A prospective study of paediatric preoperative fasting times at Red Cross War Memorial Children's Hospital

by

Dr Alison Kouvarellis

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Department of Anaesthesiology of Perioperative Medicine, University of Cape Town

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Declaration

I, **Dr Alison Kouvarellis**, hereby declare that the work on which this dissertation/thesis is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university.

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Abbreviations

RCWMCH	Red Cross War Memorial Children's Hospital
SD	Standard deviation
CI	Confidence interval
QI	Quality improvement
ASA	American Society of Anesthesiologists
NGT	Nasogastric tube
NJT	Nasojejunal tube
HREC	Human research ethics committee
GA	General anaesthesia
PS	Physical status
PEG	Percutaneous endoscopic gastrostomy
TPN	Total parenteral nutrition
CRF	Case report form
IQR	Interquartile range
IV	Intravenous
STROBE	Strengthening the Reporting of Observational Studies in Epidemiology
SAMJ	South African Medical Journal

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A prospective study of paediatric preoperative fasting times at Red Cross War Memorial Children's Hospital

A J Kouvarellis,[1] MB ChB, DA (SA); **K van der Spuy**,[1] BSc Hons (Physiotherapy), MB ChB, FCA (SA), MMed (Anaesth); **B M Biccard**,[1] MB ChB, FFARCSI, FCA (SA), MMed (Anaesth), PhD; **G Wilson**,[2] MBChB, FCA (SA)

[1]Department of Anaesthesia and Perioperative Medicine, Groote Schuur Hospital and Faculty of Health Sciences, University of Cape Town, South Africa
[2]Division of Paediatric Anaesthesia, Department of Anaesthesia and Perioperative Medicine, Red Cross War Memorial Children's Hospital and Faculty of Health Sciences, University of Cape Town, South Africa

Contact details of authors.
Corresponding author: A Kouvarellis (akouvarellis@gmail.com)
Co-authors: K van der Spuy (karenvdspuy@gmail.com), B M Biccard (bruce.biccard@uct.ac.za), G Wilson (graeme.wilson@uct.ac.za)

Background. Fasting for liquids and solids is recommended prior to procedures requiring anaesthesia, to reduce the risk of pulmonary aspiration. Children often experience excessive fasting, which is associated with negative physiological and behavioural consequences, and patient discomfort. The duration of preoperative fasting in children in South Africa is unknown.
Objectives. The aim of this study was to determine the compliance with fasting guidelines and fasting times of children prior to elective procedures performed under anaesthesia at a paediatric hospital in Cape Town, South Africa. The primary focus was fasting for clear liquid. The study also intended to identify the most common reasons for prolonged clear liquid fasting.
Methods. Over a seven-week period, we prospectively captured fasting times of consecutive patients undergoing elective surgical, medical and radiological procedures at Red Cross War Memorial Children's Hospital (RCWMCH). Measurement outcomes were defined as the period from the last clear liquid, milk or solid feed to the start of anaesthesia. For analysis of compliance with preoperative fasting guidelines, institutional preoperative fasting target limits were established based on the standard 6-4-2-hour guideline.
Results. The study included 721 elective paediatric cases. The mean (SD) fasting time for clear liquids (n=585) was 8.0 (4.8) hours, with an adherence rate of 25.5% (95% confidence interval (CI) 22-29%) to the institutional target of 2 to 4 hours. The mean (SD) fasting times for breast milk (n=92), formula milk (n=116) and solid feeds (n=560) were 7.1 (2.8), 8.8 (2.8) and 13.9 (3.6) hours respectively. The factors associated with clear liquid fasting >4 hours were: inadequate fasting instructions, poor adherence to fasting orders, procedural delays and fasting to promote theatre flexibility.
Conclusion. This study demonstrates that children in a South Africa hospital experience excessive fasting times prior to elective procedures. To reduce fasting durations and improve the quality of perioperative care, quality improvement (QI) interventions are required to create an adaptable fasting system which allows individualised fasting. Improving preoperative fasting times in children is the responsibility of all health care professionals in the multi-disciplinary management team.

Background
The routine application of preoperative fasting, first introduced in 1883, is intended to reduce the morbidity of anaesthesia-related regurgitation and pulmonary aspiration.[1] The current American Society of Anesthesiologists (ASA) Preoperative Fasting Guidelines recommend the following fasting periods: 6 hours for solids and non-human milk, 4 hours for breast milk, and 2 hours for clear liquid.[2] These guidelines apply to patients with oral and nasogastric tube (NGT) intake preparing for elective procedures requiring monitored anaesthetic care.[2] Nasojejunal tube (NJT) feeds should be discontinued 2 hours prior to anaesthesia.[2]

International paediatric literature has highlighted that preoperative fasting durations frequently exceed the minimum durations recommended by these guidelines, with average fasting times for clear liquid of 6.3 to 12.61 hours,[3-8] breast milk 6.27 to 9.82 hours,[3, 8] formula milk 9.9 hours [8] and solids 10.0 to 14.08 hours.[3-8] Extended fasting confers no advantages, but rather incites significant physiological, psychological and behavioural perturbations including hypoglycaemia, ketoacidosis, hypotension at induction of anaesthesia, hunger, thirst, sadness, irritability, and anxiety. [3, 5, 8-14] Children younger than 36 months are most vulnerable to these complications.[15, 16]

In healthy paediatric patients the risk of aspiration is low and complications from clear liquid aspiration are rare.[17-21] Reducing preoperative clear liquid fasting times improves patient comfort and quality of care without theatre disruption.[11, 22]

Objectives
Preoperative fasting of children in South Africa has not been investigated. Clinical observation would suggest that fasting times parallel the international trend. This study aimed to elucidate current fasting practices of children before anaesthesia for elective procedures at RCWMCH, a tertiary paediatric hospital, as the first step to improving quality of care. The primary objective was to determine the mean duration of preoperative fasting for clear liquid and the percentage of children fasted for two to four hours, in compliance with institutional fasting standards for clear liquids. The secondary objectives included mean fasting times for breast milk, formula milk and solids, and the percentage compliance with their respective preoperative fasting standards. Reasons for prolonged clear liquid fasting and the incidence of regurgitation and aspiration were reviewed.

Methods
This was a single centre prospective observational study conducted from 4th October to 23rd November 2018 at RCWMCH, Cape Town, South Africa. The protocol, data collection sheet and consent poster were approved by the Human Research Ethics Committee(HREC) of the Faculty of Health Sciences of the University of Cape Town (HREC REF: 410/2018) and the RCWMCH Research Committee (RXH: RCC: 15). The conduct of the study upheld patient privacy and confidentiality.

Participants
Inpatients and outpatients undergoing general anaesthesia (GA) or sedation for elective medical, surgical or radiological procedures at RCWMCH, were eligible for recruitment. This included patients under 18 years of age of all ASA physical status

(PS) classifications, receiving enteral nutrition via oral, NGT, percutaneous endoscopic gastrostomy (PEG) or NJT. Unscheduled and/or emergency cases, and those receiving total parenteral nutrition (TPN), were excluded. Patients prescribed 'bowel preparation' were excluded from all but the clear liquid analysis. Patients whose procedures were postponed or cancelled were excluded due to time and resource constraints.

Outcome measures

Measurement outcomes were fasting times, defined as the period from the last liquid, milk or solid feed time to the start time of anaesthesia.[4] For analysis of compliance with preoperative fasting guidelines, institutional preoperative fasting target limits were established using the standard 6-4-2 guideline, plus two hours for each category.[4, 23] This provided a clinically feasible goal without significant negative physiological impact. Acceptable time limits for fasting are defined in Table 1. Non-compliance was defined as fasting times outside these ranges.

Anaesthesiologists recruited consecutive patients and obtained data, including last intake time for clear liquid, milk and/or solids, via in-person interviews with parents immediately preoperatively. A standardised case report form, based on previous studies,[7, 8] was used. Parents or guardians provided verbal consent and opt-out posters were clearly displayed. Translation from English was available and performed as required. The case report form (CRF) included a checklist of reasons for prolonged clear liquid fasting and an area for additional reasons and/or comments.

Missing data, unrelated to fasting times, were retrospectively acquired from patient records. CRFs with no recorded fasting times were excluded. Patients with NGT and PEG intake were included in the oral intake group, since the same guidelines for preoperative fasting apply. For children receiving breast and formula milk, the fasting time for the primary feed was analysed. Similarly, the most recent infant formula milk or solid feed was analysed as an additional combined 'last feed' category. Distinguishing between formula milk and solids holds little clinical importance and may be a source of confounding because a mother giving formula milk might omit solid food, giving the impression of prolonged fasting for solids.

Sample size

Acceptable compliance with the institutional target fasting time for clear liquids was set at 90%. If the proportion of patients fasted for clear liquid <2 hours and >4 hours was found to be greater than 10%, with a 95% CI which did not include 10%, RCWMCH would be considered non-compliant for clear liquid fasting. A calculated sample size of 484 cases with enteral clear liquid intake data was required to prove non-compliance, with a two-sided 95% confidence interval of 6%.[24] We aimed to recruit an additional 20% (97 cases) to compensate for incomplete data.

