1.Protocol Details

1.1 Protocol Title:

Capnography Variation Survey UK - A Multicentre Survey of Waveform Capnography in the United Kingdom (CAVA - UK)

1.2 Names (titles), roles and contact details of:

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1.3 Contributing Committees

SQUARESNET (SESSA Quality improvement, Audit and Research Network)
RAFT (Research and Audit Federation of Trainees)

Version History

Version 1.1	Original

Version 1.2	• Contributor Details updated
	• Specified date to be included in protocol for completion
	• Names of forms changed to avoid confusion
	  ○ Form A (Clinical Area)
	  ○ Form B (Governance Form)
	• Updates to collection forms:
	  ○ Site Enrollment:
	  ▪ PI to be replaced with lead investigator for simplicity
	  ▪ Does CD consent to enrollment?
	  ○ Site Governance:
	  ▪ Questions 6 and 10 removed from this version
	  ▪ Question 9:to best of knowledge
	  ○ Clinical Area
	  ▪ Specified out of circulation machines may be ignored.
	  ▪ Specified input of machines used in each area
	  ▪ Removed question regarding whether screen could be standardised – committee will determine based on inputs
	  ○ Investigator Consent
	  ▪ Specify warning regarding name spelling

Version 1.3	Removal of secondary aims to comply with ACCORD Redesign of surveys to simplify surveys Appendixes updated to comply
Version 1.4	Further alterations to the enrollment form and others to simplify hospitals vs departments and divide areas into health boards rather than LETBs/Deaneries
Version 1.5	Final Check of document prior to publication via RAFT and Website. Comments by ML resolved Surveys updated in appendix to latest version electronically -removed questions for supporting TRN with CD form -removed y/n answer to inclusion in database of contributors.
Version 1.6	Updated collection endpoint as 29th September.
Version 1.7	Updated area collection form to allow clarification of some study terminology and correct an error (screen duplication or mirroring data is no longer being recorded).

Table of Contents

2. List of abbreviations

AoA: Association of Anaesthetists

AER: Adverse Event Review

CI: Critical Incident

CVP: Central Venous Pressure

ECG: Electrocardiogram

GUI: Graphical User Interface

HCI: Human Computer Interface

HMI: Human Machine Interaction

HFE: Human Factors and Ergonomics

IBP: Invasive Blood Pressure

NIBP: Non-Invasive Blood Pressure

QI: Quality Improvement

RAFT: Research Audit Federation of Trainees

RCoA: Royal College of Anaesthetists

SALG: Safe Anaesthesia Liaison Group

Sats: O2 Saturation

SQuAResNet: Southeast Scotland Quality Audit and Research Network

3. Summary/ Synopsis

Title	Capnography Variation Survey UK - A Multicentre Survey of Waveform Capnography in the United Kingdom (CAVA - UK)
Protocol Short Title	CAVA UK
Protocol Version number and Date	V1.7 7 September 2024
Study Duration	28 Days
Lead Site	Royal Infirmary Edinburgh, NHS Lothian
Chief Investigator	Dr Andrew Shepherd
Purpose of service evaluation	Identify current display of waveform capnography
Primary objective	Identify the current variation in waveform display across the UK
Secondary objective	Identify compliance with SALG statement on waveform capnography.
Number of Contributors	Potentially 277 Anaesthetic Departments – aim capture of greater than 75%
Study Type	Service Evaluation/ Audit
Endpoints	Completed Data collection of all enrolling departments
Main Inclusion Criteria	Any clinical area that: Performs anaesthetic and critical care services. Uses waveform capnography
Data collected/storage (if applicable)	Data will be collected using Microsoft Forms and stored to an NHS Lothian IT account. No patient details of any kind will be collected.

4. Introduction

Anaesthesia has seen vast improvements in delivering safe patient care throughout its history such that now, the vast majority of anaesthetic interventions occur without incident. In some cases, however, they may occur with catastrophic consequences. Waveform capnography is an example of a technology that has contributed to an improved patient safety and its adoption is now mandated by the AoA for all general anaesthesia. Further adoption for use with procedural sedation is argued by many as "unanswerable" (1).

Greater understanding of human factors in relation to anaesthetic error was demonstrated with the publication of the Anaesthetists Non-Technical Skills Framework (2003)(8). This categorises four domains of human performance in relation to tasks: Task management, Team working, Situation awareness and Decision Making (9). Deficiencies in situational awareness are a contributing factor in 80% of anaesthetic adverse events. Perception of the environment is therefore crucial to the formation of safe decision making (10). Failure to interact correctly with our graphical user interfaces (GUI) or "monitors" (for the data we require) may therefore contribute to disastrous consequences and contribute to errors in situational awareness and decision making. This issue has been raised in multiple adverse event reviews (AER's) most recently the tragic case of Ms Logsdail (2) (11). Furthermore, the variation in this crucially important monitoring would not be acceptable in any other.

Since the 1990's and the advent of integrated graphical displays, when computers became sophisticated enough to allow real time imagery, multiple studies have been conducted showing improvement in reaction times, accuracy and cognitive loading when using a graphical, noised aided GUI over conventional numerical display units. However, little evidence exists to favour particular designs (12). In the absence of solid evidence to form robust guidance, variation developed in display setup between machines, theatres, and departments. Subsequent variation in manufacture and implementation of waveform capnography – despite its critical importance in airway management therefore represents a threat to patient safety due to misinterpretation of waveforms. It is a recurring and persistent theme in critical incident and AER reports.

Recent reviews and comments in periodicals call for human factors and ergonomic work to engineer solutions to these problems. A move towards this is seen with recent AoA guidelines on ergonomics within the theatre environment and an increasing body of research on optimal anaesthetic room design alongside a growing integration of human factors and ergonomics (HFE) groups with healthcare (6) (15) (2) (16). Implementation of human factors into other similar "screen heavy industries" such as aviation, oil and gas, nuclear energy, manufacturing, militaries, or transportation has occurred with remarkable success in improving safety. The degree of variation in critical information would not be acceptable in such comparative sectors.

In response to a recent coroners report the Safe Anaesthesia Liaison Group (SALG) underwent a Delphi process to guide a recommendation for standardisation of waveform capnography. They have since released a statement advising that capnography be displayed as a solid area graph, white in colour and at the bottom of the displaying screen (1). This is to date the first recommendation from a national body aiming to standardise out graphical user interfaces.

We aim to ascertain the degree of variation in waveform capnography morphology in the UK, the compliance with this new SALG best practice statement and the governance of waveform capnography between departments in the UK.

5.Theory and Aims

5.1 Theoretical Framework

Errors in data analysis in healthcare are frequent and have negative consequences on delivery of patient care. This is particularly true of waveform capnography given its importance in airway management.

A lack of user interface guidance has led to variation in displays between and within departments. Consistency of display has been recognised as incredibly important in other industries with multiple reports commenting on reducing variation as a route to improve safety. With such universal importance placed on maintaining consistency in other industries this has been chosen for investigation within a healthcare setting.

5.2 Survey Question/Aim(s)

Primary:

- To identify the capnography waveforms utilized in anaesthesia practice across the UK.

Secondary:

- To determine what proportion of machines, comply with SALG standards.

6. Survey Design

6.1 Survey Design

CAVA-UK aims to provide a multicentre, prospective census of capnography variation in all 277 anaesthetic departments in the UK. To do so the following will be created:

1. Four structured questionnaires via Microsoft Forms:
    - Site enrolment form
    - Local governance consent form (FORM A)
    - Clinical waveform morphology and monitoring practices form (FORM B)
        - To be used several times (in each clinical area for each enrolling centre)
    - Area Investigator form
2. A comprehensive survey instruction set and standard operating procedure.
3. A webpage hosting material for enrolment.

7. Sample Selection:

1. Inclusion criteria any clinical area where:
    i. Anaesthesia or sedation is conducted.
    ii. Capnography waveform is used.
2. Aim distribution to cover all 277 anaesthetic centres with an anticipated response rate of 75%.
3. Distribute the survey via an enrolment form to clinical directors through multiple channels, including the Research and Audit Federation of Trainees (RAFT), Difficult

Airway Society (DAS), Association of Anaesthetists of Great Britain and Ireland (AAGBI) and Safe Anaesthesia Liaison Group (SALG).

4. After enrolling each centre is administered data collection forms and investigator forms to collect key data points.

8. Data

8.1 Data Collection Procedure

1. Participating centres enrol via MS Forms site enrolment form that consents to data collection within each department.

2. Distribute Form 1 and 2 to each participating centre.

3. Select data collection time period (September 9th - 29th 2024)

4. Compile the survey responses automatically in a structured dataset electronically using Microsoft Forms Survey via NHS Lothian account.

5. Collect names and contact details of contributing data collectors via investigator form with consent to be named as contributors in any subsequent publication or presentation.

8.2 Data Points

1. Clinical Area Form Questions regard waveform morphology and variation in each clinical setting:
   - Clinical Site Details: Deanery, Site, Clinical Area
   - Different Capnography morphological variants and quantities
     - Colour
     - Screen position.
     - Morphology
   - Equipment used and limitations.
     - Could display be standardised if desired?
     - What equipment in use?

2. Governance Form Questions within each department:
   - Region and site details
   - Consent to data collection
   - Awareness of SALG standard on waveform capnography

8.3 Data Handling

All study investigators are familiar with National Institute of Health Research (NIHR) Good Clinical practice procedures. No patient records will be accessed, and no patient data stored. Collected data will be treated with the same confidence and stored on an NHS Lothian server for the duration of the study.

Individual regions will be posted their own data as part of the study for their own internal use.

Data will be stored indefinitely after collection for future use in audit or standardisation work.

8.4 Data Analysis

1. Data analysis will be conducted using statistical analysis software: R Studio and associated data analysis libraries.

2. Analysis of the data using appropriate statistical methods

3. Conduct subgroup analyses to explore variations within theatres, departments, and regions.

4. Generate clear and concise summary statistics and visualisations to present the findings.

9. Ethical Considerations:

1. Research ethical and Caldicott approval is not required for format of this survey. This has been advised by NHS Lothian Research Governance department: ACCORD.

2. Clearly explain the purpose and nature of the study to participating centres including our intention to publish or present the findings.

3. Consent of participants to be included as named contributors.

10. Limitations:

1. Recognise any potential limitations of the study, such as selection bias due to voluntary participation or incomplete representation of all anaesthesia departments in the UK.

11. Dissemination:

1. Prepare a comprehensive research report highlighting the findings of the study.

2. Submit the research report for publication in peer-reviewed journals.

3. Present the results at relevant conferences or symposia.

Appendix 1: Site Enrolment Form

CAVA UK Site Enrolment Form

This form is used to enrol each anaesthetic department to CAVA UK for further dissemination of survey materials.
Most hospitals will have a single department with unified governance. In some cases, however, a single hospital site may have multiple governance teams.

For example, the Royal Infirmary of Edinburgh has a "Main" department covering several specialties but also a Paediatric Department run by a different governance team. In this case two enrolment forms will be required.

Please agree division of departments locally prior to enrolment to avoid duplication.

Many thanks for your interest,

CAVA UK Team

1. Site Lead Investigator Name

Enter your answer

2. Site Lead Investigator Email

Enter your answer

3. Name of Hospital

Enter your answer

4. Name of Trust/ Health Board

Enter your answer

5. Supporting Regional Trainee Research Network (If Applicable)

Enter your answer

Appendix 2: Site Clinical Director Form

CAVA Survey UK Site CD Form

Governance surrounding waveform capnography at your site

1. Name of Department Lead

Enter your answer

2. Hospital

Enter your answer

3. Health Board or Trust

Enter your answer

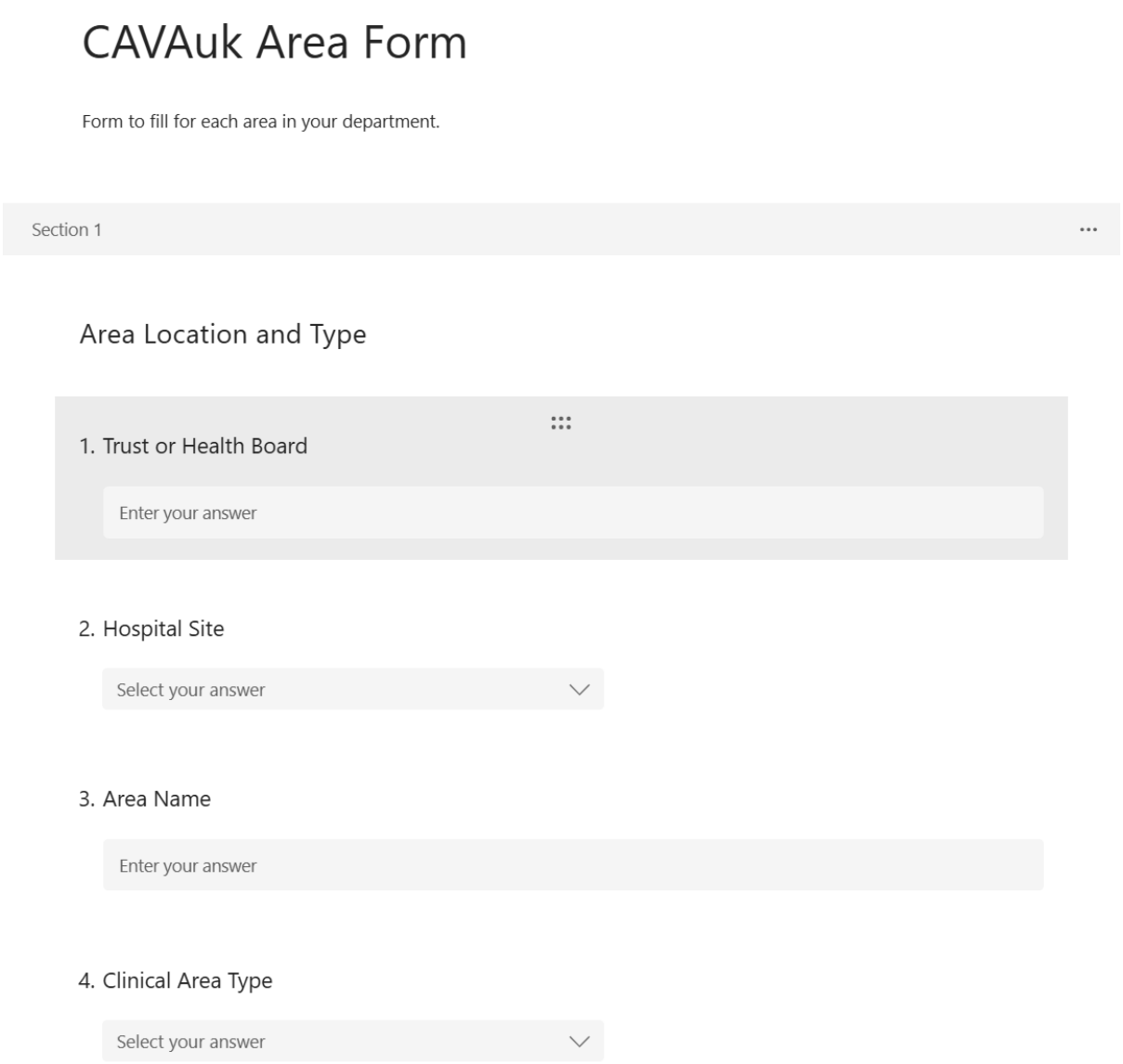
4. Are you/ were you aware of the SALG statement on waveform capnography standardisation?

- ◯ Yes
- ◯ No

5. Do you consent to data collection in your department and for subsequent publication of any results?

- ◯ Yes

Appendix 3: Clinical Area Form



Section 2

Capnography Used

Where two variants are used at the same station please use the ventilator display as Variant 1. Any duplication should be logged as another variant.

5. Variant 1: (e.g 32 RAB)

Enter your answer

6. Variant 2: (e.g. 21 CLT or N/A)

Enter your answer

7. Variant 3: (e.g. 5 GrAM or N/A)

Enter your answer

8. Other Variants: (please state numbers of machines and waveform code or NA)

Enter your answer

9. How many machines display waveforms identical in morphology to the CO2 waveform?
(e.g Pressure/ Volume/Agent)
(none = 0)

Enter your answer

Section 3

Capnography Display Equipment Log

To better understand the hardware and software limitations across the UK please include the names of machines used in this location and whether they can be modified to the SALG standard.

11. Capnography Display Equipment and numbers used (e.g.) 12DraegerPrimus

Enter your answer

Appendix 4: Investigator Form

Cava UK Investigator Form

To compile the names of all contributors with their consent.

PLEASE DOUBLE CHECK ALL SPELLINGS! Names as given will be published!

1. Name of Investigator

Enter your answer

2. Email Address

Enter your answer

3. Lead Investigator at Site?

- ◯ Yes
- ◯ No

4. I consent to my name being listed as a contributor to any subsequent academic material

- ◯ Yes