Study Protocol

Australasian MARS:

Australasian **M**ulticentre **A**spiration **R**isk **S**tudy

A pragmatic, multicentre observational cohort study comparing the incidence of pulmonary aspiration in hospitals with liberal (Sip Til Send) versus restrictive (usual care) preoperative fluid fasting

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Ethics Approval: **Australia -** Townsville Hospital Human Research Ethics Committee. HREC Reference: HREC/2025/QTHS/115991
Recognised by all Australian hospitals through the national mutual acceptance program.

New Zealand - Health and Disability Ethics Committees.
HDEC reference: 2025 EXP 22462.
Recognised by all New Zealand hospitals.

This study will be conducted in compliance with the Australian NHMRC National Statement on Ethical Conduct in Human Research 2023 and the New Zealand National Ethical Standards for Health and Disability Research and Quality Improvement and State and Commonwealth legislation 2019. All investigators will adhere to the standards of the Australian Health Practitioner Regulation Agency and Medical Council of New Zealand as well as their professional codes of conduct. Each participating centre will comply with all relevant local institutional policies and procedures pertaining to research.

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1. ADMINISTRATIVE INFORMATION

1.1 Co-ordinating centre

Department of Anaesthesia and Perioperative Medicine,
Cairns and Hinterland Hospital and Health Service.
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1.2 Participating centres

Current as of date of file version.

State	Hospital
NSW	Blacktown
NSW	Mount Druitt
NSW	Prince of Wales
NSW	Sydney Childrens
NSW	St Vincents
NSW	Royal North Shore
NSW	Tweed Valley
NSW	Concord Repatriation General
NSW	St George
NT	Palmerston Regional
NT	Royal Darwin
NZ	Te Toka Tumai - Auckland City
NZ	Greenlane Clinical Centre
NZ	Waitaha – Canterbury
NZ	Starship Children’s
NZ	Dunedin
NZ	Middlemore
QLD	Caboolture
QLD	Cairns
QLD	Hervey Bay
QLD	Mackay Base
QLD	Maryborough
QLD	Queen Elizabeth II Jubilee
QLD	Queensland Children's
QLD	Redcliffe
QLD	Redland
QLD	Royal Brisbane and Women’s
QLD	Townsville University Hospital
QLD	Prince Alexandra
QLD	Logan
SA	Flinders Medical Centre
SA	Lyell McEwin
SA	Port Augusta
SA	Modbury
SA	Noarlunga
SA	Royal Adelaide
VIC	Northeast Health Wangaratta
VIC	Sandringham
VIC	The Alfred
VIC	The Royal Children's
VIC	Northern Health (Epping)
VIC	Royal Melbourne
VIC	The Austin
WA	Joondalup
WA	Perth Children’s
TAS	Royal Hobart

1.3 Roles and responsibilities

1.3.1 Lead investigators

Dr Phuong Markman FANZCA and Dr Ruth Blank FANZCA. Cairns Hospital, Australia.

Roles: Conception of the study, study protocol development, ethics approval for Australia, management of funds, recruitment of and support for participating centres, assisting Australian and New Zealand participating centres with Site Specific Assessments or Locality Approvals, data collection & analysis, manuscript development.

1.3.2 Central study co-ordinator (research nurse)

Funding pending. Cairns Hospital, Australia.

Roles: Data collection, data management, communication with participating hospitals.

1.3.3 New Zealand co-ordinator

Dr Alec Beresford FANZCA. Christchurch Hospital, New Zealand.

Roles: Ethics approval for New Zealand, assisting New Zealand participating centres with Locality Authorisation procedure.

1.3.4 Statistician

Dr Peter Howley, PhD (Statistics) Bmath Hon 1 (Statistics).
Accredited statistician, Statistical Society of Australia.
Former Professor of Statistics (-2022), University of Newcastle.

Roles: study protocol development, data analysis, manuscript development.