Data analysis

All captured data were de-identified, entered into an Excel chart (Microsoft Excel, Redmond, WA, USA), and analysed using IBM SPSS software (version 25). Descriptive analyses were conducted and results appropriately represented as mean and SD or median and interquartile range (IQR). Frequencies of patients with fasting times consistent with compliance were expressed as percentages derived using the

total number of times available for that fasting category. Bivariate analyses were performed using parametric or non-parametric tests as appropriate. Subgroup analysis of clear liquid fasting time was performed according to the age of the children: <12 months, 12-36 months, and >36 months. The relationship between age and mean clear liquid fasting time was assessed using the Kruskal-Wallis test. A chi-square test of independence was performed to examine the relationship between age and compliance with clear liquid fasting time. To investigate for confounding variables, an independent-samples t-test was performed, comparing mean clear liquid fasting time in patients with and without preoperative intravenous (IV) maintenance fluids. To identify possible selection bias, characteristics of captured and non-captured cases were assessed as follows: age (two-tailed t-test), sex (Fisher's Exact test), weight (Mann-Whitney U Test), ASA classes (chi-square test) and admission status (Fisher's Exact Test).

Results

The study cohort included 721 patients of which 585 were eligible for analysis of the primary outcome (Figure 1). The 100 patients excluded due to missing data, did not differ significantly from recruited patients, with the exception of ASA and inpatient status. The time of last intake of clear liquid was not captured in 136 (18.9%) recruited cases, for the following reasons: two cases had an 'unknown time' of last liquid intake, 23 were exclusively breast fed, 16 were exclusively formula fed, 17 received IV preoperative fluids, and 78 cases had no oral or IV liquid intake captured preoperatively. This study included 411 ward inpatients, 13 ICU patients and 297 outpatients from a wide range of surgical specialities. Clinical and surgical patient characteristics are summarised in Table 2.

The mean (SD) clear liquid fasting time was 8.0 (4.8) hours (Table 3). The compliance of clear liquid intake with the institutional target was 25.5% (n=149; 95% CI 22-29%). Clear liquid fasting >4 hours occurred in 73% of cases (n=426; 95% CI 69-77%) and affected all age groups. Details of clear liquid fasting in age subgroups, are shown in Table 4. Age younger than 12 months was significantly associated with improved clear liquid compliance ($\chi^2(2) = 16.06$, $p<0.01$) and reduced mean fasting duration ($p<0.001$). There was no difference in the mean (SD) clear liquid fasting times of children with and without preoperative IV maintenance fluids (9.0 (5.3) vs 7.9 (4.8) hours respectively, $p=0.20$).
The compliance and mean fasting times for breast milk, formula milk, solids and semi-solids, and NJT feeds, are shown in Table 3.

Twenty-eight captured cases were fasted for a time period shorter than the fasting guidelines. Inadequate fasting times were found in 10 patients (1.7%) receiving clear liquid, 9 (9.8%) breast milk, 7 (6%) formula milk, and 2 (0.4%) solids. All of these fasting times were within one hour of the recommended fasting times. No regurgitation events were recorded in this group.

A reason for prolonged clear liquid fasting was identified in 278 of the 426 cases with clear liquid fasting periods longer than 4 hours. The key themes identified were: 1) inadequate preoperative preparation and provision of fasting instructions, 2) poor adherence to fasting instructions in the immediate preoperative period, 3) delays at the time of the procedure, and 4) provisional fasting to permit theatre list flexibility. (Table 5). Inadequate preparation for preoperative fasting included no fasting

education or instructions being provided to outpatients, fasting instructions not being documented for inpatients, universal fasting times prescribed regardless of the anticipated starting time and single fasting times ordered for liquids and solids. Parents reported not being informed that clear liquid was allowed on the morning of surgery**.** In the immediate preoperative period, ward nurses and parents did not follow fasting instructions or ward fasting guidelines. In some cases, this may not have been preventable due to the child being asleep or refusing the clear liquid offered to them. Further reasons for non-adherence to fasting orders were not investigated. Delays in the starting time of procedure were reportedly due to problems with surgical consent and other paperwork, the preceding case being of a longer duration than anticipated, changes in the order of the list and emergency cases interrupting the list. Provisional fasting to permit theatre list flexibility was considered responsible when the patient was not offered a drink during the day to promote list adaptability and avoid delays or postponements in the case of list changes.

Regurgitations were recorded in seven patients receiving general anaesthesia, with no aspirations. All preoperative fasting times for these patients met the minimum times recommended by the ASA.

Discussion

The principal finding of our study is that the compliance with the pre-specified clear liquid fasting time target of two to four hours was 25.5%, which is considerably lower than the acceptable institutional compliance rate of 90%. The mean duration of clear liquid fasting was almost eight hours. This extended to the majority of children younger than 36 months, who are most susceptible to the adverse metabolic effects of prolonged fasting.[11, 12, 15, 16] The subgroup analysis of children younger than12 months suggested better compliance with fasting times, which may indicate an awareness that younger children are at higher risk of the adverse effects of prolonged fasting, although the fasting times were still unimpressive since all age groups showed inadequate compliance and average fasting times >4 hours.

Our study is in keeping with the international published literature, which demonstrates that following a two-hour clear liquid fasting guideline consistently translates into actual clear liquid fasting times of 6.3 to 10.85 hours, with marginal improvements achieved with quality improvement interventions.[3-8, 15, 16]

The four major drivers of prolonged clear liquid fasting identified at RCWMCH are inadequate fasting instructions provided, poor adherence to fasting instructions, delays in procedural starting time and provisional fasting to promote theatre list flexibility. These barriers to improving clear liquid fasting compliance, seem to be largely similar to those experienced in well-resourced settings.[6, 25-27] Service delivery issues, including hospital operational factors and resource limitations, and patient related factors, such as language barriers, cultural beliefs and psychosocial circumstances, may be compounding influences in South Africa.[28]

This study presents an opportunity to improve the perioperative experience for staff, patients and their parents.[29] Reducing the duration of clear liquid fasting confers considerable benefits, mitigating the negative emotional, behavioural, biochemical and haemodynamic effects of fasting, and improving pain scores.[12, 15, 30-32] To

optimise compliance with preoperative fasting guidelines, the areas of failure identified should be systematically addressed using quality improvement (QI) methodology with context-appropriate interventions and ongoing monitoring using plan-do-study-act cycles. A successful QI intervention relies on a systems approach, driven by a strong guiding team with commitment from all key stakeholders and role players from ministerial to community level.

Greater adaptability in the fasting system is required to accommodate the changeable nature of theatre lists. Establishing efficient communication and regular updates between theatre staff and ward nurses facilitates appropriate adjustment of fasting times, to reduce liquid fasting times.[33, 34] In 2018 the Association of Paediatric Anaesthetists of Great Britain and Ireland and the European Society for Paediatric Anaesthesiology released a joint consensus statement,[35] subsequently endorsed by other international paediatric anaesthesia societies,[36-38] recommending that children receive clear liquid up to one hour before elective general anaesthesia. A one-hour clear liquid fasting protocol enhances theatre flexibility and assists in individualising fasting times,[39, 40] thus addressing a major obstacle to improved fasting compliance at RCWMCH. Two paediatric centres,[23, 41] which adopted this policy, demonstrated a 43% and 53% absolute risk reduction in the proportion of patients fasted of clear liquids for longer than four hours. Based on the one-hour fasting recommendation and the two studies with a number needed to treat of two to three, we would expect to improve compliance from 25.5% to between 58.8% and 75.5% [25.5% + (33.3% to 50%)]. Liberal liquid fasting policies have not been shown to increase risk of aspiration or theatre interruption, and as such promise a safe and practical strategy to reduce fasting times.[19, 23, 29, 35-37, 40-44]

Outdated and widely variable fasting instructions provided by medical staff, and non-adherence to fasting instructions by parents and ward nurses were major contributors to prolonged fasting in this study. Compliance relies greatly on the quality of fasting instructions provided but is also influenced by personal beliefs, staff availability and parental threat perception, anxiety levels, health literacy, language barriers and recall.[23, 25, 45, 46] Anaesthesiology departments caring for paediatric patients should review their institutional fasting guidelines and develop policies based on the current evidence. Readily available up-to-date preoperative fasting guidelines and educational campaigns for staff can be used to advance knowledge and promote consistent, unified fasting information.[23, 47] Verbal preoperative communication with parents supported by information leaflets, videos or posters in appropriate languages, has been shown to improve parental comprehension and memorisation, reduce anxiety and improve fasting times.[48-50] A phone call or text message reminder the night before surgery has been demonstrated to positively impact health behaviour and improve adherence.[23, 51, 52]

This prospective audit included a large cohort of paediatric in and outpatients undergoing a broad range of surgical and medical procedures. The results are consistent with the global picture which may suggest that issues that affect well-resourced environments are relevant in South Africa. In-person interviews immediately prior to anaesthesia optimised the quality of data collected by avoiding extraction error, allowing clarification of data collection variables, and minimising recall bias. Neither the ward nursing staff nor the parents were aware of the primary objective of the study to reduce possible bias introduced by the Hawthorne effect.

There are some limitations of this study. Despite a fairly robust sample, 12% of potential cases were not recruited. Analysis revealed an element of selection bias with a greater proportion of sicker inpatients not recruited for the study, which may be secondary to the urgency of these cases. We do not believe that these missed cases invalidate the findings of this study as these patients more frequently receive non-standardised fasting protocols or TPN. Secondly, the primary outcome data was missing for 14% (n=97) of the clear fluid eligible patients. However, the study protocol included oversampling to account for incomplete data capture. Finally, while this is a single centre study, it had a robust sample size to address the study question.

