1.1 Study Title: Sprint National Anaesthesia Project (SNAP-1): Patient survey on quality of anaesthesia in UK hospitals and accidental awareness under general anaesthesia.

A 2-day 'SNAP' to survey adult patient experience on the quality of anaesthesia in UK hospitals and to investigate the incidence of accidental awareness under general anaesthesia.

1.2 Names (titles), roles and contact details:

Chief Investigator and Consultant Lead for SNAPs: Dr Ramani Moonesinghe
Trainee Lead: Dr Eleanor Walker (research fellow with the NIHR UCL/UCLH Surgical Outcomes Research Centre)

1.3 Protocol details

Version number: 1.4
Final
Date 19 March 2014

2. Signature Page

INVESTIGATOR (S)

I agree to conduct this clinical study in accordance with the design and specific provisions of this protocol and will only make changes in the protocol after notifying the sponsor.

I understand that I may terminate or suspend enrolment of the study at any time if it becomes necessary to protect the best interests of the study subjects. This study may be terminated by ***UCLH***, with or without cause.

I agree to personally conduct or supervise this investigation and to ensure that all associates, colleagues, and employees assisting in the conduct of this study are informed about their obligations in meeting these commitments.

I will conduct the study in accordance with Good Clinical Practice, the Declaration of Helsinki, and the moral, ethical and scientific principles that justify medical research. The study will be conducted in accordance with all relevant laws and regulations relating to clinical studies and the protection of patients.

I will ensure that the requirements relating to Human Research Ethics Committee (HREC) review and approval are met. I will provide ***UCLH*** with any material which is provided to the HREC for Ethical approval.

I agree to maintain adequate and accurate records and to make those records available for audit and inspection in accordance with relevant regulatory requirements.

I agree to promptly report to the HREC any changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the research without HREC approval, except where necessary to ensure the safety of study participants.

Dr SR Moonesinghe	_	19 March 2014
Name	Signature	Date

3. Contents Page

4. List of Abbreviations

SNAP – Sprint National Anaesthesia Project

5. Summary

The study involves asking adult (18 years or over) hospital patients, within 24 hours of having had an operation, to complete 2 short questionnaires. In addition, basic demographic data for each patient/procedure will be recorded by an anaesthetist.

The first questionnaire (Bauer Patient Satisfaction questionnaire), asks the patients 15 questions about potential anaesthesia related discomfort (e.g. pain, nausea, cold) and their overall satisfaction with anaesthetic care.

The second questionnaire (Modified Brice questionnaire), attempts to identify patients who may have had memories of their operation i.e. accidental awareness under anaesthesia.

The objectives of this study are twofold. The primary outcome is to establish a national benchmark for patient satisfaction after anaesthesia, using a validated patient reported outcome measure.

The secondary objective is to establish an estimate of accidental awareness during general anaesthesia in the UK population. Accidental awareness has previously been thought to be a rare event, but one with potentially long-standing and significant consequences for patients who experience it.

6. Background

6.1 Literature Search and Review

In order to improve quality of patient care in hospitals, all areas of care must be understood from the patient perspective. In order to do this, a tool such as a questionnaire must be used so that all patients are asked the same questions. Furthermore, responses need to be in the form of ratings (numbers) rather than free text so that quantitative comparisons can be made between groups. A recent systematic review of patient satisfaction questionnaires concluded that the Bauer questionnaire (Bauer et al, 2001) was amongst the best for the perioperative assessment of satisfaction (Barnett et al, 2013). The Modified Brice questionnaire has previously been used and validated in a large randomized control trial (Avidan et al, 2009).

References:

Bauer M, Böhrer H, Aichele G, Bach A, Martin E. (2001) Measuring patient satisfaction with anaesthesia: perioperative questionnaire versus standardised face-to-face interview. ActaAnaesthesiol Scand. 2001 Jan;45(1):65-72

Barnett S, Alagar R, Grocott MP, Giannaris S, Dick JR, Moonesinghe SR. (2013) Patient Satisfaction Measures in Anesthesia – Qualitative Systematic Review. Anesthesiology 2013; 119:452-78

Avidan MS, Palanca BJ, Glick D, Jacobsohn E, Villafranca A, O'Connor M, Mashour GA; BAG-RECALL Study Group (2009) Protocol for the BAG-RECALL clinical trial: a prospective, multi-center, randomized, controlled trial to determine whether a bispectral index-guided protocol is superior to an anesthesia gas-guided protocol in reducing intraoperative awareness with explicit recall in high risk surgical patients. BMC Anesthesiol.;9:8. doi: 10.1186/1471-2253-9-8.

6.2 Justification

Exact figures of the risk of dying during a general anaesthetic are not available; however, if you are a healthy patient, who is having non-emergency surgery, death is very rare and has been estimated to be around 1 death per 100,000 anaesthetics. In contrast to this, the incidence of specific anaesthesia related morbidity is much higher. For example, Bauer and colleagues (Bauer 2001) found that 75% of patients experienced drowsiness (36% said this was "severe"), 55% had pain at the surgery site (nearly 20% classified this as "severe"), and >50% had thirst (with about 17% saying "severe"). When it is considered that some 2.9 million general anaesthetics are given in the UK every year (Woodall & Cook, 2011), then it becomes clear that the impact of identifying and addressing areas of frequent discomfort is vast.

The scientific justification for surveying all hospitals possible is so that we can, with as much authority as possible, comment on the patient experience after anaesthesia across England, N Ireland, Scotland and Wales.

By surveying patients across the UK over a 2-day period we hope to obtain data from several thousand operations. We believe that asking colleagues to collect data over this short period of time will ensure that the project is feasible whilst also resulting in a meaningful volume of data to analyse.

Woodall NM and Cook TM (2011) National census of airway management techniques used for anaesthesia in the UK: first phase of the Fourth National Audit Project at the Royal College of Anaesthetists. Br. J. Anaesth. 106 (2): 266-271.doi: 10.1093/bja/aeq339

7. Specific aim(s) of the study

The principal objective is to establish a national benchmark of patient satisfaction after anaesthesia across the UK. This may identify particular aspects of anaesthesia-related discomfort occurring in certain patient populations or after specific types of surgery and anaesthesia. It will allow hospitals to evaluate the service they are currently delivering, comparing themselves against others, and may in the future, serve as a reference on which to base the effectiveness of changes made to delivery of their anaesthetic services.

The secondary objective is to establish an estimate of accidental awareness during general anaesthesia in the UK population. This part of the study will complement the ongoing work by the 5th National Audit Project (NAP-5) investigating awareness under anaesthesia.

8. Study design

The study will run for 2 days and all NHS hospitals with anaesthetic departments will be invited to participate.

Each hospital taking part will have nominated anaesthetic consultants and trainees who will be responsible for data collection and the administration of the questionnaires to all the consenting patients after they have had their operation.

Each potential participant will be provided with a patient information leaflet on admission to hospital, prior to their surgery, so that they have time to consider the information provided. The leaflet will detail the background and rationale of the study and information as to where they can find out further details online, as well as how they can sign up to the project website if they wish to be notified of the outcomes of the study. It will be explained that they are entitled to refuse if they do not wish to take part and this will have no impact on the care they receive. If they agree to complete and return the questionnaires, this will be taken as implied consent to participate.

The anaesthetist responsible for the care of each consenting patient will complete a form with basic patient demographic information (e.g. age, type of surgery, type of anaesthesia) during the operation. After completion of the surgery and full recovery from anaesthesia, patients will be approached to complete 2 short (1 double sided piece of A4) paper based questionnaires and told that this should take no more than 10 - 15 minutes in total. Patients undergoing day-case procedures will be asked to complete the questionnaires before they are discharged home on the day of their surgery, and those who remain as in-patients in hospital will be approached within 24 hours of their operation once they are on a ward. The date and time of completion of the

questionnaires will be recorded on the forms themselves. If they need help understanding the questionnaire or physically filling it in, a local investigator will be available to help them do so.

The completed questionnaires will be taken directly to a secure location accessible by the local study leader who will enter the data from the paper questionnaire via a secure web-based portal onto the study database (the website and database are being developed by Netsolving Ltd (www.netsolving.com) who have track record in delivering secure websites / databases for NHS based medical research and audits, e.g. the National Emergency Laparotomy Audit; http://www.nela.org.uk/). Each patient entry on the database will generate a unique identifier; local investigators will be asked to keep a log of the unique identifiers linked to local hospital identification numbers. No patient identifiable data will be transferred outside the local hospital environment either electronically or on paper.

The study database will be closed for data entry two weeks after the study completion date. After this time, the anonymised responses from hospitals across the U.K. will be analysed by a team of researchers based at University College Hospital in London.

Analysis of patient satisfaction data:
Cases will be analysed according to the type of surgery and anaesthesia, so as to provide an overall picture of the levels of satisfaction after specific procedures and associated with different types of anaesthesia. Results will be reported at national level, but individual Trusts will also be provided with data on how their outcomes compare with the national average.

Analysis of Brice Questionnaires
These questions will be analysed so as to determine the incidence of suspected awareness under anaesthesia nationally. If cases, which may describe accidental awareness under general anaesthesia are identified by the researchers, they will refer these reports to an expert panel of assessors (consultant anaesthetists and lay representatives who have been members of the project board of the 5th National Audit Project of the Royal College of Anaesthetists, which focused on accidental awareness under anaesthesia). If at this stage there is still concern that the patient may have been "aware", then the local investigators will be contacted, and asked to break the locally held code in order to identify the patient. The local investigators will then be responsible for contacting the patient and following up this potential case of awareness according to their local guidelines.

9. Study group

Patients undergoing surgery in NHS hospitals throughout the UK on Tuesday May 13th and Wednesday May 14th 2014.

9.1 Inclusion criteria:
All adult (≥18 years) patients undergoing any type of surgery in an operating theatre.

9.2 Exclusion criteria:
Patients under the age of 18 years.
Patients unable to understand spoken or written English.
Obstetric patients.
Patients too unwell or confused to be able to complete the questionnaire.
Patient refusal.

10. Recruitment or choosing participants

Patients identified by local investigators (consultant and trainee anaesthetists) from operating department lists on the day of surgery. All eligible patients will be given a patient information sheet before having their operation. If they agree to take part, they will be visited by a local investigator within 24 hours of having had their operation and given two questionnaires to complete.

11.1 Data to be collected

Basic demographic information to be completed by the anaesthetist responsible for the patient in the operating theatre. *See Appendix 1.*

2 questionnaires to be completed by each consenting patient:

- Bauer Patient Satisfaction questionnaire. *See Appendix 2*
- Modified Brice questionnaire. *See Appendix 2*

11.2 Data handling and record keeping

The completed questionnaires will be taken directly to a secure location accessible by the local Principal Investigator who will enter the data from the paper questionnaire via a secure web-based portal onto the study database (the website and database are being developed by Netsolving Ltd (www.netsolving.com) who have track record in delivering secure websites / databases for NHS based medical research and audits, e.g. the National Emergency Laparotomy Audit; http://www.nela.org.uk/). Each patient entry on the database will generate a unique identifier; local investigators will be asked to keep a log of the unique identifiers linked to local hospital identification numbers. No

patient identifiable data will be transferred outside the local hospital environment either electronically or on paper.

The log is to be held locally until 5 years after study closure at which point it will be destroyed confidentially.

The study database will be closed for data entry two weeks after the study completion date. After this time, the anonymised responses from hospitals across the U.K. will be analysed by a team of researchers based at University College Hospital in London.

11.3 Data Archiving

UCLH and each participating site recognise that there is an obligation to archive study related documents at the end of the study (as such end is defined within this protocol). The Chief Investigator confirms that he/she will archive the study master file at UCLH for 5 year from the study end. The Principal Investigator at each participating site agrees to archive his/her respective site's study documents for 5 years from the study end.

12. Statistical considerations

No statistical power calculation has been performed. It is a qualitative study with the aim of capturing data from as many as the adult patients undergoing surgery during the study period as possible. Sample size therefore estimated, knowing that 3 million general anaesthetics are administered in the UK each year.
As a qualitative study it will only assess frequencies and associations.

13. Compliance

13.1 Subject compliance

We intend to use information from the Hospital Episode Statistics database to estimate a value for the denominator of patients undergoing operations in the selected 2-day period. In addition we will ask participating sites to provide us with the number of eligible subjects in their institution during the study period in order to estimate the response rate.

13.2 Withdrawal of subjects

Subjects will be able to withdraw at any time up until they have completed the questionnaires and handed them back to the local study investigators. If after this time they change their mind about their participation, they will need to contact the local investigators who would then either return or confidentially destroy their questionnaire responses and demographic information. Given the simple questionnaire based nature of the study it is thought unlikely that a significant proportion of subjects will choose to withdraw following completion of the questionnaires.

14. Ethical considerations

The project is being submitted for ethical review via the IRAS system.

The questionnaires do not include topics that might be sensitive, embarrassing or upsetting. They are very short and have been designed with the intention that they do not present any significant risks or burdens to the patient. However, the patient is under no obligation to participate and complete the questionnaires if they do not wish to.

The only issue of 'adverse effects' may be that by encouraging a patient to recall if they dreamed or not during the operation, we may trigger adverse memories at a sensitive time. However, given that accidental awareness is thought to be so rare (we have been involved in previous studies) and also given that this questionnaire has been used before with no report of ill effects, we are confident that the risk of stress induced by the questions is extremely low. In fact, it could certainly be considered advantageous to address this issue whilst in the care of the hospital environment, rather than to allow symptoms of illness, discomfort or adverse memories to go unexplored and unexplained or to emerge at a later time.

15. Finance

Funding in place from the National Institute for Academic Anaesthesia.

16. Reporting and Dissemination

We intend to present the results online via the study website, in peer reviewed scientific journals and in the form of conference presentations.

Information will be provided in the patient information sheet describing how they will be able to register with the study website so that they can be informed of the findings of the study when they are available.

Appendix 1: SNAP-1: Patient demographics (to be completed at time of surgery)

*See below for definitions for questions marked **

Patient name:

Hospital number: **DOB:** **Age:**

SNAP-1 unique identifier (generated once uploaded to web tool): _____

Date of operation: 13/05/14 ☐ 14/05/14 ☐ **Sex:** Male ☐ Female ☐

Operation name:

_____

ASA grade: 1☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐

Surgical urgency:* Elective ☐ Expedited ☐ Urgent ☐
Immediate ☐

Surgical severity:* Minor ☐ Intermediate ☐ Major ☐ Complex ☐

Comorbidities:

Congestive Cardiac Failure:*	Yes ☐	No ☐
Previous stroke / TIA:	Yes ☐	No ☐
Cancer within past 5 years:	Yes ☐	No ☐
Obesity (BMI ≥ 30):	Yes ☐	No ☐

Is the patient on long-term analgesics or benzodiazepines?

Opiates/Opioids: Yes ☐ No ☐ Benzodiazepines: Yes ☐ No ☐
NSAIDs / COX inhibitors: Yes ☐ No ☐ Neuropathic pain meds: Yes ☐No ☐

Congestive cardiac failure: history of congestive heart failure, pulmonary oedema, or paroxysmal nocturnal dyspnoea; physical examination showing bilateral rales or S3 gallop; or CXR showing pulmonary vascular redistribution

Surgical severity:
Minor: e.g. carpal tunnel, MUA, arthroscopy: procedure generally lasts <30min
Intermediate: e.g. hernias, ACL reconstruction, varicose veins: procedure generally lasts <1 hour
Major: e.g. lap cholecystectomy, primary joint replacement
Complex: e.g. open cavity surgery, major laparoscopic surgery, organ resections, bilateral or revision joint replacements

Surgical urgency:
Immediate: immediate life, limb or organ-saving intervention. Normally within minutes of decision to operate.
Urgent: surgery for acute onset / clinical deterioration of potentially life-threatening conditions that may threaten survival of limb or organ; fixation of many fractures & for relief of pain / distressing symptoms. Normally within hours of decision to operate.
Expedited: early treatment for a condition not immediately threatening to life /limb /organ survival. Normally within days of decision to operate.
Elective: intervention booked in advance of routine admission to hospital. Timing to suit patient, hospital & staff.

Perioperative care:

Anaesthetic induced by (please tick all that apply)**:**

Consultant ☐ Trainee/Trust grade junior ☐ Non-consultant grade senior ☐ PA(A) ☐

Induction of GA: Inhalational ☐ Intravenous ☐ Not GA ☐

Where did induction take place? Anaesthetic room ☐ Operating theatre ☐

Maintenance intraoperative anaesthesia (please tick all that apply)**:**

GA ☐ Inhalational anaesthetic ☐ TIVA ☐

Epidural ☐ Spinal ☐ Combined spinal & epidural ☐

Surgical infiltration with LA ☐ Nerve block ☐

Awake/light sedation (response to speech) ☐

Deep sedation (no response to speech, response to physical stimulus) ☐

Neuromuscular blocking agent used? Yes ☐ No ☐

Induction and intraoperative analgesia administered (please tick all that apply):

Alfentanil ☐ Fentanyl ☐ Morphine ☐ Remifentanil ☐

Paracetamol ☐ NSAID ☐ Ketamine ☐ Clonidine ☐

Other (please specify):

Antiemetic administered (please tick all that apply):

5-HT_3 antagonist ☐ Dexamethasone ☐ Cyclizine ☐ Prochlorperazine ☐

Droperidol ☐ Other (please specify):

Monitoring used:

End tidal anaesthetic agent concentration: Yes ☐ No ☐ Not applicable ☐

Bispectral Index (BIS)/E-Entropy/Narcotrend used: Yes ☐ No ☐ Not applicable ☐

Duration of surgery (not including anaesthesia time):

<30min ☐ 30m-1h ☐ 1-2h ☐ >2h ☐

Postoperative destination/ level of care:

Home (day case procedure) ☐ Inpatient ward ☐

High Dependency Unit (Level 2) ☐ Intensive Care Unit (Level 3) ☐

Many thanks for taking the time to complete this information.

Appendix 2: Bauer patient satisfaction and Modified Brice Questionnaires

Today's date:

At any stage after your operation have you had the following (please tick one box for each question 1-10):

	No	Yes, moderate	Yes, severe
1. Drowsiness	☐	☐	☐
2. Pain at the site of surgery	☐	☐	☐
3. Thirst	☐	☐	☐
4. Hoarseness	☐	☐	☐
5. Sore throat	☐	☐	☐
6. Nausea or vomiting	☐	☐	☐
7. Feeling cold	☐	☐	☐
8. Confusion or disorientation	☐	☐	☐
9. Pain at the site of the anaesthetic injection	☐	☐	☐
10. Shivering	☐	☐	☐

Satisfaction with anaesthesia care (please tick one box for each question 11-16):

11. How satisfied were you with the information you were given by the anaesthesist before the operation?

☐	☐	☐	☐
Very satisfied	**Satisfied**	**Dissatisfied**	**Very dissatisfied**

12. How satisfied were you waking up from anaesthesia?

☐	☐	☐	☐
Very satisfied	**Satisfied**	**Dissatisfied**	**Very dissatisfied**

13. How satisfied have you been with pain therapy after surgery?

☐	☐	☐	☐
Very satisfied	**Satisfied**	**Dissatisfied**	**Very dissatisfied**

14. How satisfied were you with treatment of nausea and vomiting after the operation?

☐	☐	☐	☐
Very satisfied	**Satisfied**	**Dissatisfied**	**Very dissatisfied**

15. How satisfied were you with the care provided by the department of anaesthesia in general?

☐	☐	☐	☐
Very satisfied	**Satisfied**	**Dissatisfied**	**Very dissatisfied**

16. Would you recommend this anaesthetic service to friends and family? **YES**☐ **NO**☐

17. Were you expecting to have a general anaesthetic (be completely asleep) for this operation? No ☐ Yes ☐

18. What is the last thing you remember before going to sleep (please tick one box)?

-Being in the pre-operative area	☐	-Seeing the operating room	☐
-Being with family	☐	-Hearing voices	☐
-Feeling mask on face	☐	-Smell of gas	☐
-Burning or stinging in the IV line	☐	-Not applicable	☐

-Other [Please write below]:

_____

19. What is the first thing you remember after waking up (please tick one box)?

-Hearing voices	☐	-Feeling breathing tube	☐
-Feeling mask on face	☐	-Feeling pain	☐
-Seeing the operating room	☐	-Being in the recovery room	☐
-Being with family	☐	-Being in the intensive care unit	☐
-Nothing	☐	-Not applicable	☐

-Other [Please write below]:

_____

20. Do you remember anything between going to sleep and waking up (please tick box)?

-No ☐

-Yes: -Hearing voices	☐	-Hearing events of the surgery	☐
-Unable to move or breathe	☐	-Anxiety/stress	☐
-Feeling pain	☐	-Sensation of breathing tube	☐
-Feeling surgery without pain	☐	-Not applicable	☐

-Other [Please write below]

_____

21. Did you dream during your procedure (please tick box)?

-No ☐ -Yes ☐

-What about [Please write below]:

_____

22. Were your dreams disturbing to you (please tick box)?

-No ☐ -Yes ☐

23. What was the worst thing about your operation (please tick box)?

-Anxiety	☐	-Pain	☐
-Recovery process	☐	-Unable to carry out usual activities	☐
-Awareness	☐	-Other [Please write below]:	

Thank you for taking the time to complete this questionnaire!