2. BACKGROUND

Preoperative fasting is essential to minimise the risk of aspiration and 2 hours of fluid fasting in adults and 1 hour in children has been the standard recommendation [1]. However, with unpredictable theatre schedules, patients commonly end up fasting from fluids for 7 to 13 hours [2]. Prolonged fluid deprivation can lead to thirst, nausea, anxiety, difficult IV access, hypotension during anaesthesia, and hypoglycaemia. Since 2022, a new program called "Sip Til Send" (STS) has been implemented across Australasia and in centres around the world, allowing patients to sip clear fluid until they are transported to theatre. The introduction of STS has successfully reduced fluid fasting times to between 1 and 3 hours [3].

Although STS is gaining traction, its acceptance is still based on limited safety evidence from underpowered single-centre studies. Conducting adequately powered prospective randomised trials poses challenges due to the rarity of pulmonary aspiration, making it logistically difficult and expensive.

The Australasian Sip Til Send Network is a collaboration of over 100 clinicians, mostly anaesthetists and anaesthetic trainees, across over 60 hospitals. There is consensus amongst the STS Network that the best evidence for safety will be derived from pooling aspiration data into a multicentre study.

3. AIM

Using a large dataset pooled from multiple hospitals, to determine the incidence of anaesthesia-related pulmonary aspiration of gastric contents in patient groups managed with Sip Til Send fluid fasting protocols, compared to those managed with restrictive fasting protocols.

4. OBJECTIVES

4.1 Primary objective

Determine the incidence of anaesthesia-related pulmonary aspiration of gastric contents when a Sip Til Send protocol is active, compared to that when restrictive fluid fasting is practiced (non-Sip Til Send group, or comparison group) for both elective and emergency surgery.

4.2 Secondary objectives

The secondary aims of this study are to:

- Characterise the reported cases of aspiration according to patient demographics, clinical settings, and risk factors for pulmonary aspiration
- Assess whether duration of fluid fasting is associated with aspiration
- Consider subgroup analyses of adult vs paediatric groups
- Consider the level of between-hospital variation in aspiration rates

5. METHODS

5.1 Study design

Multicentre observational cohort study of pulmonary aspiration associated with anaesthesia.

5.2 Setting

Multiple participating hospitals across Australia and New Zealand, including large metropolitan and small regional hospitals.

Central study co-ordination in Cairns Hospital, Queensland, Australia.

5.3 Study duration

The data collection period is anticipated to be 6 months, or when the aggregate number of anaesthetics delivered (denominator) reaches the required sample size in both groups.

5.4 Study population

Patients of all ages undergoing elective and emergency procedures will be included in the study.

5.1 Study outcomes

The primary outcome is the proportion of elective and emergency surgeries reporting a pulmonary aspiration when either a Sip Til Send or restrictive fasting protocol is active. Secondary outcomes include the severity of the aspiration events, i.e. number of events resulting in ventilator therapy, unplanned intensive care admission, unplanned hospital admission, or mortality.

5.2 Study procedures

5.2.1 Recruitment of participating hospitals

Participating sites will be required to meet prerequisites before data collection can commence, including local governance approval (Site Specific Approval for Australian sites and Locality Authorisation for New Zealand sites) and the presence of a robust audit system for recording cases of aspiration. When any hospital has met these prerequisites, data collection can commence for that site. We anticipate staggered start dates as each hospital will progress at their own pace. We will include retrospective data where available from hospitals which already had a robust aspiration audit in place prior to commencement of the study.

Patient recruitment will end once the data accrued meets the pre-determined sample size requirement, and all participating hospitals will hence be notified of the last date of data collection. The date of last data collection may vary between hospitals, due to staggered start dates.

While the key details of each hospital's fasting protocol will be recorded and reported, **there is no requirement for a participating hospital to change its fasting practice for the purpose of this study, nor will participation influence the timing of a hospital's planned change in fasting protocol.**

5.2.2 Voluntary and involuntary withdrawal of participating hospitals

Any participating hospital can withdraw participation at any time, with or without providing a reason. The principal investigator of the participating hospital may do so by contacting the lead investigators.

In the event of a significant breach of the study's protocol, the lead investigators reserve the right to request early withdrawal of the affected participating hospital(s) from the study. If not impacted by the protocol breach, data already obtained from a withdrawn hospital may

still be included in the analysis, but only with the agreement from lead and principal investigators. If all data provided by a participating hospital has to be withdrawn due to a protocol breach, the principal investigator and hospital forfeit all authorship rights for publications arising from the study. All study protocol breaches will be reported in the analysis, even if the data is not analysed.

5.2.3 Recruitment of patients

Due to the study's observational design and the high volume of case data required, patients will not be individually recruited.

Patients recorded as aspiration cases

Treating anaesthetists will report aspiration events (including suspected cases) to the principal investigator at each site. The most practical method of reporting is determined in each institution according to their size and characteristics. Many hospitals are using dedicated QR codes on anaesthetic trolleys in all locations where anaesthesia is performed. Smaller centres may not adopt this system if all anaesthetists have frequent contact with the principal investigator and direct reporting will be easy and timely. All identified cases of aspiration are reviewed in detail by the principal investigator of that hospital to verify diagnosis and characterise the events. The cases are then de-identified by the principal investigator prior to them sending the list to the central data co-ordinator.

Patients recorded in the denominator data

We will record a limited set of de-identified data (data points specified elsewhere in this protocol) for all patients undergoing anaesthesia at each participating hospital, forming what we call the denominator data. This Microsoft Excel file will be compiled and de-identified by the theatre data manager at each participating hospital, who will then send it to the hospital's principal investigator. The principal investigator then merges the denominator data and aspiration case data into one Excel file, then emails it to the central data co-ordinator.

Patient management will not be affected by this study, and all measures are taken to protect patient privacy. No identifiable patient information will be shared outside of each participating hospital. The material risk to patients is considered negligible to low.

5.2.4 Patient consent to participate

We will not seek individual consent from patients because the study is observational in design, with no alteration to routine clinical care and no requirement for direct participation of patients.

Justification for not seeking consent to participate:

- The research is low risk to participants as there is no intervention or change to standard clinical care
- The potential benefits to all patients of clarifying the safety of novel fasting protocols with robust data outweighs the potential risks of the project, and there is no reason to suppose that patients would not be willing to participate if asked

- As the project involves collecting data about every patient undergoing anaesthesia in participating facilities, the quantity of data makes it impractical to obtain consent from every individual (>200 000 cases)
- Privacy will be protected by minimising access to patient records to a single clinician at each participating site and de-identifying data at the earliest opportunity. All efforts will be made to protect patient confidentiality throughout the process of data access and handling
- There are no foreseeable concerns regarding identifying results of immediate significance to participant welfare, safety or privacy.
- There are no commercial or financial interests associated with this project
- There is no requirement for handling of patient tissue or specimens
- The waiver of consent for a project of this kind is consistent with legislative requirements in all participating states, namely:
    - NSW: Privacy and Personal Information Protection Act 1998 No 133, Division 3, 27B Exemptions relating to research as well as the Information Privacy Act 2002 No 71, Schedule 1 Health Privacy Principles, Section 11 Limits on disclosure of information, section (f) Research
    - NT: Northern Territory Legislation Information Act 2002, Schedule 2 Information Privacy Principles IPP2 Use and disclosure, section 2.1
    - QLD: Information Privacy Act 2009, Schedule 3 Information Privacy Principles, IPP 10—Limits on use of personal information, subsection (f)
    - VIC: Privacy and Data Protection Act 2014, Schedule 1—The Information Privacy Principles, Principle 2—Use and Disclosure
    - SA Health Care Act 2008, Part 7 Quality improvement and research Section 65—Provision of information WA Health Services Act 2016 Part 17 Information Division Section 2 Disclosure of information

5.2.5 Measurement tools used

Aspiration cases will be reviewed individually in detail by principal investigators, using a combination of anaesthetic records, medical records and medical imaging to confirm the diagnosis and document characteristics of the event.

Data pertaining to the total number of anaesthetic cases for each facility will be obtained from operating theatre data managers at each site, who are able to extract this information from electronic theatre records. Theatre data managers will filter this data to include only the parameters required for this study (specified elsewhere in this study protocol), with no requirement for patient identifiers such as name or hospital record number.

We will attempt to determine duration of fasting for all denominator cases. This will generally be extracted alongside the operating theatre data where an electronic medical record exists which records “time of last fluid intake” and “time entered theatre or procedure room”. The duration of fasting will be defined as the time interval between these two events.

5.2.6 Project involvement by participants

Patients will have no direct involvement.

5.2.7 Patient safety and risk mitigation

The study poses no risk to patient safety as routine patient care will not be affected in any way. Participation in the study does not require any hospital to alter its fasting protocol. Each patient who experiences an aspiration event will be managed by the treating clinician in a timely manner and using best practice principles appropriate to their own institutional guidelines. Once the patient's condition has been stabilised to the satisfaction of the clinician, they will report the aspiration event using their hospital's reporting methods.

The only risk associated with the project is that of accessing clinical information, and we will prioritise the protection of patient privacy by removing identifiable data at the earliest opportunity. The principal investigator will access the case file for each reported aspiration event, to confirm diagnosis of pulmonary aspiration and other case data for the study. The data will then be de-identified before it is sent to the central study co-ordinator (numerator data). At designated time intervals, the principal investigator will request basic information about all anaesthesia cases completed at their hospital during the reporting period from their theatre data managers (denominator). The denominator dataset will be de-identified from the outset.

Principal investigators are all members of the department of anaesthesia or members of staff at the hospital, and outside the scope of this study would ordinarily have access to the identifiable patient data to carry out their daily job. No identifiable patient data will be handled by anyone other than the principal investigator at their own participating hospital.

As part of a planned interim analysis after three months of data collection, we will assess the reported aspiration rates against a planned safety threshold. If the aspiration rate in the Sip Til Send group is found to be 4 or more times that in non-Sip Til Send group, *and* with power equal to or greater than 0.8, then we will notify all participating hospitals of the finding in a timely manner, to provide them an opportunity for internal review of their fasting practices.

5.2.8 Patient safety and risk mitigation specific to children and young people

This project will aim to establish the safety (or increased risk) associated with a novel fasting regimen which has already been widely implemented in mixed and dedicated paediatric facilities across Australia and New Zealand. It is critical to understanding the safety and implications of liberal fluid fasting regimens that we ensure the results of this project can be generalised across both adult and paediatric populations.

There is no requirement for direct participation of children or young people and no alteration to their routine clinical care. Appropriate steps to ensure protection of privacy

and confidentiality are outlined as above. There are no foreseeable risks to the emotional or psychological security of children and young people undergoing anaesthesia.

It is in the best interests of both children and adults who require anaesthesia that research is conducted to establish the safety of liberal fluid fasting protocols. Without a project such as this, it may never be known what its impact is on complication rates during anaesthesia, which is of relevance to all children and young people undergoing anaesthesia both now and into the future.

5.2.9 Data management

Participating hospital

The principal investigator will enter data into pre-templated Microsoft Excel spreadsheets. These data will be derived from 2 sources.

Reports of pulmonary aspiration will come from the hospital's aspiration reporting and audit system. These systems are pre-existing and established, not created specifically for the MARS project. The exact audit system varies between hospitals as outlined in section 5.2.3 above. In all systems, the treating anaesthetist involved in an aspiration case logs a report to the principal investigator in each hospital to facilitate morbidity and mortality review and departmental clinical education. This process requires the anaesthetist to access specific patient medical records to view clinical details as a part of their ordinary responsibilities to quality and safety assurance within the department.

The MARS project will require the principal investigator at each site to submit a record of these cases to the central study coordinators in a de-identified form designed to protect patient privacy and confidentiality. Once the medical record of the patient with reported aspiration has been examined by the principal investigator, and relevant data transferred to the Excel file, the record will be **de-identified** by removing the patient name and hospital record number.

At the end of each reporting period, namely the 1st, 3rd and 6th months after study commencement and every 3 months thereafter if required, each hospital's theatre data manager will provide the principal investigator **de-identified** denominator data in a Microsoft Excel file. This file will contain a record of all anaesthetics delivered at the hospital during the study reporting period without patient identifiers, including name or hospital record number.