Conclusions

In a prospective observational study of children in a South African hospital, the compliance with preoperative fasting guidelines for clear liquid was poor. Noncompliance is driven by inadequate preoperative fasting instructions, poor adherence to fasting instructions, delays in procedural starting times and fasting to promote theatre list flexibility. Reducing clear liquid fasting durations is a safe way to improve the perioperative quality of care for patients and their parents. Collaborative quality improvement programmes which support adherence and promote the individualisation of clear fluid fasting are likely to have the greatest impact.

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Author contributions:

The research protocol was developed by AJK and GW. Statistical analysis was performed by BMB. The first draft of the manuscript was written by AJK and revised by KvdS and BMB. All authors participated in critical review of the manuscript.

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Figure 1: STROBE flow diagram

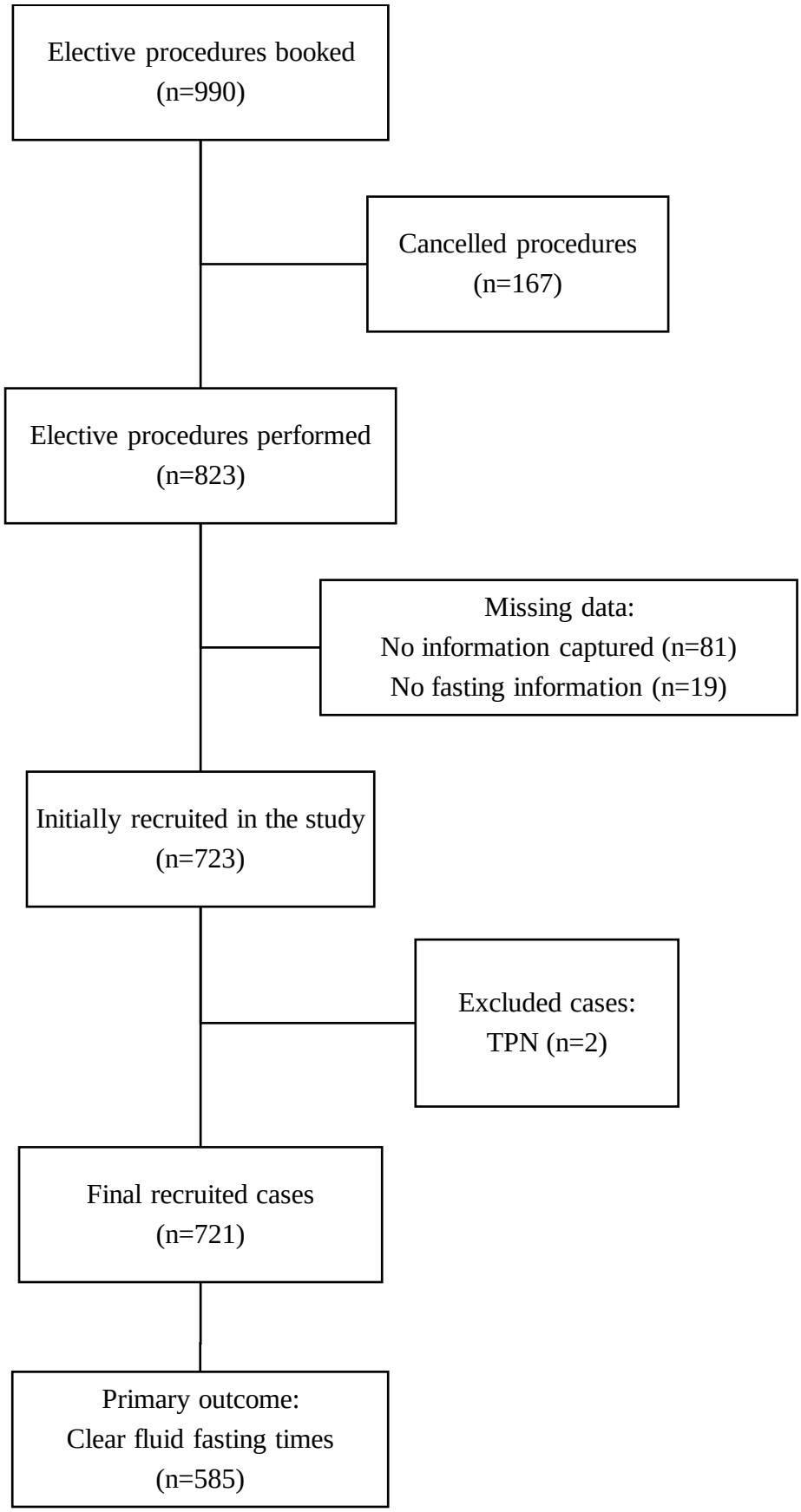

Table 1: Institutional targets for preoperative fasting durations

Fasting category	Target preoperative fasting duration (hours)
Clear liquids	2 - 4
Breast milk	4 - 6
Infant formula milk	6 - 8
Solids and semi-solids	6 - 8
Nasojejunal tube	2 - 4

Table 2: Demographic, surgical and anaesthetic information

Patient information	Captured cases (n=721)
Demographic information	
Age (months), mean (SD)	53.1 (44.6)
Weight (kg), median (IQR)	14.40 (10.0-20.7)
Female, n (%)	311 (43.1)
ASA Physical Status Class, n (%)	
1	369 (51.2)
2	224 (31.1)
3	121 (16.8)
4	7 (1.0)
Surgical information	
Preoperative location, n (%)	
Same day admission	297 (41.2)
In-patient	411 (57.0)
Intensive care unit	13 (1.8)
Timing of list, n (%)	
Morning	334 (46.3)
Afternoon	123 (17.1)
Full-day	264 (36.6)
Type of procedure or surgery, n (%)	
Burns	55 (7.6)
Cardiothoracic	44 (6.1)
Cardiology (cathlab)	26 (3.6)
Dental	24 (3.3)
Ear, nose and throat	118 (16.4)
General	140 (19.4)
Medical specialities*	20 (2.8)
Neurosurgery	25 (3.5)
Ophthalmology	63 (7.7)
Orthopaedic surgery	9 (1.2)
Plastic	75 (10.4)
Radiology	80 (11.1)
Urology	42 (5.8)
Anaesthetic information	
Anaesthesia technique, n (%)	
General anaesthesia	643 (89.2)
Sedation	78 (10.8)
Pre-operative IV fluid infusion, n (%)	
IV maintenance fluid infusion	67 (9.3)
No IV maintenance fluid infusion	640 (88.8)
Unknown	14 (1.9)

*Medical specialities: Gastroenterology, pulmonology, rheumatology
SD = standard deviation; IQR = interquartile range; ASA = American Society of Anesthesiology; IV= intravenous

Table 3: Fasting duration and compliance to preoperative fasting time targets

Fasting category	Fasting duration (hours), mean (SD)	Fasting Compliance, n (%, 95% CI)
Primary outcome		
Clear liquid (n=585)	8.0 (4.8)	149 (25.5, 21.9-29.0)
Secondary outcomes		
Breast milk (n=92)	7.1 (2.8)	35 (38.0, 28.1-48.0%)
Formula Milk (n=116)	8.8 (2.8)	53 (45.7, 36.6-54.8)
Solid feed (n=560)	13.9 (3.6)	49 (8.8, 6.4-11.1)
Last feed (n=639)	12.9 (4.0)	102 (16.0, 13.1-18.8)
Nasojejunal tube (n=5)	6.7 (3.3)	1 (0)

SD = standard deviation; CI = confidence interval

Table 4: Clear liquid fasting in age categories

Age category (months)	Fasting duration (hours) mean (SD) or median (IQR)	Fasting compliance n (% compliance, 95% CI)
<12 (n=84)	4.3 (3.0-6.9)*	36(42.8, 32.3-53.4)
12-36 (n=138)	7.7 (4.6)	34(24.6, 17.4-31.8)
>36 (n=363)	8.7 (5.0)	79(21.8, 17.5-26.0)
	p<0.001	*p<0.001*

*non-normally distributed

Table 5: Reasons for clear liquid fasting >4 hours (n=278)

Themes and Reasons	n (%)
Issues with fasting instructions	
Non-individualised fasting instructions	34 (12.2)
No fasting information or education	3 (1.1)
Poor adherence to fasting instructions	
Instructions to give clear liquid not followed	77 (27.7)
Child asleep	29 (10.4)
Child refused clear liquid	22 (7.9)
Lack of flexibility in liquid fasting time	
No liquid offered while waiting	83 (29.9)
Delays	
Delay in start of procedure	30 (10.8)

Part B: Supporting documents

Appendix 1 – Data capture instrument

DEPARTMENT OF ANAESTHESIA & PERIOPERATIVE MEDICINE
UNIVERSITY OF CAPE TOWN

R.C.W.M.C.H. R.O.H.V.K.

PLEASE PLACE PATIENT STICKER HERE OR COMPLETE
Folder number:
Date of birth:
Gender:

Date: DD/MM/YYYY

Discussion with: ☐ Parent ☐ Nurse
Parent with child overnight ☐ Yes ☐ No

1. Weight: _____Kg
2. ASA status: I | II | III | IV
3. Preoperative location: (Please specify ward) ☐ Admitted same day ☐ In-patient ☐ ICU

4. Case **Urgency**: ☐ Elective (scheduled) ☐ Emergency (Unscheduled)
5. **Half-day** or Full-day list: ☐ AM ☐ PM ☐ Full day
6. **Specialty**:
   - ☐ Burns
   - ☐ Cardiothoracics
   - ☐ Cardiology (cathlab)
   - ☐ Dental
   - ☐ ENT
   - ☐ General surgery
   - ☐ Medical specialties
   - ☐ Neurosurgery
   - ☐ Ophthalmology
   - ☐ Orthopaedics
   - ☐ Plastics
   - ☐ Radiology (CT/MRI)
   - ☐ Urology
   - ☐ Other:

7. TPN: ☐ Yes ☐ No
8. "Bowel prep" regimen: ☐ Yes ☐ No
9. **IV** maintenance fluid **preoperatively:** ☐ Yes ☐ No
10. **FASTING TIMES**: Time of last intake for **each of the following**

		Day before	*Same day*
a. Clear liquid		:	:
b. Milk	☐ Breast Milk	:	:
	☐ Infant formula milk	:	:
c. Solid/ semi-solid food		:	:
d. Other	☐ NGT feeds	:	:
	☐ NJT feeds	:	:

11. **IV** fluids received **intra-operatively:** ☐ Yes ☐ No

12. Anaesthetic type: ☐ GA ☐ Sedation
13. **ANAESTHETIC START TIME**: :
14. **Clear fluids >4** hours pre-operatively: Please select the most likely reason(s) for this
    - ☐ Fluid withheld - concern that patient will not be fasted in time
    - ☐ Patient position on list changed/ moved to later
    - ☐ Instructions to give clear liquid not followed
    - ☐ Child refused clear liquid offered
    - ☐ Child asleep
    - ☐ Fluid withheld due to aspiration risk
    - ☐ Other: ☐ Unknown
15. **Regurgitation** event: ☐ In theatre ☐ Recovery

16. **Comments:**

Appendix 2 – Patient consent poster

DEPARTMENT OF ANAESTHESIA & PERIOPERATIVE MEDICINE
UNIVERSITY OF CAPE TOWN

R.C.W.M.C.H. R.O.H.V.K.

IMPORTANT PATIENT INFORMATION

A RESEARCH STUDY IS BEING CONDUCTED AT RED CROSS WAR MEMORIAL CHILDREN'S HOSPITAL

WHAT YOU NEED TO KNOW:

* This research is being done by the **Department of Anaesthesia and Perioperative Medicine**
* Some **routine information about your child's surgical care** at RCWMCH will be collected
* This research will **evaluate the quality of care** your child receives
* The results of the study may be used to **improve care for patients in the future**
* Information gathered is **anonymous** and **confidential**
* Your child's care and **management will not be altered**
* The study is **safe**
* Should you wish **not to be included in the study**, please inform your anaesthetist

FOR FURTHER INFORMATION, PLEASE CONTACT:

Lizel Loo 021-404-5035
Melissa Williams 021-658-5183

If you have questions about your rights or welfare as a research participant, please contact the UCT Faculty of Health Sciences Human Research Ethics Committee on 021 406 6338

Appendix 3 – HREC approval letter

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room E53-46 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6492
Email: sumayah.ariefdien@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

06 September 2018

HREC REF: 410/2018

Dr G Wilson
Department of Anaesthesia & Perioperative Medicine
Red Cross Children's Hospital
Rondebosch

Dear Dr Wilson

PROJECT TITLE: A PROSPECTIVE STUDY OF PAEDIATRIC FASTING TIMES BEFORE ANAESTHESIA FOR ELECTIVE PROCEDURES AT RCWMCH (MMED CANDIDATE - DR ALISON KOUVARELLIS)

Thank you for your response letter, addressing the issues raised by the Human Research Ethics Committee (HREC).

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year until the 30 September 2019.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

We acknowledge that the student: Dr Alison Kouvarellis will also be involved in this study.

Please quote the HREC REF in all your correspondence.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval, where necessary, before the research may occur.

Yours sincerely

Signature Removed

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE

Federal Wide Assurance Number: FWA00001637.

Appendix 4 – RCWMCH research committee approval letter

Western Cape Government
Health

DR AN PARBHOO
Manager: Medical Services
Red Cross War Memorial Children's Hospital
Email: Anita.Parbhoo@westerncape.gov.za
Tel: +27 21 658 5430 Fax: +27 21 658 5006/5166

28 September 2018

Dr A Kouvarellis
Department of Anaesthesia and Perioperative Medicine

Dear Kouvarellis,

RESEARCH: RXH: RCC 151

PROJECT TITLE: A prospective study of paediatric fasting times before Anaesthesia for elective procedures at RCWMCH

It is a pleasure to inform you that approval is hereby granted to conduct above-mentioned study at Red Cross War Memorial Children's Hospital,

Yours sincerely,

Signature Removed

DR AN PARBHOO
MANAGER: MEDICAL SERVICES

Appendix 5 – SAMJ instructions to authors

Available from:
http://www.samj.org.za/index.php/samj/about/submissions#authorGuidelines

Author Guidelines

The *SAMJ* has launched a new submission and tracking system. Authors will be required to register a profile on the Editorial Manager platform in order to submit a manuscript.

To submit a manuscript, please proceed to the *SAMJ* Editorial Manager website:

www.editorialmanager.com/samj

To access and submit an article already in production, please see the guidelines here.

Author Guidelines

Please view the Author Tutorial for guidance on how to submit on Editorial Manager.

Please take the time to familiarise yourself with the policies and processes below. If you still have any questions, please do not hesitate to ask our editorial staff (tel.: +27 (0)21 532 1281, email: submissions@hmpg.co.za).

SAMJ policies

- Types of articles considered by the SAMJ
- Article Processing Charges
- Authorship
- Conflict of interest
- Research ethics committee approval
- Clinical trials
- Protection of patient's rights to privacy
- Copyright notice
- Privacy statement
- Ethnic classification
- CPD

Manuscript preparation

- Preparing an article for anonymous review
- General article format/layout
- Preparation notes by article type
- Illustrations
- Tables
- References

From submission to acceptance

- Submission and peer-review
- Production process
- Changing contact details or authorship

Publication

- Online versus print
- Errata and retractions
- Indexing

SAMJ Policies

Type of articles considered by the SAMJ

The *SAMJ* will no longer limit the articles accepted to those that have 'general medical content', but is intending to capture the spectrum of medical and health sciences, grouped by relevance to the country's burdens of disease. This content will include research in the social sciences and economics that is relevant to the medical issues around our burden of disease. Please see 'A new vision for the *SAMJ* – and a call for papers' for a full discussion of the new directions for the *SAMJ*.

We accept the following types of articles:

- Research
- Reviews
- Clinical trials
- Editorials
- In Practice (Previously Forum incl. Case Reports)
- Correspondence
- Obituaries
- Book reviews
- Ad hoc supplements e.g. guidelines, conference/congress abstracts, Festschrifts*

The following articles are by invitation only:

- Guest editorial
- Continuing Medical Education (CME)

*Contact claudian@hmpg.co.za for information on submitting ad hoc/commissioned supplements, including guidelines, conference/congress abstracts, Festschrifts, etc.

Publication Fees

All articles published in the *South African Medical Journa*l are open access and freely available online upon publication. This is made possible by applying a business model to offset the costs of peer review management, copyediting, design and production, by charging a publication fee of R5 565 (ex vat) for each research article published. The charge applies only to **Research** articles submitted after 1 March 2017. The publication fee is standard and does not vary based on length, colour, figures, or other elements.

When submitting a Research article to the *SAMJ*, the submitting author must agree to pay the publication fee should the article be accepted for publication. The publication fee is payable when your manuscript is editorially accepted and before production commences for publication. The submitting author will be notified that payment is due and given details on the available methods of payment. Prompt payment is advised; the article will not enter into production until payment is received.
Queries can be directed to claudian@hmpg.co.za.

Please refer to the section on 'Sponsored Supplements' regarding the publication of supplements, where a charge is applicable. Queries can be directed to dianes@hmpg.co.za or claudian@hmpg.co.za

Authorship

Named authors must consent to publication. Authorship should be based on: (*i*) substantial contribution to conceptualisation, design, analysis and interpretation of data; (*ii*) drafting or critical revision of important scientific content; or (*iii*) approval of the version to be published. These conditions must all be met (uniform requirements for manuscripts submitted to biomedical journals; refer to www.icmje.org)

If authors' names are added or deleted after submission of an article, or the order of the names is changed, all authors must agree to this in writing.

Please note that co-authors will be requested to verify their contribution upon submission. Non-verification may lead to delays in the processing of submissions.

Author contributions should be listed/described in the manuscript.

Conflicts of interest

Conflicts of interest can derive from any kind of relationship or association that may influence authors' or reviewers' opinions about the subject matter of a paper. The existence of a conflict – whether actual, perceived or potential – does not preclude publication of an article. However, we aim to ensure that, in such cases, readers have all the information they need to enable them to make an informed assessment about a publication's message and conclusions. We require that both authors and reviewers declare all sources of support for their research, any personal or financial relationships (including honoraria, speaking fees, gifts received, etc) with relevant individuals or organisations connected to the topic of the paper, and any association with a product or subject that may constitute a real, perceived or potential conflict of interest. If you are unsure whether a specific relationship constitutes a conflict, please contact the editorial team for advice. If a conflict remains undisclosed and is later brought to the attention of the editorial team, it will be considered a serious issue prompting an investigation with the possibility of retraction.

Research ethics committee approval

Authors must provide evidence of Research Ethics Committee approval of the research where relevant. Ensure the correct, full ethics committee name and reference number is included in the manuscript.

If the study was carried out using data from provincial healthcare facilities, or required active data collection through facility visits or staff interviews, approval should be sought from the relevant provincial authorities. For South African authors, please refer to the guidelines for submission to the National Health Research Database. Research involving human subjects must be conducted according to the principles outlined in the Declaration of Helsinki. Please refer to the National Department of Health's guideline on structures to ensure that the appropriate requirements for conducting research have been met, and that the HPCSA's General Ethical Guidelines for Health Researchers have been adhered to.

Clinical trials

As per the recommendations published by the International Committee of Medical Journal Editors (ICMJE), clinical trial research is any research that assigns individuals to an intervention, with or without a concurrent comparison/control group to study the cause-and-effect relationship between the intervention and health outcomes. All clinical trials should be registered with the appropriate national clinical trial registry (or any international primary register, if relevant), and the trial registration number should be cited at the end of the abstract. All clinical trial reports must also contain a data sharing statement as per the recommendations of the ICMJE. Statements are to indicate:

- whether individual deidentified participant data will be shared;
- what data in particular will be shared; whether additional, related documents will be available;
- when the data will become available and for how long; by what access criteria data will be shared.

Please see the ICJME announcement for further details and illustrative examples of data sharing statements: ICMJE Data Sharing Statements for Clinical Trials

Since 1st December 2005, all clinical trials conducted in South Africa have been required to be registered in the South African National Clinical Trials Register. The SAMJ therefore requires that clinical trials be registered in the relevant public trials registry at or before the time of first patient enrolment as a condition for publication. The trial registry name and registration number must be included in the manuscript.

Please refer to the general guidelines for all papers at the top of this article for additional requirements with respect to ethics approval, funding, author contributions, etc. The format of original research articles should be followed for reporting of clinical trial results.

Patient Consent

Information that would enable identification of individual patients should not be published in written descriptions, photographs, and pedigrees unless the information is essential for scientific purposes and the patient (or parent or guardian) has given informed written consent for publication and distribution. We further recommend that the published article is disseminated not only to the involved researchers but also to the patients/participants from whom the data was drawn. Refer to Protection of Research Participants. The signed consent form should be submitted with the manuscript to enable verification by the editorial team.

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Use of racial or ethnicity classifications in research is fraught with problems. If you choose to use a research design that involves classification of participants based on race or ethnicity, or discuss issues with reference to such classifications, please ensure that you include a detailed rationale for doing so, ensure that the categories you describe are carefully defined, and that socioeconomic, cultural and lifestyle variables that may underlie perceived racial disparities are appropriately controlled for. Please also clearly specify whether race or ethnicity is classified as reported by the patient (self-identifying) or as perceived by the investigators. Please note that is not appropriate to use self-reported or investigator-assigned racial or ethnic categories for genetic studies.

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Manuscript preparation

Preparing an article for anonymous review

To ensure a fair and unbiased review process, all submissions are to include an anonymised version of the manuscript. The exceptions to this are Correspondence, Book reviews and Obituary submissions.

Submitting a manuscript that needs additional blinding can slow down your review process, so please be sure to follow these simple guidelines as much as possible:

- An anonymous version should not contain any author, affiliation or particular institutional details that will enable identification.
- Please remove title page, acknowledgements, contact details, funding grants to a named person, and any running headers of author names.
- Mask self-citations by referring to your own work in third person.

General article format/layout

Accepted manuscripts that are not in the correct format specified in these guidelines will be returned to the author(s) for correction, which will delay publication.

General:

- Manuscripts must be written in UK English.
- The manuscript must be in Microsoft Word format. Text must be single-spaced, in 12-point Times New Roman font, and contain no unnecessary formatting (such as text in boxes).
- Please make your article concise, even if it is below the word limit.
- Qualifications, ***full*** affiliation (department, school/faculty, institution, city, country) and contact details of ALL authors must be provided in the manuscript and in the online submission process.
- Abbreviations should be spelt out when first used and thereafter used consistently, e.g. 'intravenous (IV)' or 'Department of Health (DoH)'.
- Include sections on Acknowledgements, Conflict of Interest, Author Contributions and Funding sources. If none is applicable, please state 'none'.
- Scientific measurements must be expressed in SI units except: blood pressure (mmHg) and haemoglobin (g/dL).
- Litres is denoted with an uppercase L e.g. 'mL' for millilitres).
- Units should be preceded by a space (except for % and ºC), e.g. '40 kg' and '20 cm' but '50%' and '19ºC'.
- Please be sure to insert proper symbols e.g. µ not u for micro, a not a for alpha, b not B for beta, etc.
- Numbers should be written as grouped per thousand-units, i.e. 4 000, 22 160.
- Quotes should be placed in single quotation marks: i.e. The respondent stated: '...'
- Round brackets (parentheses) should be used, as opposed to square brackets, which are reserved for denoting concentrations or insertions in direct quotes.
- If you wish material to be in a box, simply indicate this in the text. You may use the table format –this is the *only* exception. Please DO NOT use fill, format lines and so on.

SAMJ is a generalist medical journal, therefore for articles covering genetics, it is the responsibility of authors to apply the following:

- Please ensure that all genes are in italics, and proteins/enzymes/hormones are not.
- Ensure that all genes are presented in the correct case e.g. TP53 not Tp53.

** NB: Copyeditors cannot be expected to pick up and correct errors wrt the above, although they will raise queries where concerned.

- Define all genes, proteins and related shorthand terms at first mention, e.g. '188del11' can be glossed as 'an 11 bp deletion at nucleotide 188.'
- Use the latest approved gene or protein symbol as appropriate:
    - Human Gene Mapping Workshop (HGMW): genetic notations and symbols
    - HUGO Gene Nomenclature Committee: approved gene symbols and nomenclature
    - OMIM: Online Mendelian Inheritance in Man (MIM) nomenclature and instructions
    - Bennet et al. Standardized human pedigree nomenclature: Update and assessment of the recommendations of the National Society of Genetic Counselors. J Genet Counsel 2008;17:424-433: standard human pedigree nomenclature.

Preparation notes by article type

- Research
- Editorials
- CME
- In Practice and Case reports
- Reviews
- Clinical trials
- Correspondence
- Obituaries
- Book reviews
- Guidelines

Research

Guideline word limit: 4 000 words

Research articles describe the background, methods, results and conclusions of an original research study. The article should contain the following sections: introduction, methods, results, discussion and conclusion, and should include a structured abstract (see below). The introduction should be concise – no more than three paragraphs – on the background to the research question, and must include references to other relevant published studies that clearly lay out the rationale for conducting the study. Some common reasons for conducting a study are: to fill a gap in the literature, a logical extension of previous work, or to answer an important clinical question. If other papers related to the same study have been published previously, please make sure to refer to them specifically. Describe the study methods in as much detail as possible so that others would be able to replicate the study should they need to. Results should describe the study sample as well as the findings from the study itself, but all interpretation of findings must be kept in the discussion section, which should consider primary outcomes first before any secondary or tertiary findings or post-hoc analyses. The conclusion should briefly summarise the main message of the paper and provide recommendations for further study.

Select figures and tables for your paper carefully and sparingly. Use only those figures that provided added value to the paper, over and above what is written in the text.

Do not replicate data in tables and in text .

Structured abstract

- This should be 250-400 words, with the following recommended headings:
  - **Background:** why the study is being done and how it relates to other published work.
  - **Objectives:** what the study intends to find out
  - **Methods:** must include study design, number of participants, description of the intervention, primary and secondary outcomes, any specific analyses that were done on the data.

    - **Results:** first sentence must be brief population and sample description; outline the results according to the methods described. Primary outcomes must be described first, even if they are not the most significant findings of the study.
    - **Conclusion:** must be supported by the data, include recommendations for further study/actions.
- Please ensure that the structured abstract is complete, accurate and clear and has been approved by all authors.
- Do not include any references in the abstracts.

Here is an example of a good abstract.

Main article

All articles are to include the following main sections: Introduction/Background, Methods, Results, Discussion, Conclusions.

The following are additional heading or section options that may appear within these:

- Objectives (within Introduction/Background): a clear statement of the main aim of the study and the major hypothesis tested or research question posed
- Design (within Methods): including factors such as prospective, randomisation, blinding, placebo control, case control, crossover, criterion standards for diagnostic tests, etc.
- Setting (within Methods): level of care, e.g. primary, secondary, number of participating centres.
- Participants (instead of patients or subjects; within Methods): numbers entering and completing the study, sex, age and any other biological, behavioural, social or cultural factors (e.g. smoking status, socioeconomic group, educational attainment, co-existing disease indicators, etc)that may have an impact on the study results. Clearly define how participants were enrolled, and describe selection and exclusion criteria.
- Interventions (within Methods): what, how, when and for how long. Typically for randomised controlled trials, crossover trials, and before and after studies.
- Main outcome measures (within Methods): those as planned in the protocol, and those ultimately measured. Explain differences, if any.

Results

- Start with description of the population and sample. Include key characteristics of comparison groups.
- Main results with (for quantitative studies) 95% confidence intervals and, where appropriate, the exact level of statistical significance and the number need to treat/harm. Whenever possible, state absolute rather than relative risks.
- Do not replicate data in tables and in text.
- If presenting mean and standard deviations, specify this clearly. Our house style is to present this as follows:
- E.g.: The mean (SD) birth weight was 2 500 (1 210) g. Do not use the ± symbol for mean (SD).

- Leave interpretation to the Discussion section. The Results section should just report the findings as per the Methods section.

Discussion

Please ensure that the discussion is concise and follows this overall structure – sub-headings are not needed:

- Statement of principal findings
- Strengths and weaknesses of the study
- Contribution to the body of knowledge
- Strengths and weaknesses in relation to other studies
- The meaning of the study – e.g. what this study means to clinicians and policymakers
- Unanswered questions and recommendations for future research

Conclusions

This may be the only section readers look at, therefore write it carefully. Include primary conclusions and their implications, suggesting areas for further research if appropriate. Do not go beyond the data in the article.

Editorials

Guideline word limit: 1 000 words

These opinion or comment articles are usually commissioned but we are happy to consider and peer review unsolicited editorials. Editorials should be accessible and interesting to readers without specialist knowledge of the subject under discussion and should have an element of topicality (why is a comment on this issue relevant now?) There should be a clear message to the piece, supported by evidence.

Please make clear the type of evidence that supports each key statement, e.g.:

- expert opinion
- personal clinical experience
- observational studies
- trials
- systematic reviews.

CME (by invite only)

CME is intended to provide readers with practical, up-to-date information on medical and related matters. It is aimed at those who are not specialists in the field.

From January 2016, all CME articles will be printed in full in the *SAMJ*. Please try to adhere strictly to the guidelines on word count as we have a page limit for the print issue of the *SAMJ*. We reserve the right to place some tables and reference lists online if this is necessary for space.

In practice, this means that each CME topic usually covers two issues of the print issue of the *SAMJ*.

The guest editor, in consultation with the editor, is responsible for convening a team of authors, deciding on the subjects to be covered and for reviewing the manuscripts submitted. The suggestion is for 4 - 5 articles, although there is some room for flexibility contingent on discussions with the editor.

For queries about these guidelines please feel free to contact the CME editor, Dr Bridget Farham, by email (ugqirha@iafrica.com) or telephone (+27 (0)82 452 2860)

Review process

The guest editor reviews the articles and returns them to the CME editor for review and final approval.

Guest editorials

Guideline word limit: 1 000 words

- Include the guest editor's personal details (qualifications, positions, affiliation, e-mail address, and a short personal profile (50words)).
- If possible, include a photograph of the author(s) at high enough resolution for print. It is preferable to provide two guest editorials, one for each issue, so that the content of the articles in each issue is covered.

Articles

Guideline word limit: 2 000 - 3 000 words

- Each article requires an abstract of ±200 words.
- The editor reserves the right to shorten articles but will send a substantially shortened article back for author approval.

Personal details

Please supply: Your qualifications, position and affiliations and MP number (used for CPD points); Address, telephone number and fax number, and your e-mail address; and a short personal profile (50words)and a few words about your current fields of interest.

In Practice

Guideline word limit: 2 000 - 3 000words

This section includes articles that would previously have been accepted into the Forum section, and case reports.

In practice articles are those that draw attention to specific issues of clinical, economic or political interest regarding medicine and healthcare in southern Africa. They are assigned to a topic:

- Case report
- Clinical practice
- Clinical alert
- Issues in medicine
- Issues in public health
- Healthcare delivery
- Medicine and the environment
- Medicine and the law
- Cochrane corner

An In Practice article should follow the following format – sub-headings are not necessary, but may be used for clarity:

- Author affiliations and qualifications: to be the same as for Research. Provide all authors' names and initials, qualifications and full affiliations, and corresponding author.
- Short abstract: does not need to be structured, but should capture the essential features of the article
- Introduction: the reason for the article and the issue being addressed
- Recent research, discussion, local policy around the issue – include your own research where appropriate
- All statements should be referenced and, if opinion only, this should be stated
- Discussion: how this article adds to the discussion around a particular topic
- If a clinical practice or policy point is at issue, this needs to be emphasised, using a box with highlights if appropriate.

Essentially In practice is an opportunity for a more discursive approach to topics of clinical, economic or political importance in southern African health systems. It is not an opportunity to put forward unsubstantiated opinions!

Case reports

The *SAMJ* has recently started to accept case reports. The cases must come from Africa, preferably southern Africa unless the condition is common to all African countries, and must be either a completely new description of a clinical condition or result (use Google!) or a case that highlights important practice or management issues.

Please use the following format for case reports:

- Title of case: do not include the words 'a case report' in the title
- Summary/abstract: up to 150 words summarising the case presentation and outcome
- Background: why is this case important and why did you write it up?
- Case presentation: presenting features, medical, social, family history as appropriate
- Case management: should be according to best practice, and if not, please explain why

- Investigations, if relevant: save space by simply saying 'normal' if, for example, renal function was completely normal, rather than listing normal results, highlight the abnormal – or indeed the normal if this is clinically significant
- Differential diagnosis, if relevant
- Treatment, if relevant
- Outcome and follow-up
- Discussion – a VERY BRIEF review of similar published cases
- Teaching points: 3 - 5 bullet points
- References: as per the *SAMJ* house style
- Tables and figures: keep to a minimum. Use clinical images where relevant – we need hi-res versions for print, and identifiable persons must have a consent form
- Patient consent: please include a statement about patient consent to a written case report. This should be uploaded as a supplementary file.

Clinical trials

Guideline word limit: 4000 words

As per the recommendations published by the International Committee of Medical Journal Editors (ICMJE), clinical trial research is any research that assigns individuals to an intervention, with or without a concurrent comparison/control group to study the cause-and-effect relationship between the intervention and health outcomes. All clinical trials should be registered with the appropriate national clinical trial registry (or any international primary register, if relevant), and the trial registration number should be cited at the end of the abstract. Since 1st December 2005, all clinical trials conducted in South Africa have been required to be registered in the South African National Clinical Trials Register. The *SAMJ* therefore requires that clinical trials be registered in the relevant public trials registry at or before the time of first patient enrolment as a condition for publication. The trial registry name and registration number must be included in the manuscript.

Please refer to the general guidelines for all papers at the top of this article for additional requirements with respect to ethics approval, funding, author contributions, etc. The format of original research articles should be followed for reporting of clinical trial results.

Review articles

Guideline word limit: 4 000 words

These are welcome, but should be either commissioned or discussed with the Editor before submission. A review article should provide a clear, up-to-date account of the topic and be aimed at non-specialist hospital doctors and general practitioners.

Please ensure that your article includes:

- Abstract: unstructured, of about 100-150 words, explaining the review and why it is important

- Methods: Outline the sources and selection methods, including search strategy and keywords used for identifying references from online bibliographic databases. Discuss the quality of evidence.
- When writing: clarify the evidence you used for key statements and the strength of the evidence. Do not present statements or opinions without such evidence, or if you have to, say that there is little or no evidence and that this is opinion. Avoid specialist jargon and abbreviations, and provide advice specific to southern Africa.
- Personal details: Please supply your qualifications, position and affiliations and MP number (used for CPD points); address, telephone number and fax number, and your e-mail address; and a short personal profile (50 words) and a few words about your current fields of interest.

Correspondence (Letters to the Editor)

Guideline word limit: 500 words

Letters to the editor should relate either to a paper or article published by the SAMJ or to a topical issue of particular relevance to the journal's readership

- May include only one illustration or table
- Must include a correspondence address.

Book reviews

Guideline word limit: 400 words

Should be about 400 words and must be accompanied by the publication details of the book. Provide a hi-res image of the cover if possible (with permission from the copyright holder).

Obituaries

Guideline word limit: 400 words

Should be offered within the first year of the practitioner's death, and may be accompanied by a photograph.

Guidelines

Guidelines should always be discussed with the Editor prior to submission.

Because of the intensive review process required to ensure Guidelines are independent, evidence-based and free from commercial bias, they are usually published as a supplement to the *SAMJ*, the costs of which must be covered by sponsorship, advertising or payment by the guideline authors/association. We will provide a quote based on the expected length of the guideline and whether it is to appear online only, or in print, which must be accepted by the body putting the guidelines together before submitting the work to the SAMJ.

The Editor reserves the right to determine the scheduling of supplements. Understandably, a delay in publication must be anticipated dependent upon editorial workflow.

All guidelines should include a clear, transparent statement about all sources of funding and an explicit, clear statement of conflicts of interest of any of the participants in the guidelines about industry funding for lectures, research, conference participation etc.

All guidelines should be structured according to Agree II.

Please access this website before putting the guidelines together, download the Agree 11 instrument and use this to put the guidelines together.

All submitted guidelines will be sent to the local Agree II appraisal committee for review and must be endorsed by an appropriate body prior to consideration and all conflicts of interest expressed.

A structured abstract not exceeding 400 words (recommended sub-headings: *Background, Recommendations, Conclusion*) is required. Sections and sub-sections must be numbered consecutively (e.g. 1. Introduction; 1.1 Definitions; 2.etc.) and summarised in a Table of Contents.

Illustrations/photos/scans

- If illustrations submitted have been published elsewhere, the author(s) should provide consent to republication obtained from the copyright holder.
- Figures must be numbered in Arabic numerals and referred to in the text e.g. '(Fig. 1)'.
- Each figure must have a caption/legend: Fig. 1. Description (any abbreviations in full).
- All images must be of high enough resolution/quality for print.
- All illustrations (graphs, diagrams, charts, etc.) must be in PDF or jpeg form.
- Ensure all graph axes are labelled appropriately, with a heading/description and units (as necessary) indicated. Do not include decimal places if not necessary e.g. 0; 1.0; 2.0; 3.0; 4.0 etc.
- Scans/photos showing a specific feature e.g. *Intermediate magnification micrograph of a low malignant potential (LMP) mucinous ovarian tumour. (H&E stain).* –include an arrow to show the tumour.
- Each image must be attached individually as a 'supplementary file' upon submission (not solely embedded in the accompanying manuscript) and named Fig. 1, Fig. 2, etc.

Tables

- Tables should be constructed carefully and simply for intelligible data representation. Unnecessarily complicated tables are strongly discouraged.
- Large tables will generally not be accepted for publication in their entirety. Please consider shortening and using the text to highlight specific important sections, or offer a large table as an addendum to the publication, but available in full on request from the author

- Embed/include each table in the manuscript Word file - do not provide separately as supplementary files.
- Number each table in Arabic numerals (Table 1, Table 2, etc.) and refer to consecutively in the text.
- Tables must be cell-based (i.e. not constructed with text boxes or tabs) and editable.
- Ensure each table has a concise title and column headings, and include units where necessary.
- Footnotes must be indicated with consecutive use of the following symbols: * † ‡ § ¶ || then ** †† ‡‡ etc.

Do not: Use [Enter] within a row to make 'new rows':

Rather: Each row of data must have its own proper row:

Do not: use separate columns for *n* and %:

Rather: Combine into one column, *n* (%):

Do not: have overlapping categories, e.g.:

Rather: Use <> symbols or numbers that don't overlap:

References

NB: *Only complete, correctly formatted reference lists in Vancouver style will be accepted. Reference lists must be generated manually and not with the use of reference manager software. Endnotes must* ***not*** *be used.*

- Authors must verify references from original sources.
- Citations should be inserted in the text as superscript numbers between square brackets, e.g. These regulations are endorsed by the World Health Organization,[2] and others.[3,4-6]
- All references should be listed at the end of the article in numerical order of appearance in the Vancouver style (not alphabetical order).
- Approved abbreviations of journal titles must be used; see the List of Journals in Index Medicus.
- Names and initials of all authors should be given; if there are more than six authors, the first three names should be given followed by et al.
- Volume and issue numbers should be given.
- First and last page, in full, should be given e.g.: 1215-1217 **not** 1215-17.
- Wherever possible, references must be accompanied by a digital object identifier (DOI) link). Authors are encouraged to use the DOI lookup service offered by CrossRef:
    - On the Crossref homepage, paste the article title into the 'Metadata search' box.
    - Look for the correct, matching article in the list of results.
    - Click Actions > Cite

- Alongside 'url =' copy the URL between { }.
- Provide as follows, e.g.: https://doi.org/10.7196/07294.937.98x

Some examples:

- *Journal references:* Price NC, Jacobs NN, Roberts DA, et al. Importance of asking about glaucoma. Stat Med 1998;289(1):350-355. http://dx.doi.org/10.1000/hgjr.182
- *Book references:* Jeffcoate N. Principles of Gynaecology. 4th ed. London: Butterworth, 1975:96-101.
- *Chapter/section in a book:* Weinstein L, Swartz MN. Pathogenic Properties of Invading Microorganisms. In: Sodeman WA, Sodeman WA, eds. Pathologic Physiology: Mechanisms of Disease. Philadelphia: WB Saunders, 1974:457-472.
- *Internet references:* World Health Organization. The World Health Report 2002 - Reducing Risks, Promoting Healthy Life. Geneva: WHO, 2002. http://www.who.int/whr/2002 (accessed 16 January 2010).
- Legal references
  - Government Gazettes:

    National Department of Health, South Africa. National Policy for Health Act, 1990 (Act No. 116 of 1990). Free primary health care services. Government Gazette No. 17507:1514. 1996.

    In this example, 17507 is the Gazette Number. This is followed by :1514 - this is the notice number in this Gazette.
  - Provincial Gazettes:

    Gauteng Province, South Africa; Department of Agriculture, Conservation, Environment and Land Affairs. Publication of the Gauteng health care waste management draft regulations. Gauteng Provincial Gazette No. 373:3003, 2003.
  - Acts:

    South Africa. National Health Act No. 61 of 2003.
  - Regulations to an Act:

    South Africa. National Health Act of 2003. Regulations: Rendering of clinical forensic medicine services. Government Gazette No. 35099, 2012. (Published under Government Notice R176).
  - Bills:

    South Africa. Traditional Health Practitioners Bill, No. B66B-2003, 2006.
  - Green/white papers:

    South Africa. Department of Health Green Paper: National Health Insurance in South Africa. 2011.
  - Case law:

    Rex v Jopp and Another 1949 (4) SA 11 (N)

    Rex v Jopp and Another: Name of the parties concerned

    1949: Date of decision (or when the case was heard)

(4): Volume number

SA: SA Law Reports

11: Page or section number

(N): In this case Natal - where the case was heard. Similarly, (C) woud indicate Cape, (G) Gauteng, and so on.

NOTE: no . after the v

- *Other references (e.g. reports)* should follow the same format*:* Author(s). Title. Publisher place: Publisher name, year; pages.
- Cited manuscripts that have been accepted but not yet published can be included as references followed by '(in press)'.
- Unpublished observations and personal communications in the text must **not** appear in the reference list. The full name of the source person must be provided for personal communications e.g. '...(Prof. Michael Jones, personal communication)'.

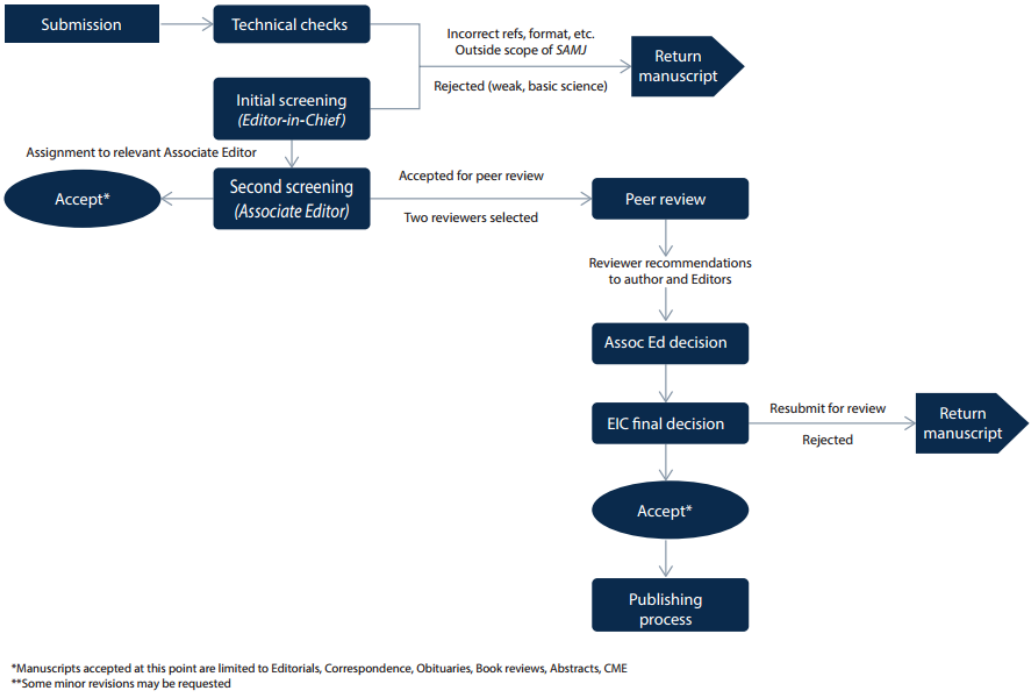
From submission to acceptance

Submission and peer-review

To submit an article:

- Please ensure that you have prepared your manuscript in line with the SAMJ requirements.
- All submissions should be submitted via Editorial Manager
- The following are required for your submission to be complete:
    - Anonymous manuscript (unless otherwise stated)
    - Manuscript
    - Any supplementary files: figures, datasets, patient consent form, permissions for published images, etc.
- Once the submission has been successfully processed on Editorial Manager, it will undergo a technical check by the Editorial Office before it will be assigned to an editor who will handle the review process. If the author guidelines have not been appropriately followed, the manuscript may be sent back to the author for correcting.

Peer-review process



Production process

Please note that there is a 6-month waiting time for publication, once an article has been sent to the production team.

The following process will follow:

1. An accepted manuscript is passed to a Managing Editor to assign to a copyeditor (CE).
2. The CE copyedits in Word, working on house style, format, spelling/grammar/punctuation, sense and consistency, and preparation for typesetting.
3. If the CE has an author queries, he/she will contact the corresponding author and send them the copyedited Word doc, asking them to solve the queries by means of track changes or comment boxes.
4. <u>The authors are typically asked to respond within 1-3 days.</u> Any comments/changes must be clearly indicated e.g. by means of track changes. Do not work in the original manuscript - work in the copyedited file sent to you and make your changes clear.
5. The CE will finalise the article and then it will be typeset.
6. Once typeset, the CE will send a PDF of the file to the authors to complete their final check, while simultaneously sending to the 2nd-eye proofreader.
7. <u>The authors are typically asked to complete their final check and sign-off within 1-2 days.</u> No major additional changes can be accommodated at this point.
8. The CE implements the authors' and proofreader's mark-ups, finalises the file, and prepares it for the upcoming issue.

Changing contact details or authorship

Please notify the Editorial Department of any contact detail changes, including email, to facilitate communication.

Publication

Online v. print

The *SAMJ* is an online journal. The online version of the journal is the one that has the widest circulation, is indexed by bibliographic databases including PubMed and SciELO, and is accessible in academic libraries. A printed edition , containing material selected by the Editor is also published each month and distributed to the membership of the South African Medical Association.

Online

- The full text of all accepted articles is published in full online, open access.
- Citation information of each article is based on its online publication.
- You may want to make use of the advantages of online publication e.g. specify web links to other sources, images, data or even a short video.

Print

- Not all articles will be selected for print.
- An article may be selected for print in a different month from that in which it was published online.
- Research articles will appear *in abstract form only*, if selected for a print edition.

Errata and retractions

Errata

Should you become aware of an error or inaccuracy in yours or someone else's contribution after it has been published, please inform us as soon as possible via an email to publishing@hmpg.co.za,including the following details:

- Journal, volume and issue in which published
- Article title and authors
- Description of error and details of where it appears in the published article
- Full detail of proposed correction and rationale

We will investigate the issue and provide feedback. If appropriate, we will correct the web version immediately, and will publish an erratum in the next issue. The correction will be indexed, as PubMed has a function for linking errata back to the original article. All investigations will be conducted in accordance with guidelines provided by the Committee on Publication Ethics (COPE).

Retractions

Retraction of an article is the prerogative of either the original authors or the editorial team of HMPG. Should you wish to withdraw your article before publication, we need a signed statement from all the authors.

Should you wish to retract your published article, all authors have to agree in writing before publication of the retraction.

Send an email to publishing@hmpg.co.za, including the following details:

- Journal, volume and issue to which article was submitted/in which article was published
- Article title and authors
- Description of reason for withdrawal/retraction.

We will make a decision on a case-by-case basis upon review by the editorial committee in line with international best practices. Comprehensive feedback will be communicated with the authors with regard to the process. In case where there is any suspected fraud or professional misconduct, we will follow due process as recommended by the Committee on Publication Ethics (COPE), and in liaison with any relevant institutions.

When a retraction is published, it will be linked to the original article.

Indexing

The *SAMJ* has an impact factor of 1.5.

Published articles are covered by the following major indexing services. As such articles published in the *SAMJ* are immediately available to all users of these databases, guaranteed a global and African audience:

- Index Medicus (Medline/PubMed)
- ExcerptaMedica (EMBASE)
- Biological Abstracts (BIOSIS)
- Science Citation Index (SciSearch)
- Current Contents/Clinical Medicine
- Scopus
- AIM
- AJOL
- Crossref
- Sabinet
- Scielo

Sponsored supplements

Contact claudian@hmpg.co.za for information on submitting ad hoc/commissioned supplements, including guidelines, conference/congress abstracts, Festschrifts, etc.

Copyright Notice

Privacy Statement

Appendix 6 – SAMJ Reviewer response letter

May 18, 2020

Dear Dr Kouvarellis,

Reviewers have now commented on your paper. You will see that they are advising that you revise your manuscript.

For your guidance, reviewers' comments are appended below.

If you are prepared to undertake the work required, please submit a list of changes or a rebuttal against each point which is being raised when you submit the revised manuscript.

Your revision is due by Jun 14, 2020. Please let us know if you require additional time.

To submit a revision, go to https://www.editorialmanager.com/samj/ and log in as an Author. You will see a menu item called Submission Needing Revision.

Best wishes

Bridget Farham, PhD
Editor
South African Medical Journal

Reviewers' comments:

Reviewer's Responses to Questions

Please comment on your General impression of this manuscript - bear the following in mind:

Is the article relevant?

Does it offer anything new?

Are there similar studies in our region/outside the region?

Does it add to the existing medical body of knowledge?

On first glance, are the methods, results and conclusions reasonable?

Do the conclusions actually draw on the results?

Does the article have a clear message?

Will it help SAMJ readers make better clinical decisions and, if so, how?

Is a general medical journal the right place for it?

Reviewer #1: Yes article is relevant, especially to general practitioners. Anaesthetists generally know the recommendations, but this is a multidisciplinary responsibility.
Doesn't offer much that is new, but does emphasise the lack of coherence on actioning the guidelines.
Not that I am aware of (similar studies in the region)
Yes the methods, results and conclusions look reasonable.
Yes the article has a clear message which will make the readers make better clinical decisions.
Yes a general journal is the right place for it. Fasting guidelines have been discussed on the anaesthetic journal SAJAA, however this is a problem that paed surgeons, paediatrics, parents etc should be aware of. I don't think there is enough discussion on this matter in a general platform.

Please comment on the Methods and analysis presented in this manuscript

Study design

Is the research question and planned outcomes clearly defined?

Was the sample adequate and sufficiently described?

Are the methods adequately described and appropriate to the study objectives?

Statistical considerations

Are simple statistical methods applied appropriately?

Reviewer #1: Yes

Please comment on the Results, Discussion and Conclusions presented in this manuscript

Results

Is the population/sample adequately described?

Are the results clearly presented?

Are they credible and do they answer the research question?

Are tables clear and useful, not simply mirroring data discussed in the Results text?

Reviewer #1: Yes

Discussion

Are the results well discussed in light of previous evidence and the literature?

Are the limitations of the study sufficiently discussed?/ Are the strengths and weakness discussed?

Is the meaning and relevance of the study discussed?

Reviewer #1: Yes

Conclusion

Are the implications of the research summarised?

Do the authors make relevant recommendations for future research or application?

Reviewer #1: Yes

Reviewer #1: Well written research that emphasises the problem of poor adherence to preop fasting guidelines!
Would have liked to see more emphasis on last year's consensus statement of reducing fasting period for clear fluids to 1hr.

Reviewers comments within manuscript:

Discussion

Query 1: More recent /up to date preop fasting recommendations have advocated for a 1-4-6hr fasting period. I appreciate that this study was done in 2018, the write up /

publication is taking place with these new recommendations. Could they be mentioned in the discussion?

Query 2: Please expand and discuss in more detail (see above comment on current fasting recommendations).

References

Query 3: Review references

Appendix 7 – SAMJ Revision cover letter

UNIVERSITY OF CAPE TOWN

Department of Anaesthesia and Perioperative Medicine

Faculty of Health Science,
Anzio Road, Observatory
Western Cape, South Africa 7925
Telephone: (021) 406-6143
Fax No. (021) 406-6589

Professorial Staff:

JLC Swanevelder MB ChB, MMed (Anes) (U Stell), FCA (SA), FRCA (Hon)
Head of Department
Email: justiaan.swanevelder@uct.ac.za
BM Biccard MBChB (UCT), FCA (SA), FFARCSI, MMed (UKZN), PhD
2nd Chair of Anaesthesia
Email: bruce.biccard@uct.ac.za
Administrative Officer: C Wyngaard, Email: cheryl.wyngaard@uct.ac.za

Dear Dr Farham,

Ref.: SAMJ14814
Title: A prospective study of paediatric preoperative fasting times at Red Cross War Memorial Children's Hospital

Thank you for the opportunity to submit a revised draft of our manuscript titled "A prospective study of paediatric preoperative fasting times at Red Cross War Memorial Children's Hospital" to The South African Medical Journal. We appreciate the time and effort that you and the reviewer dedicated to providing valuable feedback. We are grateful to the reviewer for the insightful comments. We have been able to incorporate changes in accordance with the suggestions made by the reviewer. We have highlighted the changes within the manuscript in red.

Please find below a point-by-point response to the reviewer's comments and concerns.

Reviewer's responses to questions:
Please comment on your General impression of this manuscript - bear the following in mind:

Is the article relevant?
Comment: Yes, article is relevant, especially to general practitioners. Anaesthetists generally know the recommendations, but this is a multidisciplinary responsibility.

Does it offer anything new?
Comment: Doesn't offer much that is new but does emphasise the lack of coherence on actioning the guidelines.

Are there similar studies in our region/outside the region?
Comment: Not that I am aware of (similar studies in the region)

Does it add to the existing medical body of knowledge?

On first glance, are the methods, results and conclusions reasonable?
Comment: Yes, the methods, results and conclusions look reasonable.

Do the conclusions actually draw on the results?

Does the article have a clear message?
Comment: Yes, the article has a clear message which will make the readers make better clinical decisions.

Will it help SAMJ readers make better clinical decisions and, if so, how?

Is a general medical journal the right place for it?
Comment: Yes, a general journal is the right place for it. Fasting guidelines have been discussed on the anaesthetic journal SAJAA, however this is a problem that paed surgeons, paediatrics, parents etc should be aware of. I don't think there is enough discussion on this matter in a general platform.

Reviewer #1:
Comment: Yes, article is relevant, especially to general practitioners. Anaesthetists generally know the recommendations, but this is a multidisciplinary responsibility. