setting

The study will be carried out in secondary care in England. The first hospital will act as a pilot for the study and will inform development of the study in two other sites in different hospital trusts in England.

At the time of writing the protocol these sites still need to be confirmed.

Other sites would be recruited and will follow this protocol but the Principal Investigator (PI) and hospital trust will differ and will be the subject of a minor amendment to this protocol.

The Registered Nurse or doctor involved with the trial will operate the NGPOD® device and check the position of the NGT (using current NHS Trust guidelines), prior to feeding.

If for any reason the Clinical Research Nurses (CRNs) are not available to perform the test with the device then an appropriately qualified nurse or clinician, who has received the appropriate product and clinical trial training, will perform the test.

6 Eligibility Criteria

Inclusion – All adults over the age of 18 who require a NGT as part of their treatment.

Exclusion – All patients who have undergone oesophageal gastro-intestinal surgery within the last 3 months; all patients who have partial or total gastrectomy; patients with bleeding gastric and/or duodenal ulcers; patients with gastric cancer; those with oesophageal varices; those considered by their medical team to be inappropriate (e.g. at the end of life); patients who are un-befriended and lack the capacity to give informed consent.

Withdrawal – No follow up of patients is required for the study. Patients themselves may withdraw from the study at any time.

7 Study Procedures

The study flow chart in Table 1, provides an overview of study procedures. Standard Operating Procedures (SOPs) will be developed for each study site. The procedure for the use of NGPOD® after initial NGT insertion is outlined in Appendix 18.2, and the procedure for use of NGPOD® for repeat checking of nasogastric tubes is outlined in Appendix 18.3.

Recruitment

Patient recruitment will use the following procedures:

Posters will be placed on ward notice boards informing patients, relatives and staff the clinical study is recruiting patients.

Patients will be selected by ward medical teams, because they require NG nutrition, hydration or medication. The ward medical team may start a brief conversation with the patient about participating in the study, with the CRN (or appropriately qualified nurse or clinician) giving more in depth information.

Recruitment of participants into the study will be by means of inclusion and exclusion criteria (see below). Each patient will be given an information sheet with information about the study. The participant will be informed as to why they have been chosen and the potential benefits of taking part. They will be informed that there are only very minimal risks in taking part as this test is in addition to standard testing, and inclusion into the trial will be confidential. The patient will be informed they can change their mind at any point in the trial and will be given details who to contact if they are unhappy with the treatment and wish to make a complaint.

Patients, who are unable to give consent because they are unconscious or lack capacity, will be assessed using hospital protocols based on the Mental Capacity Act and Deprivation of Liberty Policy. (Lancashire Teaching Hospital NHS Foundation Trust Mental Capacity Assessment is supplied in IRAS documentation.) Their relative, partner or close friend or person named in the registered Lasting Power of Attorney (LPA) (known as the consultee) will be asked if the patient would have wished, before admission to hospital, to participate in clinical research. These wishes will be documented, by the signature of the consultee on the declaration form. This study is not taking consent for the insertion of a NGT, or for nutrition, hydration or medication to commence. Those are subject to separate consent and are outside the scope of this study.

Appropriately trained nurses (Registered General Nurses or Clinical Research Nurses) or Doctors will insert the NGT. The first check will be with the NGPOD®. The second confirmatory test will be the current method of aspirating stomach contents and using universal indicator paper check the aspirate is pH 5.5 or lower. It is important the NGPOD test is performed as the first test. The process of aspirating stomach contents may cause small amounts of aspirate to remain in the NG tube. If the sensor is then introduced to the NG tube, the pH sensitive tip may come in to contact with the remaining aspirate and deliver a false positive result.

The study will include adults over the age of 18 who require a NGT as part of their treatment in order to receive hydration, nutrition or medication via the NGT or who are having the initial insertion of the NGT for other reasons.

7.1 Participant identification

Trial participants will be selected because they require nasogastric nutrition, hydration or medication using the inclusion and exclusion criteria below:

Inclusion – All adults over the age of 18 who require a NGT as part of their treatment.

Exclusion – All patients who have undergone oesophageal gastro-intestinal surgery within the last 3 months; all patients who have partial or total gastrectomy; patients with bleeding gastric and/or duodenal ulcers; patients with gastric cancer; those with oesophageal varices; those considered by their medical team to be inappropriate (e.g. at the end of life); Patients who are un-befriended and lack the capacity to give consent.

The Study is to include 2 cohorts of research participants:

- Patients who require the insertion of a NGT with the correct position of the NGT being established immediately following insertion. This known as “initial insertion”.

- Patients who already have a NGT inserted and require the position of the NGT re-confirming prior to a new episode of therapy being administered. This is known as “repeat testing”.

- In the repeat testing cohort there are two subgroups of patients, those being fed intermittently and those fed continuously.

Information leaflets will be provided to give more information to patients, their relatives, friends or those named in registered LPA who may be acting as consultees, and for the patient when they regain consciousness.

For both groups the NGPOD® system will be used **before** standard testing.

Following the NGPOD® test, confirmation of NGT position will be made by pH testing (using universal indicator paper) of gastric aspirate obtained from the NGT. If aspirate cannot be obtained or the results from the pH test are inconclusive, the standard secondary test of Chest X-ray will be used to determine the position of the NGT, in line with local hospital guidelines.

The results from one or both standard tests will be compared to the result from the NGPOD® system to determine whether the NGPOD® System is at least as accurate as the current standard testing methods.

For the duration of the study the correct position of the NGT, before nutrition, hydration or medication, **will not** be confirmed using NGPOD®.

NGT position will **only** be confirmed by the aspirate pH change test or by CXR.

After the procedure the patient will be asked to complete a quick questionnaire to gain more qualitative information and feedback on their experience of the procedure.

7.2 Consent

The Chief Investigator (CI) will retain overall responsibility for the conduct of the research at their site, including consent of participants at the site. The taking of consent from participants will be delegated to Registered General Nurses, Clinical Research Nurses or Doctors who are appropriately trained.

Those nurses and clinicians who will be taking the informed consent of participants will be authorised, trained and competent to participate and will conform to the Declaration of Helsinki.

Those patients (and consultees acting on behalf of patients) who do not want to participate will not be questioned as to their reasons and their rights will be respected.

Participants will remain free to withdraw from the trial at any time without giving reasons and without prejudicing their further treatment. Data collected up to the point of withdrawal will only be used after withdrawal if the participant has consented for this.

The CI will take responsibility for ensuring that all vulnerable participants are protected and participate voluntarily in an environment free from coercion or undue influence.

7.2.1 Recruitment and consent process for unconscious patients

Patients who require continuous 24 hour nutrition by nasogastric tube, and are considered suitable candidates for the study will be assessed under the Hospital Trust's Mental Capacity Assessment process.

If the patient is assessed to lack the capacity to make their own decision because of unconsciousness, the Decision Maker who would be Lead Clinician from the Medical team would need to make a decision in the patient's Best Interests. "Best interests" go far wider than "best medical interest", and include factors such as the patient's wishes and beliefs when competent, their current wishes, their general well-being and their spiritual and religious welfare.

The named decision maker should consider all relevant circumstances of which s/he is aware, and which it is reasonable to regard as relevant in making the decision on behalf of a person who lacks capacity. This should include medical, social, welfare, emotional and ethical matters. As the patient is unconscious an approach can be made to anyone deemed close to the patient such as relatives, carers or friends in order to source the patient's views and wishes around participation to take part in clinical research.

If the patient has a registered Lasting Power of Attorney for Health and Welfare they would act in the patient's best interests as long as the decision comes within this remit and the LPA documentation has been checked. Additionally any Advance Decisions to Refuse Treatment (ADRT) or written statements made by the patient must be respected.

Furthermore, if the patient is un-befriended and there is no one to consult with other than paid staff, an Independent Mental Capacity Advocate (IMCA) may be required, dependent on the urgency of the situation. For the purpose of this study, those patients are who are un-befriended and lack the capacity to give informed consent, will be excluded.

When the patient regains consciousness they will be given information about the clinical study. If they agree to continue participating in the study they will be asked to sign the regaining consciousness consent form.

If clinical staff consider the patient is a suitable trial candidate, they will be assessed, and a completed copy of the "Mental Capacity Assessment" will be included in the clinical trial's confidential paperwork.

The consultee will be asked if the patient would normally wish to participate in clinical trials. The purpose of the trial will be explained to them, and they will be given the Patient Information Sheet (CF 13). See Appendix 18.7. All their questions will be answered. They will register their approval for the patient to participate by completing the "Consultee Form" (CF 12). See Appendix 18.8 for "Consultee Form".

If the patient's relatives, partner, registered attorney or close friends think the patient would not consent to participate, their rights will be respected. They will not be pressurised to give approval and medical care and legal rights will not be affected.

The Consultee Form will be retained in the trial confidential paperwork, and be available for monitoring and audit.

When the patient regains the ability to give informed consent, the clinical staff will discuss their participation to date and ask them to give their formal consent to continue to participate.

The patient will be given the "Continued Participation Information Leaflet" (CF 14), Appendix 18.9, to read and will be asked to sign the "Continued Participation Consent Form" (CF 15), Appendix 18.10

If a patient loses the capacity to give consent after signing the consent form they will continue to be included in the study. The medical team will discuss with the relatives, partner or close friend the patient continuing in the study. If the relatives, partner or close friend does not wish them to continue the patient will be not continue to participate in the study.

Accompanying Documents:
Best Interest Form – Lancashire Teaching Hospital NHS Foundation Trust document
Paperwork for consultee agreement to recruit unconscious patients
CF16 Consultee information leaflet
CF12 Consultee declaration of agreement form
CF14 Continued participation information sheet
CF15 Continued participation consent form

Figure 6 Recruitment flow diagram

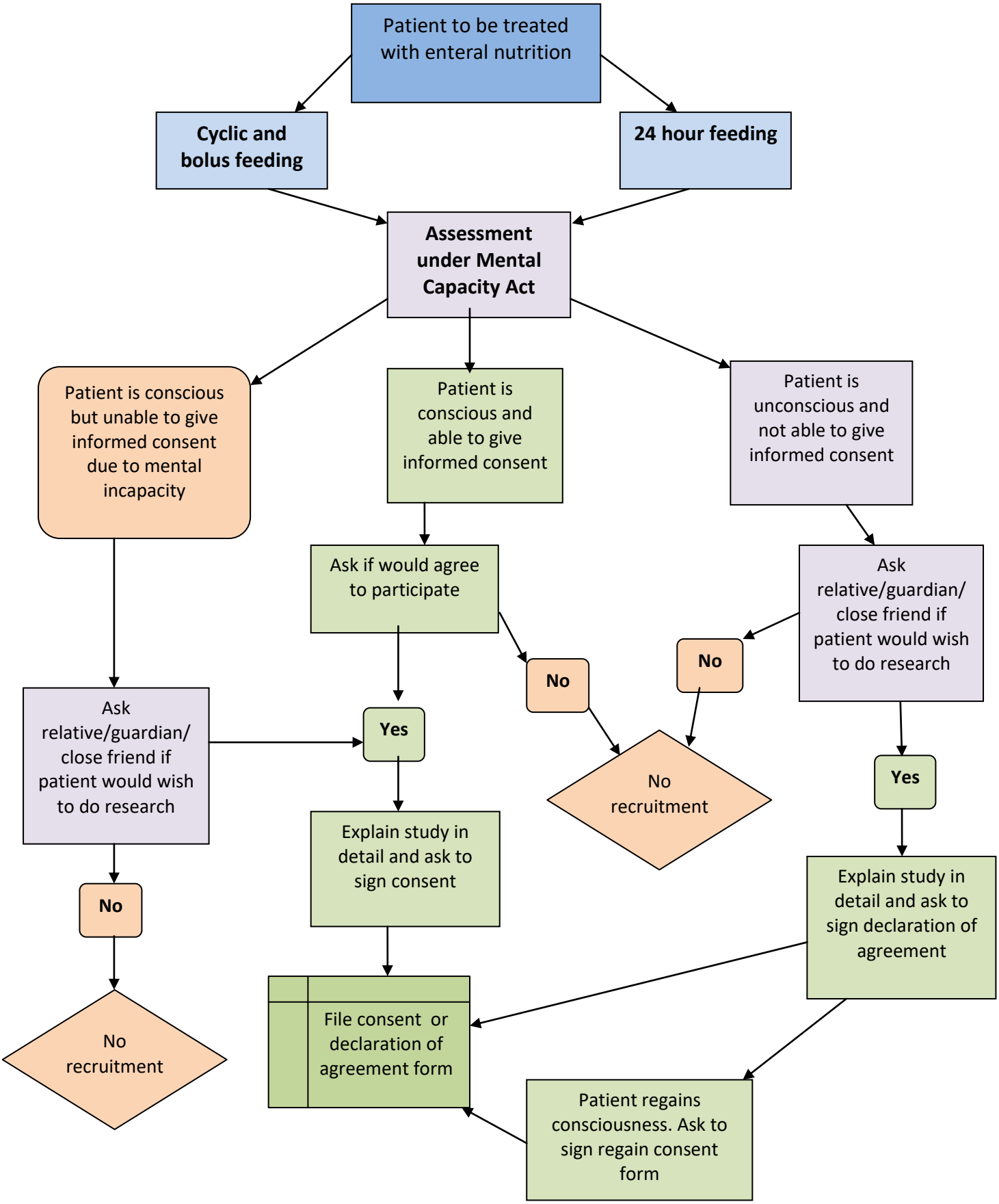
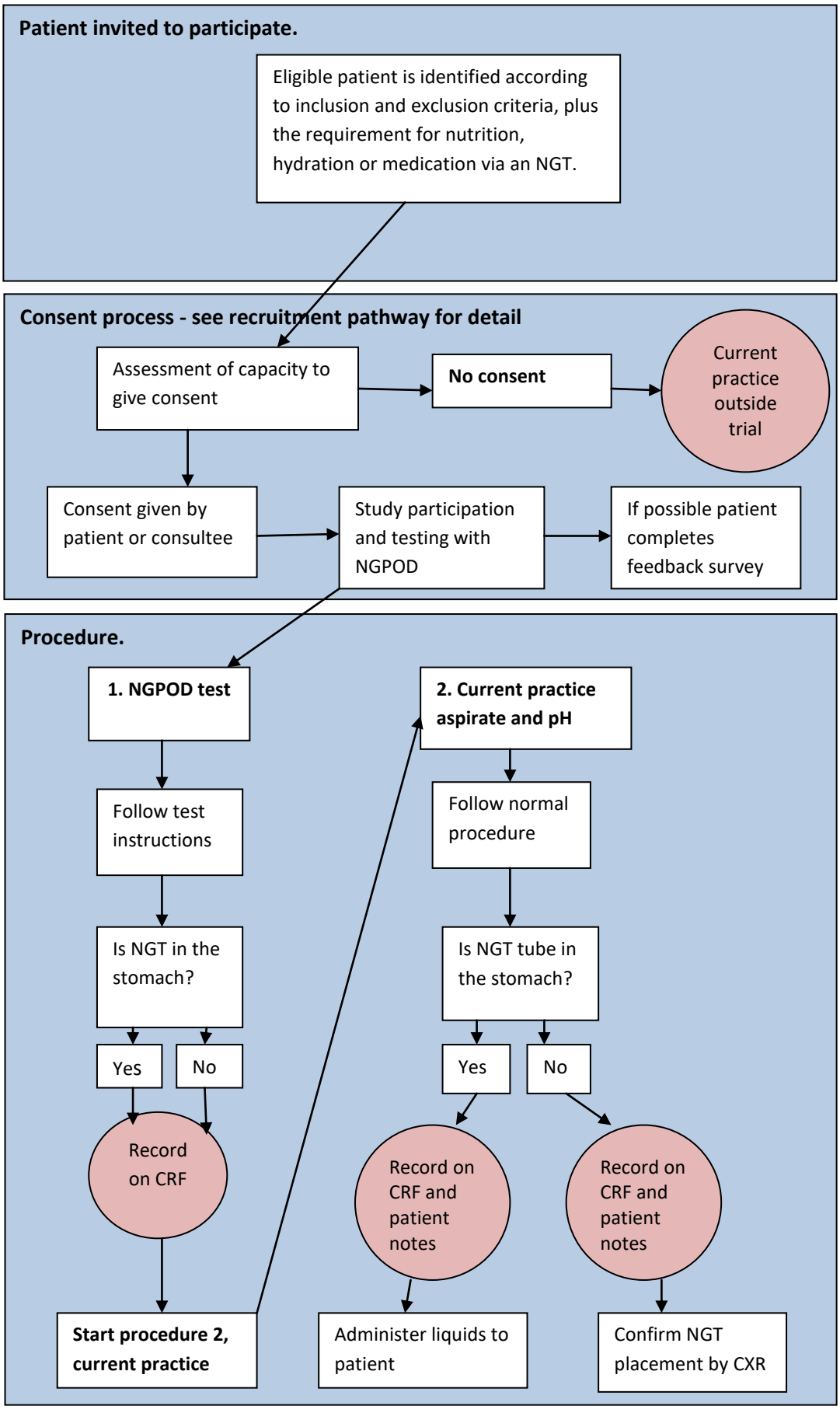


Table 2. Study Flow Chart



8 Study Interventions

Once the consent or declaration of agreement form has been signed all eligible, patients will be tested with the NGPOD® device first. The order of testing does not require randomisation. The NGPOD® test must be performed first because errors may occur if aspirate is in the tube prior to insertion of the sensor.

The researchers state that in this study the NGPOD® results **will not** be used to confirm correct placement of the NG tube in order to start nutrition, hydration or medication. Administration of liquids through the NG tube will only commence after correct placement of the NG tube has been checked using clinically approved Hospital Trust guidelines or by Chest X-ray.

8.1 Methodology:

Gloves will be worn by all nurses and clinicians inserting nasogastric tubes, using NGPOD® and checking NGT placement by aspiration of stomach contents.

8.1.1 Process for newly Inserted NGTs - INITIAL INSERTIONS

- Consent obtained for the additional procedure from the patient. If the patient lacks capacity to give informed consent, the process outlined in section 7.2.1 will be followed.
- Record time and Date that nutrition, hydration, medication by NGT was prescribed
- Explain procedure to the patient
- NGT insertion is undertaken according to hospital guidelines and performed by a Registered Nurse or Doctor.

8.1.2 NGPOD® test – perform first

NGPOD® Test Timer started

- Nurse Insulfates 10 mls of air into NGT in line with NPSA guidance, this removes any residual NGT liquid.
- Nurse fully inserts NGPOD® Sensor until the tip of the sensor reaches the internal tip of the NGT
- Nurse connects NGPOD® Sensor to NGPOD® Device and conducts test

If Green (Tick) test result obtained:-

- NGPOD® Device disconnected from NGPOD® Sensor
- NGPOD® Sensor removed from NGT
- NGPOD® Test result recorded
- NGPOD® Test Timer Stopped

If Red (X) Test result obtained:-

- Nurse disconnects NGPOD® Sensor from NGPOD® Device
- Nurse advances NGT with NGPOD® Sensor in place 5cm
- If swallow reflex is intact and patient is not NBM (Nil by Mouth), ask the patient to drink pineapple or orange juice to increase volume of fluids in stomach. Retest 30 minutes later.
- 30 minutes later - Nurse connects NGPOD® Device to NGPOD® Sensor and conducts repeat test

If Green (Tick) test result obtained

- NGPOD® Device disconnected from NGPOD® Sensor
- NGPOD® Sensor removed from NGT
- NGPOD® Test result recorded

- NGPOD® Test Timer Stopped

If Red (X) Test result obtained;

- Nurse disconnects NGPOD® Sensor from NGPOD® Device
- Patient is positioned onto their side.
- Nurse connects NGPOD® Device to NGPOD® Sensor and conducts repeat test

If Green (Tick) test result obtained

- NGPOD® Device disconnected from NGPOD® Sensor
- NGPOD® Sensor removed from NGT
- NGPOD® Test result recorded
- NGPOD® Test Timer Stopped

If Red (X) Test result obtained;

- NGPOD® Device disconnected from NGPOD® Sensor
- NGPOD® Sensor removed from NGT
- NGPOD® Test result recorded
- NGPOD® Test Timer Stopped
-

See appendix 18.2 for a summary of the NGPOD® procedure – After Initial Insertion

8.1.3 Tube placement confirmed by aspiration and pH testing

Standard Practice Starts.

Test timer started & time recorded

- NHS Trust Registered Nurse or Physician starts to obtain aspirate
- If aspirate obtained within 5 minutes of starting;
- Syringe disconnected & NG Cap Replaced
- Aspirate tested with universal indicator pH sticks
- Result interpreted
- Result Recorded
- Aspirate Test Timer stopped

If aspirate not obtained after 5 minutes carry out standard procedures to try to obtain aspirate

- Insufflate 10mls of air
- Manipulate tube
- Reposition patient
- Give patient a drink (if able to swallow)

If after these procedures no aspirate is obtained

- Stop Aspirate Test Timer & Record time
- Registered Nurse or Physician requests Chest X-ray for the confirmation of position of NGT
- Record Time & Date of request
- Record Time & Date X-ray performed
- Record X-ray result
- Record Time & Date X-ray reported
- Record Time and Date nutrition/hydration/medication administered

See appendix 18.1 for a summary of how to check the correct placement of a nasogastric tube following the current NHS Hospital Trust procedure.

8.1.4 Process for retest of Nasogastric tube position - REPEAT TESTING

- Consent obtained for additional NGPOD procedure from patient. If the patient lacks capacity to give consent, the process in section 7.2.1 will be followed.
- Procedure explained to patient
- The NGT check chart is reviewed
- Check measurement at nose, check if patient has vomited, violently coughed, or

complained of feed reflux, look in patient's mouth to check if tube is coiled at back of throat. If measurement is the same at the nose, no vomiting or violent coughing, tube not coiled in throat, proceed with NGPOD® test.

- NGPOD® test timer started
- Nurse insufflates 10mls of air to ensure tube is clear
- Nurse inserts NGPOD® sensor until the tip of the sensor reaches the internal tip of the NGT
- Nurse connects NGPOD® sensor to NGPOD® device and conducts test

If Green (Tick) test result obtained:-

- NGPOD® Device disconnected from NGPOD® Sensor
- NGPOD® Sensor removed from NGT
- NGPOD® Test result recorded
- NGPOD® Test Timer Stopped

If Red (X) Test result obtained;

- Nurse disconnects NGPOD® Sensor from NGPOD® Device
- Patient is positioned onto their side.
- Nurse connects NGPOD® Device to NGPOD® Sensor and conducts repeat test

If Green (Tick) test result obtained

- NGPOD® Device disconnected from NGPOD® Sensor
- NGPOD® Sensor removed from NGT
- NGPOD® Test result recorded
- NGPOD® Test Timer Stopped

If Red (X) Test result obtained;

- NGPOD® Device disconnected from NGPOD® Sensor
- NGPOD® Sensor removed from NGT
- NGPOD® Test result recorded
- NGPOD® Test Timer Stopped

At the end of the procedure the patient will be asked to complete the study questionnaire.

See appendix 18.3 for a summary of the NGPOD® procedure to check a NGT.

8.1.5 Tube placement confirmed by aspiration and pH testing

Standard Practice starts. Aspirate Test Timer Started & Time recorded

- Nurse or clinician starts to obtain aspirate.
- If aspirate obtained within 5 minutes of starting
- Syringe disconnected & NG Cap Replaced
- Aspirate tested with universal indicator pH sticks
- Result interpreted
- Result Recorded

Aspirate Test Timer stopped

If aspirate not obtained after 5 minutes carry out standard procedures to try to obtain;

- Insufflate 10mls of air,
- manipulate tube,
- Reposition patient,
- Give patient a drink

If after these procedures no aspirate is obtained

- Stop Aspirate Test Timer & Record time.
- Nurse or clinician Physician requests Chest X-ray for the confirmation of position of NGT
- Record Time & Date of request
- Record Time & Date X-ray performed
- Record X-ray result
- Record Time & Date X-ray reported
- Record Time and Date nutrition/hydration/medication administered

At the end of the procedure the patient will be asked to complete the study questionnaire.

See appendix 18.1 for a summary of how to check the correct placement of a nasogastric tube following the current NHS Hospital Trust procedure.

8.1.6 Time to conduct each part of the study procedure – update all of these timings

The time to conduct each part of the study procedure is as follows:

Twenty minutes at patient bedside, for initial insertion of NGT (including consent, tube insertion and testing by two methods):

- Verbal agreement or consultee consent for NGT 10mins.
- Written consent or consultee consent for NGPOD® 10mins
- Insertion of NGT less than 20 mins
- NGPOD® test 5 mins
- Confirmation of NGT placement using aspirate up to 20mins.
- If aspirate unsuccessful in confirmation of correct placement then follow-up X-ray either in patient bed area or in radiography department. Time depends on hospital work flow.

It will take approximately 25 minutes for repeat checks of NGT position.

8.1.7 Nasal bridle[7] – a device to secure NGTs

A nasal bridle is a means of securing the NGT to discourage patients from pulling on the NGT. It has been reported to be an effective and safe way to secure a NGT. The bridle tubing is passed through both nostrils and around the Vomer bone, using the structure of the nasal cavity to hold the NGT in place. A magnetic clip secures the bridle in position behind the Vomer bone. If patients pull on the tube they will feel a little pressure on the bone making the bridle uncomfortable for a moment but not painful.

It is anticipated that some patients may have a NGT bridle to secure the position of the nasogastric tube. Even though a bridle may be used, the position of the NGT still needs to be tested prior to nutrition, hydration or medication. Where the bridle is clipped to the NGT it should not inhibit the passage of the NGPOD® sensor through the NGT. The Case Report Form will document the presence of a nasal bridle.

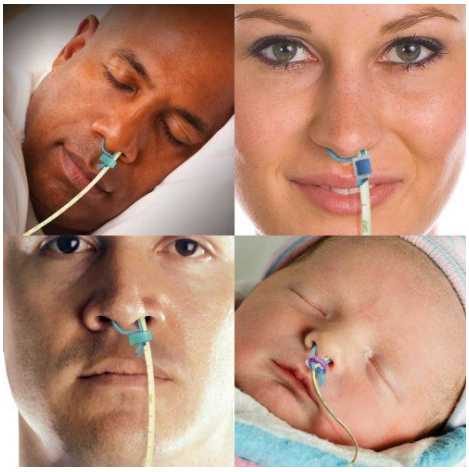


Illustration 1. Nasogatric bridle in position[7]

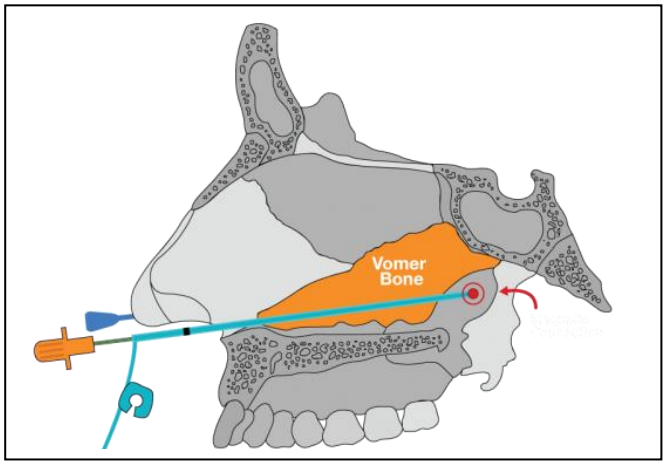


Illustration 2. Nasogastric tube secured behind Vomer Bone[7]

9 Diagnostic Procedures

Diagnostic procedures for this study are:

- using NGPOD® to identify a pH change at the tip of the fibre-optic sensor
- using the current practice of aspirating stomach contents and measure the colour change with universal pH indicator paper
- confirmatory CXR if the aspiration test is inconclusive

10 End of trial

The end of the trial will be when there are 100 results following initial insertion of NGT, and 300 repeat testing results, from a site. Each patient will have data recorded for the NGPOD® test and current practice test.

In the event of equipment failure the sponsor will replace the faulty equipment and if the malfunction is of a serious nature, the trial will be halted and the cause analysed, and if possible corrected.

The sponsor will notify the MHRA of the end of the clinical trial within 90 days of its completion.

11 Statistics and Data Analysis

For the sample size calculation, we have assumed that the outcome being tested for was the requirement to progress to X-ray, and the two tests being compared were universal pH indicator paper and NGPOD®. We have made no assessment with regard to the ultimate determination of the positioning of the NG tube, as this will not be an outcome of the study.

We have assumed that using universal pH indicator paper, it will be possible to obtain an aspirate in 87% of patients and in 82.2% of patients with a successful aspirate the pH test is positive (i.e. acidic or below pH 5.5). Patients with no aspirate or a negative result (pH above 5.5) will require an X-ray. Thus 28.5% of patients overall will require an X-ray.

At the moment, we do not have performance data available for NGPOD®. However, we have assumed that testing will give a result for 95% of patients and of these, positive confirmation of placement will be available for 95%. Thus 9.8% of patients will require an X-ray.

We have further assumed that 90% of those patients with a negative or unsuccessful NGPOD® test will also have a negative or unsuccessful pH test, while 10% will have a discordant result.

These assumptions have been used to construct the 2X2 table below:

	pH positive	pH test negative/no aspirate	TOTAL
NGPOD® positive	70.5%	19.7%	90.2%
NGPOD® negative/unsuccessful	1.0%	8.8%	9.8%
TOTAL	71.5%	28.5%	100%

The appropriate analytical technique for paired nominal data of this type is the McNemar test. We have estimated the sample size required for this study based on the method described by Machin et al; 2009[6].

Assuming alpha-value of 0.01 and a beta-value of 0.05, the number of paired data points required is 99. The proposed study design therefore has a 95% power to determine equivalence between the NGPOD® and pH strip testing at a significance level of p=0.01 for the initial placement cohort (proposed 100 patients). The assessment of retesting, which is proposed to comprise 300 further paired readings, is more than adequately powered to treat the hypothesis independently of the initial placement analysis.

12 Data Handling

Written consent forms will be retained as essential documents and held by the Foundation Trust, but items such as contact details will be deleted as soon as they are no longer required.

Clinical Investigators will assign a study number to each participant using the study number form. This study number will be entered on the case report form in order to anonymise the data.

Personal Data:
Study data and material may be looked at by individuals from the Hospital NHS Trust, or from regulatory authorities, for monitoring and auditing purposes, and this may well include access to personal information.

The sponsor will not have access to confidential data.

The sponsor will only have access to the anonymised case report forms (CRF).

In this study confidential data will be handled in the following way:

Consent and consultee declaration forms
After consent is obtained by a registered nurse or Dr, the consent form will be held by the NHS Hospital Trust.

Patient details and allocation of study number
The form recording patient details, (name, date of birth, hospital number) will be kept in the site file during the study, and retained by the NHS Hospital Trust after the completion of the study.

Case Report Form (CRF)
The CRF will be anonymised. The patient study number will allow traceability to specific individuals if required. The CRF will be available for data capture and analysis of results. It will finally be retained by the NHS Hospital Trust.

Patient survey
The patient survey will be anonymised. The patient study number will allow traceability to the patient if required. The patient survey will be retained by the sponsor.

Personal Data: Study data and material may be looked at by individuals from the Hospital NHS Trust, or from regulatory authorities, for monitoring and auditing purposes, and this may well include access to personal information.

13 Monitoring, Audit and Inspection

The study will be subject to the audit and monitoring regime of the Lancashire Teaching Hospitals NHS Foundation Trust.

13.1 Training and Study Implementation

All NHS staff involved in the study will be appropriately qualified. Staff conducting the NGPOD® test will be fully trained by NGPOD® Ltd.
Each research site will appoint a Study Representative

13.2 Routine Monitoring Procedures

The Study Co-ordinator and NGPOD® Ltd representative will review progress and issues with Site Study Representatives on a weekly basis throughout the duration of the study.

13.3 Adverse Event Reporting

NGPOD® Ltd has a Quality Management System which documents the process for customer complaints and adverse event reporting. The purpose of these documents is to outline the procedure for Medical Device Reporting should NGPOD® Ltd be informed, or become aware of any incident which may have caused serious injury or death or a serious deterioration in an individual's state of health, whilst the medical device is in use.

NGPOD® Global Ltd's Quality Management System has been composed in line with the following: FDA and Canadian Regulations, ISO standards, IVD & MDD Directive, MEDDEV Guidelines.

Medical Devices may have caused or contributed to a death or serious injury or deterioration of the health of a patient, user, or other persons as a result of:

- Failure
- Malfunction
- Improper or inadequate design
- Manufacture
- Labelling or user error

NGPOD® Global Ltd will comply with local reporting regulations. In the UK this is The Medical Device Vigilance System: European Guidelines; MEDDEV 2.12.1.

The maximum allowable elapsed times for determining the relevant facts and making an initial report are:

Serious public health threat: report immediately (without any delay that could not be justified) but not later than 2 calendar days after awareness by the manufacturer of this threat.

Death or UNANTICIPATED serious deterioration in state of health: report immediately (without any delay that could not be justified) after the manufacturer established a link between the device and the event but not later than 10 elapsed calendar days following the date of awareness of the event.

Others: report immediately (without any delay that could not be justified) after the manufacturer established a link between the device and the event but not later than 30 elapsed calendar days following the date of awareness of the event.

The actions will be carried out or co-ordinated by the Head of Quality.

The Notified Body responsible for issuing the CE mark and the UK MHRA will be contacted and informed of the adverse event.

The document in Appendix 18.4 provides a template for information required to enable Medical Device Reporting, and will be used to provide the relevant information to the Notified Body and the UK MHRA.

The NHS Hospital Foundation Trust Research Department will be informed of any incident which may have caused serious injury or death or a serious deterioration in an individual's state of health, whilst the medical device is in use within 24 hours.

The CI will be responsible for the reporting of related and unexpected Serious Adverse Events (SAEs) to be submitted to the REC. These will be sent within 15 days of the Chief Investigator becoming aware of the event.

All parties will comply with the agreed SOPs for AE reporting. SOPs will be made available before commencement of the study and retained in the site file.

The study will be subject to the audit and monitoring regime of the NHS Foundation Trust.

13.4 Terminating the study before completion

The progress of the study will be reviewed monthly. If the performance of the NGPOD® is not acceptable, a joint decision will be made between the Chief Investigator and NGPOD® Global Ltd to terminate the study before completion.

In the unlikely occasion of a "Never Event" where liquid enters the lungs, the study may be paused to allow investigation. As the decision to administer nutrition, hydration and/or medication will **only** be made on a result from the current hospital procedure of aspiration and pH change or CXR, the NGPOD will **not** be the cause of the "Never Event". When the investigation has been completed and the cause address, the study may restart.

13.5 Training and study Implementation

All NHS staff involved in the study will have completed training on how to complete the paperwork and take a patient consent. All staff using NGPOD® device will be fully trained by NGPOD® Global Ltd.

14 Ethical and Study Administration

All recruitment and other procedures will be conducted on Hospital premises.

All such procedures will be conducted by substantive or honorary NHS staff; the NHS indemnity scheme will apply.

The Sponsor, NGPOD Global Ltd has clinical trial insurance, and manufacturer's indemnity insurance.

The LTHTR will arrange insurance for research involving human subjects that provides cover for legal liabilities arising from its actions or those of its staff or supervised students, subject to policy terms and conditions.

For the purposes of the proposed study the intention is to add the use of NGPOD® into the current Standard Operating Procedure (SOP) of the Trust. The Trust SOP meets the requirements of the NHS England Patient Safety Alert PSA/W/2013/001.

pH testing with NGPOD® is a non-invasive procedure and therefore poses no new or additional risk to the subject. The test that is being carried out is a new method of testing for the same pH level that is currently used as the established 1st line bedside testing for NGT placement and therefore the proposed study is not seeking to establish a new biological marker for confirming NGT position.

The result of the NGPOD® will **not** be used to confirm NGT placement and the clinician will confirm placement in the usual way following the NGPOD® test.

The main consideration from an ethical and legal perspective is that patients will need to give informed consent, or, where appropriate consultee declaration of agreement, for the use of the additional procedure that will take place before the standard test is carried out. This will be done through a standard consent form administered by Registered Nurses immediately prior to testing. Should there be the opportunity to perform subsequent tests on the same subject following the first test, there will be no requirement for a new consent form to be signed.

As required by the HRA:

- Before the start of the trial, approval will be sought from a Research Ethics Committee (REC), for the trial protocol, informed consent forms, patient information letters, ward posters giving information about the trial taking place on the ward, and post-procedure patient survey.
- Substantial amendments that require review by REC will not be implemented until the REC grants a favourable opinion for the trial.
- All correspondence with the REC will be retained in the Investigator Site File.
- An annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the trial is declared ended.
- It is the Chief Investigator's responsibility to produce the annual reports as required.

- The Chief Investigator will notify the REC of the end of the trial.
- If the trial is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination.
- Within one year after the end of the trial, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

14.1 Peer review

This protocol has been peer reviewed by:
Ms Alison Young, Consultant Nurse in Nutrition, Royal Liverpool and Broadgreen University NHS Hospitals Trust, Department of Gastroenterology. Her comments have been integrated in to the protocol.

14.2 Public and Patient Involvement

This clinical study will ask the patient to complete a short questionnaire after the NGT position has been checked.

Patients will be encouraged (where possible), to give their own opinion of the device under investigation.

The results of the study will be disseminated on public access forums.

14.3 Protocol compliance

Protocol compliance will be managed and documented.

For the purpose of this study protocol non-compliances are departures from the approved protocol.

- Recruitment of patients will conform to the protocol inclusion and exclusion criteria.
- Any accidental protocol deviations will be adequately documented on the relevant forms and reported to the Chief Investigator and Sponsor immediately.
- Any deviations from the protocol which are found to be frequently recurring will receive immediate action and as they may be regarded as a serious breach of protocol. These deviations will be made known to the Chief Investigator and Sponsor, so action can be taken.
- the sponsor of this clinical trial will notify the licensing authority in writing of any serious breach of:
    1. the conditions and principles of GCP in connection with the trial
    2. the protocol within 7 days of becoming aware of that breach

15 Data protection and patient confidentiality

In this study confidential data will be handled in the following way:

Consent and consultee / LPA appointee declaration of agreement form
After appropriate consent is obtained, the form will be held by the NHS Hospital Trust.

Patient details and allocation of study number
The form recording patient details, (name, date of birth, hospital number) will be kept in the site file during the study, and retained by the NHS Hospital Trust after the completion of the study.

Case Report Form (CRF)
The CRF will be anonymised. The patient study number will allow traceability to specific individuals required. The CRF will be available for data capture and analysis of results. It will finally be retained by the sponsor.

Patient survey
The patient survey will be anonymised. The patient study number will allow traceability to the patient if required. The patient survey will be retained by the sponsor.

Personal Data: Study data and material may be looked at by individuals from the Hospital NHS Trust, or from regulatory authorities, for monitoring and auditing purposes, and this may well include access to personal information.

16 Dissemination Policy

The trial will be registered on the ISRCTN website:
https://www.isrctn.com/

The results will be available via the Trust Website
http://www.lancsteachinghospitals.nhs.uk/

A brief report of the trial may also be published on the sponsor's website:
http://NGPOD®Global.com/

Study results will be disseminated to clinicians, nursing practitioners, patients and the general public by the CI and Principal Investigators and by NGPOD® Global Ltd, through peer reviewed clinical papers and website information.

Academic output from the study will be published in peer reviewed scientific journals, and at relevant conferences and events by the team at the NHS Hospital Foundation Trust.

17 References

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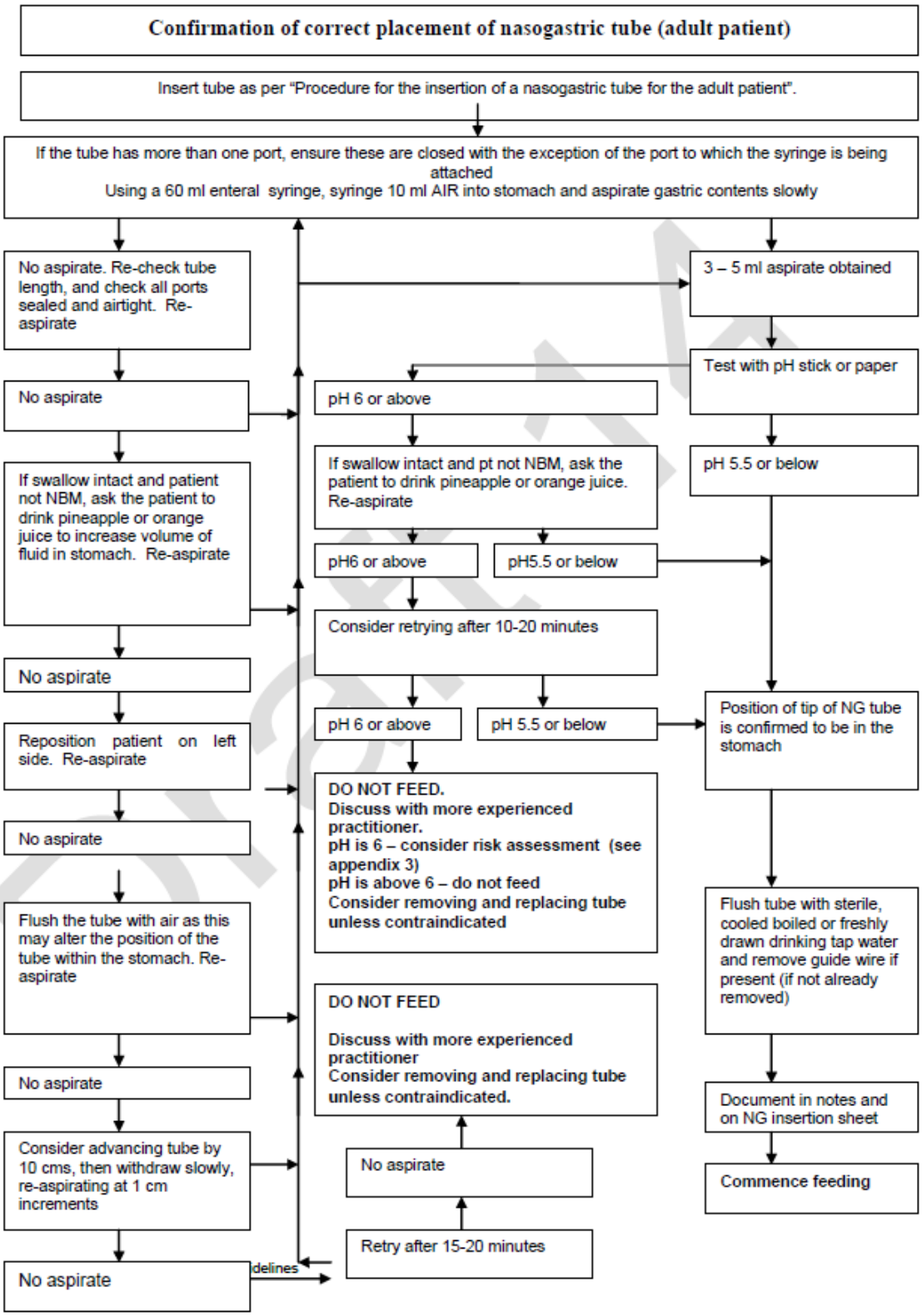
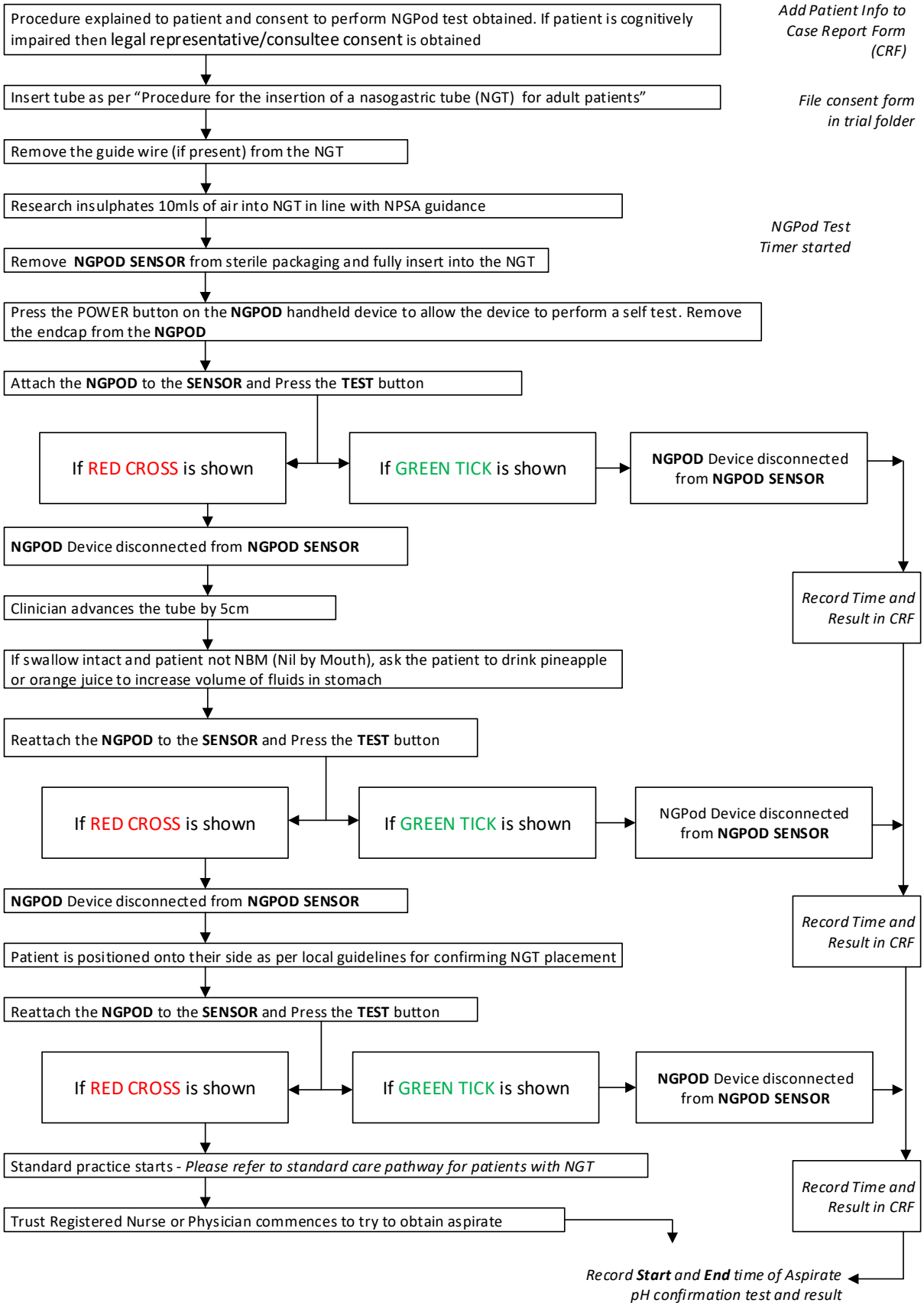
18 Appendices

18.1 Confirmation of correct placement of a nasogastric tube



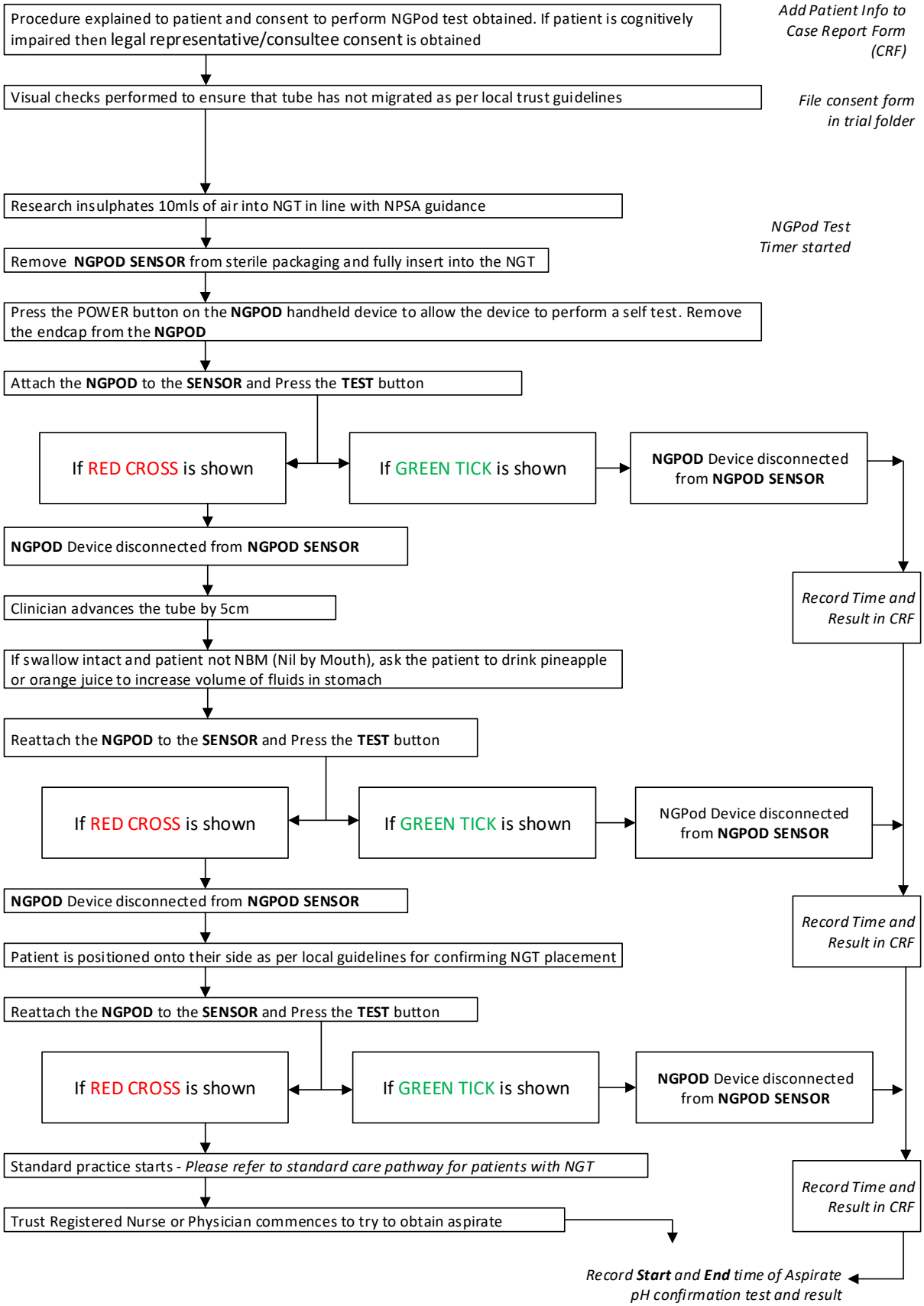
18.2 NGPOD® procedure – After Initial Insertion

Flow diagram of NGPOD Procedure (INITIAL INSERTIONS)



18.3 NGPOD® procedure – Repeat testing

Flow diagram of NGPOD Procedure (REPEAT TESTING)



18.4 Form to enable medical device adverse event report

Ref No: *(Anonymised hospital reference number, so NHS Trust retains confidential patient information.)*

1. Product Details

NGPOD® device

Instrument Serial Number:

REF number:

Possibility of return of product from hospital site:

DISPOSABLE

Lot No:

Ref No:

Sterilisation date:

Use by date:

2. Customer Details:

Contact Name: *(NHS staff member)*

Order Details:

Facility Name: *(NHS Trust name)*

Address: *(NHS Trust address)*

Telephone Number:

Email:

3. User Details (if different from 2).

4. Details of Adverse event or product problem

Identification of event or problem:

Outcome:

Date of event:

Date of initial report:

Detailed description of event and follow-up:

Detailed History

Actions taken to date by subsidiary:

Classification of incident:

(a) Death or unanticipated serious deterioration in state of health, serious public health threat

(b) All other reportable incidents

5. Patient information:

6. Results of investigation:

Manufacturing/ subsidiary response:

Completed by: *(Name)*

Date:

Closed by: Date:

NB: Additional information may be required by local regulations and these should be referred to should a decision be made to enact Medical Device Reporting.

18.5 Patient Acceptability Survey – example form

If patient responsive complete this survey for initial insertion and testing of NGT, and also once on repeat testing of NGT position.

Today you took part in a clinical trial using a new device to check the position of your nasogastric tube, and also by the usual hospital way of checking the correct position of the tube.

The following questions are about which you preferred and why.

Please tick one box only for each question:

The new device the NGPOD, was the first test.

Q1. Which was test was the quickest for the nurse to perform?:

First test NGPOD device ☐

Or

Second test, to withdraw liquid from stomach and test with pH paper ☐

Q2. Did you find each type of recording equally acceptable?:

Yes ☐

No ☐

Q3. Which test felt more comfortable, the first NGPOD or second withdrawal of liquid test?:

First test was more comfortable, NGPOD ☐

Second test was more comfortable, withdrawal of liquid test ☐

No difference between each test ☐

Q4. Do you think the NGPOD, if accepted in the hospital would reduce the delay in you receiving liquids through the tube?:

Yes NGPOD would reduce the delay in having liquids through the tube ☐

No NGPOD would nor reduce the delay in having liquids through the tube ☐

Q5. If a friend/family had to have these tests, which one would you recommend?

First test with NGPOD ☐

Second test the withdrawal of liquid ☐

Q6. Home testing - how would you feel if you were to use this new device to check a NGT at home?

Do you have any other comments?.....

……

……

Thank you for helping with our study and for your time and valuable feedback

Patient study number……

18.6 Patient Information Sheet

Patient Information Sheet

This information sheet will give you information about a research study taking place in the hospital. The study is named:

NGPOD® pH test compared to current NHS Trust practice to determine Nasogastric Tube (NGT) position.

Hospital nurses or Doctors will carry out the study. The study is run by researchers from the Lancashire Teaching Hospital NHS Foundation Trust.

Before you decide to take part we would like you to understand why the research is being
performed and what it will involve for you.

Part 1 of this information sheet tells you about the purpose of this study and what will happen if you decide to take part.

Part 2 provides more details about the conduct and management of the study, and where you can get further information.

Part 1
Your medical team will have told you that as part of your treatment, you need to have a tube passed through your nose and in to your stomach. This is so the medical team can give you liquid food, water and medicine directly in to your stomach. You may already have the tube in place.

It is important the position of the tube is checked before giving you any liquid food, water or medicine, to make sure it is safe.

The way the nurse checks the position of the tube is to draw up some of the liquid in your stomach, and see if it is acidic using a pH paper which changes colour. Your stomach contents are usually acidic. Sometimes it is difficult to obtain any liquid from your stomach to do this test, so you have to be sent for a chest X-ray. This process can sometimes be time consuming and may delay you being given liquids or medicine by the tube.

New test device
This study will test a new way of checking your tube is in the correct position. The device is called NGPOD® and will test to see if the end of the tube has come into contact with the acid in your stomach. The new test will be used just after the tube is passed in to your stomach, and before you are given any liquid or medicine through the tube. It will be compared to the way the tube is usually checked. All the results will be recorded, so they can be analysed at a later date.

The new test will **not** be used to make a decision about giving you liquids. You will **always** have the usual checks at your bedside, and if those do not confirm the correct position of the tube, you will be sent for a chest X-ray.
The study will also see if the number of chest X-rays used to check the position of the tube can potentially be reduced.

NGPOD® system

There are two parts to the NGPOD® system. A fibre-optic sensor and a hand held test device.

Figure 1 – The NGPod System

The Fibre-optic sensor is threaded down the feeding tube, so the tip of the sensor is at the end of the feeding tube. The hand held test device is then connected to the connector at the end of the sensor. The nurse will press the button, and if the feeding tube has come into contact with your stomach acid, a green tick will light up. If the feeding tube has not come into contact with stomach acid, a red cross will light up.

The NGPOD® system gives YES/NO results and helps to reduce the risk of making errors reading colour changes on pH paper.

Advantages of the NGPOD® system are that it is very quick and easy for the nurse to check the position of your feeding tube, meaning that you can start liquid feeding and oral drugs without delay. It is hoped that this study will show that NGPOD® will reduce the number of chest X-rays you need to check the position of the feeding tube.

Consent form
If you decide to take part in the study, a Registered Nurse or Doctor will ask you to read this leaflet. If you have any questions you can ask the nurse or doctor. When your questions have been answered and you decide to take part, you will be asked to sign a consent form. The study consent form is just to say you are happy to for the nurse to test with the new device.

You will be asked to sign a separate consent form to have the tube passed in to your stomach. This is the normal procedure in this hospital.

Time taken to check your tube is in the correct position
When you have signed the consent form, and before you are given liquid food, water or medicine through the tube, the position of the tube will be checked. The first check to be carried out will be the new device, NGPOD®. The test with NGPOD® will take about 5 minutes. For the second check the nurse will try and withdraw liquid from your stomach with a syringe. This is the usual way of checking the tube is in the correct position and will take no longer than 20 minutes. If the result of the second test is not clear, then you will have a chest X-ray.

If you do not want to take part
If you do not want to take part in the study, you will not be questioned on your reasons, and your rights will be respected. Your decision will not affect any other part of your treatment.

Why have I been invited to take part?
You have been invited to take part in this study because your medical team would like to treat you with liquid food, water or medicine, given to you through a tube going in to your stomach.

You may have had a feeding tube in place for a few days, and this gives a good opportunity to test how the new device compares to normal practice.

Who else has been invited to take part?
Other patients over the age of 18 years who need to have a feeding tube, or who are already having liquids through a tube in to the stomach, are being invited to take part. There will be 4 hospitals and nearly 100 patients in each hospital.

What will happen after the test?
Your normal treatment will continue in hospital until the next time you have liquid food, water or medication, and the test with the new device will be repeated, as the nurse or doctor checks your feeding tube is in the right place.

What are the benefits of taking part?
Taking part in research like this helps doctors and nurses develop new tests and treatments. We can only test how well new devices like this work with the help of patients.

This new device is designed to be a very quick, easy to use and an accurate way of checking the feeding tube is in the right place in the stomach. We need to check it is as good as, if not better than the current way of testing. We also want to see if we can reduce the number of times patients need a chest X-ray to check the position of the feeding tube.

If we can show the new device is quicker, easier to use and more accurate, and the NHS begin to use it, it may help to improve the care for patients and reduce cost in the NHS.

Are there any risks or discomfort involved?
You should not have any discomfort when the new device is being used.

Any risks with the use of the device have been reduced to a minimum by safety testing, checks and extensive healthy human studies. The company (NGPOD Global Ltd) records

any risks and how they can be controlled in a risk management file. The safety and performance of the device is very important and will be regularly checked throughout the study.

All NHS Trust nurses and doctors involved in the study have been fully trained to use the device. They are also trained to carry out research studies. If you have any worries or concerns about the tests, or the study, you can discuss them with the nurse, doctor or researcher at any time.

If you change your mind and want to withdraw from the research study you can do so at any time.

Part 2. Further Information

Who can I contact for more information about taking part in the study?

If you need any further information about taking part in the study, you should talk to the Registered Nurse who has invited you to take part, the senior ward nursing staff, or your hospital doctor.

Who will know I have taken part in the study?

You can tell anyone you wish about the study. It may help you to discuss your part in the study with your partner, family or friends. Only the hospital staff looking after you will have access to your hospital records and the study consent form. For the study you will have a unique study number. All other documents used for the trial do **not** contain your personal details, you are only known by a study number. The company who have developed NGPOD® do **not** see your personal details.

What will happen to data from the tests I have?

The results from the study will be recorded on a case report form. This will only have your study number **not** your personal details. The team at Lancaster Teaching Hospital NHS Trust will store the data anonymously for up to 10 years, and it may be used for the future development of the NGPOD® device. The results will be written down and presented as clinical papers for the medical community, and also made available to the public through the company website. www.ngpodglobal.com

Who is developing NGPOD® System?

NGPOD® is being developed by the company NGPOD® Global Limited. You can find out more about the company and their device on the website www.ngpodglobal.com

Who can I contact to find out more about the management of the study and how it is carried out?

If you have any concerns about how the study is being managed or have any further questions you should contact the Chief Investigator, Tracy Earley. Contact details are: telephone 01772 523 057; and e mail tracy.earley@lthtr.nhs.uk

What happens to my data under General Data Protection Regulation (GDPR)?
What happens to patient data under General Data Protection Regulation (GDPR)?
NGPOD Global Ltd is the sponsor for this study based in the United Kingdom. Lancashire Teaching Hospitals NHS Foundation Trust will be using information from you in order to undertake this study and will act as the data controller for this study. This means that the NHS Trust is responsible for looking after your information and using it

properly. The NHS Trust will keep identifiable information about you 5 years after the study has finished.

Your rights to access, change or move your information are limited, as the NHS Trust needs to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, the NHS Trust will keep the information about you that has been obtained. To safeguard your rights, the NHS Trust will use the minimum personally-identifiable information possible.

You can find out more about how the NHS Trust uses your information at: https://www.lancsteachinghospitals.nhs.uk/privacy-notice The NHS Trust will keep your name, NHS number and contact details confidential and will not pass this information to NGPOD Global Ltd. The NHS Trust will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from regulatory organisations may look at your medical and research records to check the accuracy of the research study. NGPOD Global will only receive information without any identifying information. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

The NHS Trust will keep identifiable information about you from this study for 5 years after the study has finished.

Complaints
If the Chief Investigator is unable to resolve your concern or you wish to make a complaint regarding the study, please contact the Research Governance Lead at Lancashire Teaching Hospital NHS Trust.

Research Governance lead - Centre for Health Research and Innovation at Lancashire Teaching Hospitals by contacting 01772 522031.

Who should I contact if I am unhappy with my treatment and wish to make a complaint

If you have a specific concern or query about the research you can contact the study team on the details below. For a more independent contact, you can contact the Research Governance lead within the Centre for Health Research and Innovation at Lancashire Teaching Hospitals by contacting 01772 522031. You may also wish talk to the hospitals Patient Advice and Liaison Service (PALS) which provides support to patients, families and visitors. Hopefully, in most cases they will be able to sort out your concerns very quickly. However if you are not satisfied with the response that you receive you can make a complaint in writing. Please contact the Trust's Customer Care department on 01772 522521 or email customer.care@lthtr.nhs.uk who can they will assist you with your complaint.

Research study contact details:
Chief Investigator, Tracy Earley. Contact details are: telephone 01772 523 057; and e mail tracy.earley@lthtr.nhs.uk

Research Governance lead - Centre for Health Research and Innovation at Lancashire Teaching Hospitals by contacting 01772 522031.

Harm

In the event that something does go wrong and you are harmed during the research, you may have grounds for a legal action for compensation against Lancashire Teaching Hospital NHS Trust or NGPOD® Global Ltd, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Appendix 18.7

Consultee Information Sheet

This information sheet will give you information about a research study taking place in the hospital. The study is named:

NGPOD® pH test compared to current NHS Trust practice to determine Nasogastric Tube (NGT) position.

Hospital nurses or Doctors will carry out the study. The study is run by researchers from the Lancashire Teaching Hospital NHS Foundation Trust.

You have been given this Information Sheet, because the medical team consider your relative, partner or close friend to be a suitable candidate in a clinical study taking place in the hospital. If you are the health representative for the patient under Lasting Power of Attorney legislation, or you are the primary relative, partner or close friend, in this research study you are known as the "consultee". Before you give approval for the patient to take part we would like you to understand why the research is being performed and what it will involve.

Part 1 of this information sheet tells you about the purpose of this study and what will happen if you give approval.

Part 2 provides more details about the conduct and management of the study, and where you can get further information.

Part 1

The medical team will have told you that as part of treatment, the patient will need to have a tube passed through their nose and in to their stomach. This is so the medical team can give liquid food, water and medicine directly in to their stomach. The patient may already have the tube in place.

It is important the position of the tube is checked before giving any liquid food, water or medicine, to make sure it is safe.

The way the nurse checks the position of the tube is to draw up some of the liquid from the stomach, and see if it is acidic using a pH paper which changes colour. Stomach contents are usually acidic. Sometimes it is difficult to obtain any liquid from the stomach to do this test, so the patient may have to be sent for a chest X-ray. This process can sometimes be time consuming and may delay liquids or medicine being given by the tube.

New test device

This study will test a new way of checking the tube is in the correct position. The device is called NGPOD® and will test to see if the end of the tube has come into contact with the acid in the stomach. The new test will be used just after the tube is passed in to the stomach, and before the patient is given any liquid or medicine through the tube. It will be compared to the way the tube is usually checked. All the results will be recorded, so they can be analysed at a later date.

The new test will not be used to make a decision about giving liquids. The patient will always have the usual checks at the bedside, and if those do not confirm the correct position of the tube, they will be sent for a chest X-ray.

The study will also see if the number of chest X-rays used to check the position of the tube can potentially be reduced.

NGPOD® system

There are two parts to the NGPOD® system. A fibre-optic sensor and a hand held test device.

Figure 1 – The NGPod System

The Fibre-optic sensor is threaded down the feeding tube, so the tip of the sensor is at the end of the feeding tube. The hand held test device is then connected to the connector at the end of the sensor. The nurse will press the button, and if the feeding tube has come into contact with stomach acid, a green tick will light up. If the feeding tube has not come into contact with stomach acid, a red cross will light up.

The NGPOD® system gives YES/NO results and helps to reduce the risk of making errors reading colour changes on pH paper.

The NGPOD® system is very quick and easy for the nurse to check the position of a feeding tube, meaning that liquid feeding and oral medication can be started without delay. It is hoped that this study will show that NGPOD® will reduce the number of chest X-rays needed to check the position of feeding tubes.

Consultee declaration form

If you are considering the participation of your relative, partner, friend or are acting as attorney for the patient, a Registered Nurse or Doctor will ask you to read this leaflet. If you have any questions you can ask the nurse or doctor. When your questions have been answered and you decide participation is appropriate, you will be asked to sign the consultee declaration form. The study consultee declaration form gives written confirmation you agree the nurse may test with the new device.

Time taken to check the tube is in the correct position
When you have signed the consultee declaration form, and before liquid food, water or medicine is given through the tube, the position of the tube will be checked. The first check to be carried out will be the new device, NGPOD®. The test with NGPOD® will take about 5 minutes. For the second check the nurse will try and withdraw liquid from the stomach with a syringe. This is the usual way of checking the tube is in the correct position and will take no longer than 20 minutes. If the result of the second test is not clear, then the patient may have a chest X-ray.

If you do <u>not</u> want your relative, partner or friend to take part
If you do not want your relative, partner or friend to take part in the study, you will not be questioned on your reasons, and your rights and the rights of the patient will be respected. Your decision will not affect any other part of the treatment.

Why has your relative, partner or friend been invited to take part?
Your relative, partner or friend has been invited to take part in this study because their medical team would like to treat them with liquid food, water or medicine, given through a tube in to the stomach.

The patient may have had a feeding tube in place for a few days, and this gives a good opportunity to test how the new device compares to normal practice.

Who else has been invited to take part?
Other patients over the age of 18 years who need to have a feeding tube, or who are already having liquids through a tube in to the stomach, are being invited to take part. There will be 3 hospitals and nearly 100 patients in each hospital.

What will happen after the test?
Normal treatment will continue in hospital until the next time liquid food, water or medicine needs to be given. The test with the new device will be repeated, as the nurse or doctor checks the feeding tube is in the right place.

What are the benefits of taking part?
Taking part in research like this helps doctors and nurses develop new tests and treatments. We can only test how well new devices like this work with the help of patients.

This new device is designed to be a very quick, easy to use and an accurate way of checking the feeding tube is in the right place in the stomach. We need to check it is as good as, if not better than the current way of testing. We also want to see if we can reduce the number of times patients need a chest X-ray to check the position of the feeding tube.

If we can show the new device is quicker, easier to use and more accurate, and the NHS begin to use it, it may help to improve the care of patients and reduce cost in the NHS.

Are there any risks or discomfort involved?
The patient should not have any discomfort when the new device is being used.

Any risks with the use of the device have been reduced to a minimum by safety testing, checks and extensive healthy human studies. The company (NGPOD Global Ltd) records

any risks and how they can be controlled in a risk management file. The safety and performance of the device is very important and will be regularly checked throughout the study.

All NHS Trust nurses and doctors involved in the study have been fully trained to use the device. They are also trained to carry out research studies. If you have any worries or concerns about the tests, or the study, you can discuss them with the nurse, doctor or researcher at any time.

If you change your mind and want your relative, partner or friend to withdraw from the research study you can do so at any time.

Part 2. Further Information

Who can I contact for more information about taking part in the study?
If you need any further information about the study, you should talk to the person who has asked you to give approval for your relative, partner or friend to take part.

Who will know my relative, partner or friend has taken part in the study?
You can tell anyone you wish about the study. It may help you to discuss giving approval with other family members or friends. Only the hospital staff looking after the patient will have access to hospital records and the study consultee declaration form. The study will give a unique study number to the patient. All other documents used for the trial do not contain personal details, so the patient is only known by a study number. The company who have developed NGPOD® do not see any personal details.

What will happen to data from the tests?

The results from the study will be recorded on a case report form. This will only have the study number not any personal details. The team at Lancashire Teaching Hospital NHS Trust will store the data anonymously for up to 10 years, and it may be used for the future development of the NGPOD® device. The results will be written down and presented as clinical papers for the medical community, and also made available to the public through the company website. www.ngpodglobal.com

Who is developing NGPOD® System?

NGPOD® is being developed by the company NGPOD® Global Limited. You can find out more about the company and their device on the website www.ngpodglobal.com

Who can I contact to find out more about the management of the study and how it is carried out?

If you have any concerns about how the study is being managed or have any further questions you should contact the Chief Investigator, Tracy Earley. Contact details are: telephone 01772 523 057; and e mail tracy.earley@lthtr.nhs.uk

What happens to patient data under General Data Protection Regulation (GDPR)?

NGPOD Global Ltd is the sponsor for this study based in the United Kingdom. Lancashire Teaching Hospitals NHS Foundation Trust will be using information from you in order to undertake this study and will act as the data controller for this study. This means that the NHS Trust is responsible for looking after your information and using it properly. The NHS Trust will keep identifiable information about you 5 years after the study has finished.

Your rights to access, change or move your information are limited, as the NHS Trust needs to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, the NHS Trust will keep the information about you that has been obtained. To safeguard your rights, the NHS Trust will use the minimum personally-identifiable information possible.

You can find out more about how the NHS Trust uses your information at: https://www.lancsteachinghospitals.nhs.uk/privacy-notice The NHS Trust will keep your name, NHS number and contact details confidential and will not pass this information to NGPOD Global Ltd. The NHS Trust will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from regulatory organisations may look at your medical and research records to check the accuracy of the research study. NGPOD Global will only receive information without any identifying information. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

The NHS Trust will keep identifiable information about you from this study for 5 years after the study has finished.

Complaints
If the Chief Investigator is unable to resolve your concern or you wish to make a complaint regarding the study, please contact the Research Governance Lead at Lancashire Teaching Hospital NHS Trust.

Research Governance lead - Centre for Health Research and Innovation at Lancashire Teaching Hospitals by contacting 01772 522031.

Who should I contact if I am unhappy with treatment and wish to make a complaint
If you have a specific concern or query about the research you can contact the study team on the details below. For a more independent contact, you can contact the Research Governance lead within the Centre for Health Research and Innovation at Lancashire Teaching Hospitals by contacting 01772 522031. You may also wish talk to the hospital's Patient Advice and Liaison Service (PALS) which provides support to patients, families and visitors. Hopefully, in most cases they will be able to sort out your concerns very quickly. However if you are not satisfied with the response you can make a complaint in writing. Please contact the Trust's Customer Care department on 01772 522521 or email customer.care@lthtr.nhs.uk who can assist you with your complaint.

Research study contact details:
Chief Investigator, Tracy Earley. Contact details are: telephone 01772 523 057; and e mail tracy.earley@lthtr.nhs.uk

Research Governance lead - Centre for Health Research and Innovation at Lancashire Teaching Hospitals by contacting 01772 522031.

Harm

In the event that something does go wrong and the patient is harmed during the research, you may have grounds for legal action and compensation against Lancashire Teaching Hospital NHS Trust or NGPOD® Global Ltd, but you may have to pay legal costs. The normal National Health Service complaints mechanisms will still be available to you.

18.8 Consultee declaration of agreement form

Centre Number: [pending]
Study Number: IRAS no. 217 641
Name of Chief Investigator:
Ms Tracy Earley

Royal Preston Hospital
Sharoe Green Lane
Fulwood
Preston
PR2 9HT

Participant Identification Number for this trial: .....

Title of Project: NGPOD® pH test compared to current NHS Trust practice to determine Nasogastric Tube (NGT) position.

Please initial box to indicate agreement.

1. I confirm that I have read the Patient Information Sheet for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that as the consultee I am giving my confirmation that the patient is known to me and would voluntarily wish to participate in the research study. I understand that their participation can be withdrawn at any time any time without giving any reason, and their medical care or legal rights will not be affected. ☐

3. I understand that relevant sections of the medical notes and data collected during the study may be looked at by individuals from the Lancashire Teaching Hospitals NHS Foundation Trust, from regulatory authorities or from the NHS Trust where it is relevant to their taking part in this research. I give permission for these individuals to have access to the patient's records. ☐

4. I understand that the information collected about the patient will be used to support other research in the future, and may be shared anonymously with other researchers. ☐

5. I understand that the information held and maintained by the NHS Hospital Consultant and other central UK NHS bodies may be used to help contact the patient or provide information about their health status. ☐

6. I agree the patient, if able, would wish to take part in the study IRAS Project ID-217 614. As soon as the patient is able to give informed consent, they will be asked if they wish to continue participating in the research study. ☐

Testing with NGPOD® will be after each placement of the feeding tube, and if appropriate each time liquids are given through the tube.

.....	.....	.....
Name of consultee Print	Date	Signature
.....	.....	.....
Relationship to patient	Date	Signature
.....	.....	.....
Taking consent – print name	Date	Signature

18.9 Patient Information Sheet – Continued participation

This information sheet will give you information about a research study taking place in the hospital. The study is named:

NGPOD® pH test compared to current NHS Trust practice to determine Nasogastric Tube (NGT) position.

Hospital nurses or Doctors will carry out the study. The study is run by researchers from the Lancashire Teaching Hospital NHS Foundation Trust.

Whilst you have been unconscious your Legal Representative/consultee agreed for you to participate in the clinical study. As you have regained consciousness we would like you to give your consent to continue taking part in this clinical trial.

This information sheet allows you to understand why the research is being performed and what it will involve for you.

Part 1 of this information sheet tells you about the purpose of this study and what will happen if you decide to take part.

Part 2 provides more details about the conduct and management of the study, and where you can get further information.

Part 1

Your medical team will have told you that as part of your treatment, you need to have a tube passed through your nose and in to your stomach. This is so the medical team can give you liquid food, water and medicine directly in to your stomach. You may already have the tube in place.

It is important the position of the tube is checked before giving you any liquid food, water or medicine, to make sure it is safe.

The way the nurse checks the position of the tube is to draw up some of the liquid in your stomach, and see if it is acidic using a pH paper which changes colour. Your stomach contents are usually acidic. Sometimes it is difficult to obtain any liquid from your stomach to do this test, so you have to be sent for a chest X-ray. This process can sometimes be time consuming and may delay you being given liquids or medicine by the tube.

New test device

This study tests a new way of checking your tube is in the correct position. The device is called NGPOD® and will test to see if the end of the tube has come into contact with the acid in your stomach. The new test will be used just after the tube is passed in to your stomach, and before you are given any liquid or medicine through the tube. It will be compared to the way the tube is usually checked. All the results will be recorded, so they can be analysed at a later date.

The new test will not be used to make a decision about giving you liquids. You will always have the usual checks at your bedside, and if those do not confirm the correct position of the tube, you will be sent for chest X-ray.

The study will also see if the number of chest X-rays used to check the position of the tube can potentially be reduced.

NGPOD® system

There are two parts to the NGPOD® system. A fibre-optic sensor and a hand held test device.

Figure 1 – The NGPOD System

The Fibre-optic sensor is threaded down the feeding tube, so the tip of the sensor is at the end of the feeding tube. The hand held test device is then connected to the connector at the end of the sensor. The nurse will press the button, and if the feeding tube has come into contact with your stomach acid, a green tick will light up. If the feeding tube has not come into contact with stomach acid, a red cross will light up.

The NGPOD® system gives YES/NO results and helps to reduce the risk of making errors reading colour changes on pH paper.

Advantages of the NGPOD® system are that it is very quick and easy for the nurse to check the position of your feeding tube, meaning that you can start liquid feeding and oral medicines without delay. It is hoped that this study will show that NGPOD® will reduce the number of chest X-rays you need to check the position of the feeding tube.

Consent form

If you decide to continue to take part in the study, a Registered Nurse or Doctor will ask you to read this leaflet. If you have any questions you can ask the nurse or doctor. When your questions have been answered and you decide to continue taking part, you will be asked to sign a consent form. The study consent form is just to say you are happy to for the nurse to test with the new device.

You will be asked to sign a separate consent form to have the tube passed in to your stomach. This is the normal procedure in this hospital.

Time taken to check your tube is in the correct position

When you have signed the consent form, and before you are given liquid food, water or medicine through the tube, the position of the tube will be checked. The first check to be carried out will be the new device, NGPOD®. The test with NGPOD® will take about 5 minutes. For the second check the nurse will try and withdraw liquid from your stomach with a syringe. This is the usual way of checking the tube is in the correct position and will take no longer than 20 minutes. If the result of the second test is not clear, then you will have a chest X-ray.

If you do not want to take part
If you do not want to take part in the study, you will not be questioned on your reasons, and your rights will be respected. Your decision will not affect any other part of your treatment.

Why have I been invited to take part?
You have been invited to take part in this study because your medical team would like to treat you with liquid food, water or medicine, given to you through a tube going in to your stomach.

You may have had a feeding tube in place for a few days, and this gives a good opportunity to test how the new device compares to normal practice.

Who else has been invited to take part?
Other patients over the age of 18 years who need to have a feeding tube, or who are already having liquids through a tube in to the stomach, are being invited to take part. There will be 4 hospitals and 100 patients in each hospital.

What will happen after the test?
Your normal treatment will continue in hospital until the next time you have liquid food, water or medication, and the test with the new device will be repeated, as the nurse or doctor checks your feeding tube is in the right place.

What are the benefits of taking part?
Taking part in research like this helps doctors and nurses develop new tests and treatments. We can only test how well new devices like this work with the help of patients.

This new device is designed to be a very quick, easy to use and an accurate way of checking the feeding tube is in the right place in the stomach. We need to check it is as good as, if not better than the current way of testing. We also want to see if we can reduce the number of times patients need a chest X-ray to check the position of the feeding tube.

If we can show the new device is quicker, easier to use and more accurate, and the NHS begin to use it, it may help to improve the care for patients and reduce cost in the NHS.

Are there any risks or discomfort involved?
You should not have any discomfort when the new device is being used.

Any risks with the use of the device have been reduced to a minimum by safety testing, checks and extensive healthy human studies. The company (NGPOD Global Ltd) records any risks and how they can be controlled in a risk management file. The safety and

performance of the device is very important and will be regularly checked throughout the study.

All NHS Trust nurses and doctors involved in the study have been fully trained to use the device. They are also trained to carry out research studies. If you have any worries or concerns about the tests, or the study, you can discuss them with the nurse, doctor or researcher at any time.

If you change your mind and want to withdraw from the research study you can do so at any time.

Part 2. Further Information

Who can I contact for more information about taking part in the study?
If you need any further information about taking part in the study, you should talk to the Registered Nurse who has invited you to take part, the senior ward nursing staff, or your hospital doctor.

Who will know I have taken part in the study?

You can tell anyone you wish about the study. It may help you to discuss your part in the study with your partner, family or friends. Only the hospital staff looking after you will have access to your hospital records and the study consent form. For the study you will have a unique study number. All other documents used for the trial do not contain your personal details, you are only known by a study number. The company who have developed NGPOD® do not see your personal details.

What will happen to data from the tests I have?

The results from the study will be recorded on a case report form. This will only have your study number not your personal details. The team at Lancaster Teaching Hospital NHS Trust will store the data anonymously for up to 10 years, and it may be used for the future development of the NGPOD® device. The results will be written down and presented as clinical papers for the medical community, and also made available to the public through the company website. www.ngpodglobal.com

Who is developing NGPOD® System?

NGPOD® is being developed by the company NGPOD® Global Limited. You can find out more about the company and their device on the website www.ngpodglobal.com

Who can I contact to find out more about the management of the study and how it is carried out?

If you have any concerns about how the study is being managed or have any further questions you should contact the Chief Investigator, Tracy Earley. Contact details are: telephone 01772 523 057; and e mail tracy.earley@lthtr.nhs.uk

What happens to my data under General Data Protection Regulation (GDPR)?

NGPOD Global Ltd is the sponsor for this study based in the United Kingdom. Lancashire Teaching Hospitals NHS Foundation Trust will be using information from you in order to undertake this study and will act as the data controller for this study. This means that the NHS Trust is responsible for looking after your information and using it properly. The NHS Trust will keep identifiable information about you 5 years after the study has finished.

Your rights to access, change or move your information are limited, as the NHS Trust needs to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, the NHS Trust will keep the information about you that has been obtained. To safeguard your rights, the NHS Trust will use the minimum personally-identifiable information possible.

You can find out more about how the NHS Trust uses your information at: https://www.lancsteachinghospitals.nhs.uk/privacy-notice The NHS Trust will keep your name, NHS number and contact details confidential and will not pass this information to NGPOD Global Ltd. The NHS Trust will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from regulatory organisations may look at your medical and research records to check the accuracy of the research study. NGPOD Global will only receive information without any identifying information. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

The NHS Trust will keep identifiable information about you from this study for 5 years after the study has finished.

Complaints
If the Chief Investigator is unable to resolve your concern or you wish to make a complaint regarding the study, please contact the Research Governance Lead at Lancashire Teaching Hospital NHS Trust.

Research Governance lead - Centre for Health Research and Innovation at Lancashire Teaching Hospitals by contacting 01772 522031.

Who should I contact if I am unhappy with my treatment and wish to make a complaint?
If you have a specific concern or query about the research you can contact the study team on the details below. For a more independent contact, you can contact the Research Governance Lead within the Centre for Health Research and Innovation at Lancashire Teaching Hospitals by contacting 01772 522031. You may also wish talk to the hospitals Patient Advice and Liaison Service (PALS) which provides support to patients, families and visitors. Hopefully, in most cases they will be able to sort out your concerns very quickly. However if you are not satisfied with the response that you receive you can make a complaint in writing. Please contact the Trust's Customer Care department on 01772 522521 or email customer.care@lthtr.nhs.uk who can they will assist you with your complaint.

Research study contact details:
Chief Investigator, Tracy Earley. Contact details are: telephone 01772 523 057; and e mail tracy.earley@lthtr.nhs.uk

Research Governance lead - Centre for Health Research and Innovation at Lancashire Teaching Hospitals by contacting 01772 522031.

Harm

In the event that something does go wrong and you are harmed during the research, you may have grounds for a legal action for compensation against Lancashire Teaching Hospital NHS Trust or NGPOD® Global Ltd, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

18.10 **CONSENT FORM – Continued participation**

Royal Preston Hospital
Sharoe Green Lane
Fulwood
Preston
PR2 9HT

Centre Number: 01
Study Number: IRAS no. 217 641
Name of Chief Investigator: Ms Tracy Earley

Participant Identification Number for this trial: .....

Title of Project: NGPOD® pH test compared to current NHS Trust practice to determine Nasogastric Tube (NGT) position.

Please initial box to indicate consent.

1. I confirm that I have read the information sheet "CF14 Patient Information Sheet – Regain Capacity" (Version 0.2) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐

3. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the Lancashire Teaching Hospitals NHS Foundation Trust, from regulatory authorities or from the NHS Trust where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐

4. I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers. ☐

5. I understand that the information held and maintained by my NHS Hospital Consultant and other central UK NHS bodies may be used to help contact me or provide information about my health status. ☐

6. I agree to continue to take part in the study IRAS Project ID-217 614. ☐

I consent to continue to take part in the study. Testing with NGPOD® will be after each placement of the feeding tube, and if appropriate each time liquids are given through the tube.

.....	.....	.....
Name of Participant - print	Date	Signature

.

.....	.....	.....
Taking consent – print name	Date	Signature