The principal investigator will email one password-protected Excel file to the central study co-ordinator at the end of each reporting period, containing **only de-identified** data for the reporting period. **No patient-identifiable data leaves participating hospitals**.

Central co-ordinating hospital

At the end of each reporting period, the central study co-ordinator at the co-ordinating hospital will receive Excel files sent to them from the participating hospitals. The central

study coordinator will compile these into a single (unified) password-protected Excel file containing all cases from across all participating centres. At pre-designated intervals and at the conclusion of data collection, the central study co-ordinator will email the de-identified unified Excel file to the statistician for data analysis.

All hospitals

Original Excel data files will be stored in one online location that is behind their respective hospital firewall on the hospital cloud server. The files will remain stored securely for a minimum of 5 years after the publication of the study's results, then permanently deleted. In the case of participating hospital, this refers to the periodic reports in Excel file format. In the case of the co-ordinating hospital, this refers to the reports sent by participating hospitals, as well as the unified Excel file. Data will be backed up and accessible only to the study investigators. Data will only be reviewed by study investigators. Project data will not be stored on personal computers or portable storage devices.

Disclosure of information

Information collected as part of the study will be disclosed to the project's statistician to facilitate data analysis. The data will only be disclosed in a form which is de-identified with regards to individual patient details, as well as having the hospital name removed so that individual facilities cannot be identified. The data will not be disclosed to any other individuals or organisations outside of the study investigators.

Risks or harms from data collection and management

All possible efforts will be made to ensure that patient privacy and confidentiality are protected. As a result, the risk of harm from use of this data is considered negligible to low. This is consistent with all state legislation requirements (as outlined in section 5.2.1) as well as the principles outlined in Section 1 of the National Statement on Ethical Conduct in Human Research, namely that:

- The methods are appropriate to achieve the aims and the team have adequate expertise to achieve this
- The research is fair and inclusive, and has merit and potential benefits that exceed the anticipated risks
- Patients are treated with respect by making all efforts to protect their privacy and confidentiality

5.2.10 Data management relating to children and young people

The data pertaining to children and young people will be managed in an identical manner to that of adults, as outlined in section 5.2.2. There are no additional concerns regarding the safety and wellbeing of children and young people, aside from protecting the privacy and confidentiality of their data as described above. As the study is observational and not interventional, data will be stored securely for a minimum of 5 years after the publication of the results.

5.3 Sample size and data analysis

5.3.1 Sample size and statistical power

According to published reports focusing on aspiration risk since 1990, in patients managed with restrictive fluid fasting protocols, the reported rates of aspiration in elective surgery range from 1 in 7,103 to 1 in 3,303 and in emergency surgery range from 1 in 895 to 1 in 373 [4-9]. Somewhat at odds with the preceding reports, Walker et al reported 1 aspiration in 4498 children undergoing emergency surgery [6].

Due to the differing risks of aspiration for elective and emergency surgery, we have performed separate sample size calculations for each context. This study will consider a doubling of the baseline rate of aspiration a clinically significant increase. Thus, the study is powered to assess whether the STS aspiration rate is at least double that of the non-STS rate (equivalent to a one-tailed test).

Thus, assuming a baseline aspiration rate (i.e, under restrictive fluid intake protocol) of 1 in 5,000 elective anaesthetics and 1 in 1,000 emergency anaesthetics, to test for an aspiration rate under STS protocol being at least twice the baseline, at the 5% significance level, with power 0.8, requires 204,932 elective anaesthetics (102,466 from STS hospitals, and 102,466 from no/pre-STS hospitals) and 40,940 emergency anaesthetics (20,470 from STS hospitals, and 20,470 from no/pre-STS hospitals).

From preliminary information gathered from participating hospitals up until the writing of this study protocol, approximately 230,000 anaesthetics are delivered by the participating hospitals every 6 months. Of these, it is anticipated 138,000 will be patients managed with STS. There is uncertainty with these estimates due to some participating hospitals planning to implement a Sip Til Send program during the course of the study, but with unknown launch dates. The planned interim analysis 3 months into the study will provide an opportunity to recalculate sample size according to the observed aspiration rates and proportion of cases managed under STS vs fluid-restrictive fasting protocols.

On an intention-to-treat basis, anaesthesia cases count towards the STS group if they belong to a patient group in a hospital in which there is an active STS program. These patients will be counted whether or not they were individually eligible for STS or actually participated in STS. All other anaesthetic cases will count towards the restrictive fasting group. For example, if a hospital runs STS in all patients **except** endoscopy and obstetric cases, then **all** endoscopies and obstetric cases count towards the non-STS group, while **all** other cases count towards the STS group, regardless of individual patients' STS eligibility or participation in the consumption of fluids. If during the study period, that hospital changes its fasting protocol to include endoscopy and obstetric cases, then those anaesthetics will from that point in time count towards the STS group.

5.3.2 Data collection

At the end of each reporting period, the principal investigator from each participating hospital will provide a report to the central study co-ordinator. Reporting will be submitted at 1, 3, and 6 months after each participating hospital starts data collection. Should the target sample sizes not have been reached by 6 months, an assessment of the deficit will be considered and a timeframe for a subsequent reporting period determined based on previous periods and numbers of records received. The data collection period will terminate once the total number of anaesthetics delivered across all participating hospitals achieves the target sample size.

Each study period report will include:

- Number of verified pulmonary aspirations, with detailed information to be collected regarding each of these events (see below)
- Number of procedures under anaesthesia and their characteristics (see below)
- Fluid fasting duration from last fluid intake until time entered operating/procedure room.

For each case of pulmonary aspiration event, the report will contain the following data:

- Event date and time
- Age (on date of procedure)
- Urgency of the operation (elective or emergency)
- ASA
- Sub-specialty under which the operation or procedure was conducted
- Name of procedure or operation
- Anaesthesia start and end time
- Phase of anaesthesia when event occurred (induction, maintenance or emergence)
- Airway in situ at onset of aspiration event (none, nasal prong, high flow nasal prongs, Hudson mask, facemask, supraglottic airway, endotracheal tube, other)
- Mode of anaesthesia - (general anaesthesia, unconscious sedation, conscious sedation/awake)
- Anaesthesia technique (general, anaesthetic, sedation, regional (without or with sedation/GA, awake, etc)
- Hospital location where event occurred (e.g. operating theatre, endoscopy, radiology)
- Escalation of care associated with the aspiration event:
    - Prolongation of stay in recovery unit as a direct consequence of the aspiration
    - Unplanned over-night hospital admission
    - Unplanned admission to intensive or high dependency care unit
    - Ventilator therapy
    - Commencement of antibiotics to treat or prevent pneumonia in response to the aspiration
    - Hypoxic brain injury

    - Death
- What fasting policy was active in the cohort to which the patient belonged?
    - Nil by mouth
    - Adult 6-2 – 6hr solids/cow's milk, 2hr clear fluid
    - Adult 6-0 (SipTilSend) – 6hr solids/cow's milk, sip clear fluid until surgery
    - Child 6-4-2 – 6hr solids/cow's milk, 4hr breast milk, 2hr clear fluid
    - Child 6-4-1 – 6hr solids/cow's milk, 4hr breast milk, 1hr clear fluid
    - Child 6-4-0 (SipTilSend) – 6hr solids/cow's milk, 4hr breast milk, sip clear fluid until surgery
    - Child 4-3-1 – 4hr solids/cow's milk, 3hr breast milk, 1hr clear fluid
    - Child 4-3-0 (SipTilSend) – 4hr solids/cow's milk, 3hr breast milk, sip clear fluid until time of surgery
- Compliant with fasting policy?
- Premedication within 1 hour of entering theatre
- Time entered theatre/procedure room
- Time of last clear fluid intake, type of fluid and volume
- Time of last solid food intake, type of food and volume
- For paediatric cases, time of last breast milk intake
- Aspiration diagnostic criteria that were met:
    - New supplemental oxygen requirement that persisted beyond the recovery unit stay
    - Liquid gastric content observed/suctioned from the trachea
    - Solid gastric content observed/suctioned from the trachea
    - Did the aspiration lead to chest imaging? If so, did the radiologist report findings consistent with aspiration?
- Presence of risk factors for aspiration.
    - Weight, height, Body-mass-index
    - Obesity (BMI≥30 and/or Weight≥100)
    - Documented history of diabetes
    - Documented history of gastro-oesophageal reflux
    - Use of GLP-1 receptor agonist within preceding 4 weeks
    - In preceding 24 hours: documented severe pain (NRS ≥7/10), pain crisis or review for inadequate analgesia
    - Quantity of opioid consumption likely sufficient to induce gastric hypomotility: ≥90 mg oral morphine equivalent (OME) in the preceding 24 hours, or ≥25mg in the preceding 6 hours
    - History of bariatric surgery including but not limited to gastric bypass, gastric sleeve, gastric stapling, or gastric band
    - Parkinson's disease on medication therapy
    - Current sepsis
    - GI tract obstruction
    - Pregnant or within 48 hours after delivery

The following data will be collected for all denominator anaesthetic cases:

- Gender
- ASA

- Age (on the date of procedure)
- Date of procedure
- Time of last fluid intake
- Time into theatre
- Urgency of procedure
- Surgical subspecialty
- Name of procedure
- Anaesthesia technique (general, anaesthetic, sedation, regional (without or with sedation/GA, awake, etc)

Principal investigators will be provided with a template Microsoft Excel spreadsheet to facilitate data collection. Embedded in the file is a *data dictionary* as a tool to promote data integrity and standardisation.

Where hospitals can provide robust data for both aspiration and denominator data that pre-dates the start of this study, we will include their retrospective data.

5.3.3 Data quality

Aspiration reporting systems
A single standardised system is not feasible across jurisdictions due to workflows, information technology setup and historic considerations. Nonetheless, site data will be accepted only where the reporting system:

- publicises MARS clearly within the department; and
- instructs anaesthetists to report every suspected aspiration (not only cases of special interest, medico-legal significance or educational value), to reduce selective under-reporting.

Fasting programs
Fasting programs are highly complex systems with many stakeholders and multiple factors influencing their rules. Hospital size, case-mix, workflows, staffing and risk culture are amongst the factors that influence a hospital's fasting program. We will not standardise fasting rules. Instead, we will document each site's program and record any changes during the study period to provide context for analysis.

5.3.4 Data analysis plan

The study's primary aim will be reported upon and assessed principally via frequency tabulations, cross-tabulations, chi-squared tests and/or independent samples t-tests.

The study's secondary aims will be reported upon and assessed via frequency tabulations, cross-tabulations, chi-squared tests, and/or independent samples t-tests. Multiple logistic regression will be employed to simultaneously assess potential factors associated with aspiration. Generalised linear mixed models may be employed, incorporating a random effect (Hospital) and adjusting for hospital size (number of patients) to consider between-hospital variation in rates.

6. ETHICS AND GOVERNANCE

6.1 Australia

The lead investigators will submit for multicentre ethics approval in early 2025 at an NHMRC-recognised ethics committee, which is recognised by all Australian hospitals through the national mutual acceptance program.
Once multicentre ethics approval has been obtained, the Australian study co-ordinators will be available to assist principal investigators at participating hospitals to obtain local governance approval via a Site-Specific Assessment (one for each hospital).

6.2 New Zealand

The New Zealand co-ordinator will complete an ethics review process via the Health and Disability Ethics Committees (HDEC). Once the multicentre ethics approval has been obtained, the lead investigators and New Zealand co-ordinator will be available to assist principal investigators at participating hospitals to obtain Locality Authorisation (one for each District Health Board).

7. DISSEMINATION OF RESULTS AND PUBLICATIONS

It is anticipated that the results of the study will be published in a major peer-reviewed journal. One principal investigator from each hospital will be listed as author. All principal investigators will be provided ample opportunity to contribute to editing the manuscript.

If all data provided by a participating hospital must be withdrawn due to protocol breach, the principal investigator and hospital forfeit all authorship rights for publications arising from the study.

8. OUTCOMES AND SIGNIFICANCE

The safe fasting of patients before surgery and prevention of aspiration under anaesthesia are fundamental goals in daily practice for anaesthetists, surgeons and theatre teams. STS is a simple and pragmatic solution to prolonged preoperative fasting, but robust aspiration safety data beyond small single-centre audits do not yet exist. The Australasian MARS is world-first in the era of STS and unprecedented in scale. The outcome of Australasian MARS is highly likely to be of worldwide interest and widely generalisable to most patient groups. As such, we expect that this study will make in impact in anaesthetic literature and be used to inform future national fasting guidelines.

9. BUDGET

9.1 Funding

Grant application to FNQ Hospital Foundation - $25,000 (outcome pending).
Cairns Anaesthesia Association - up to $10,000
In-kind support from Cairns Hospital department of anaesthesia and perioperative medicine

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Total funding potentially available $35,000

9.2 Expenditures

Some hospitals may incur fee from their hospital for local governance assessment - $5,500

Statistical support - $10,000

Salary for central study co-ordinator (research nurse) ($50/hr x 6hr/wk x 35 weeks) - $10,500

Publication costs $4,000

Total expenditure $30,000

10. ABBREVIATIONS AND DEFINITIONS

Pulmonary aspiration	Clinical suspicion of aspiration of gastric contents on the basis of coughing, bucking, regurgitation or vomiting during the induction, maintenance or emergence phases of anaesthesia, in conjunction with at least one of: - New oxygen requirement persisting beyond the recovery unit - Presence of gastric contents in the sub-glottic airways, as determined by bronchoscopy or endotracheal suctioning - New radiographic findings suggestive of aspiration
Verified pulmonary aspiration	A case manually verified by the principal investigator as having met the study's definition of pulmonary aspiration.
Anaesthesia-related pulmonary aspiration of gastric contents	Aspiration of stomach contents that occurs during an anaesthetic delivered by an anaesthetist or anaesthesia trainee, occurring during the induction, maintenance or emergence phases of the anaesthetic. This includes cases under general anaesthesia, conscious or unconscious sedation.
Liberal fluid fasting	Patients permitted to drink fluids until transported to the operating theatre or theatre complex. This assumes that education, systems and resources have been put in place to promote drinking and support staff to provide patients with fluids. "Sip Til Send" is an example of liberal fluid fasting.
Restrictive fluid fasting	In contrast to liberal fluid fasting, restrictive fluid fasting dictates that patients must have fasted from fluids a minimum duration (typically 2 hours for adults and 1 hour for children) before undergoing anaesthesia.
STS	Sip Til Send
Incidence of aspiration	The number of verified aspirations (the numerator) divided by the total number of anaesthetics (the denominator) delivered by anaesthetists at the participating hospital during the study period.
Numerator	Number of cases of verified pulmonary aspiration
Denominator	Number of anaesthetic cases completed under general anaesthetic or sedation by anaesthetists.
GLP-1 RA	Glucagon-like peptide-1 receptor agonist. Examples available in Australia include: dulaglutide (Trulicity),

	semaglutide (Ozempic / Wegovy), tirzepatide (Mounjaro), liraglutide (Saxenda).
HDEC	Health and Disability Ethics Committees for New Zealand
Reporting period	After the 1st, 3rd, 6th months from commencement of the study, (then 3-monthly, if needed), the participating hospital will send a report containing numerator and denominator data to the co-ordinating hospital. Each of these reports covers a "reporting period", or time elapsed since the previous report.
Participating hospital	A satellite hospital that contributes data to the study. Each participating hospital has only one principal investigator. One principal investigator may represent multiple participating hospitals.
Central co-ordinating hospital	Where the lead investigators and central study co-ordinator are based. Responsible for running the study.
Principal investigator	Head of the study at their participating hospital. One principal investigator may represent multiple participating hospitals.

11. REFERENCES

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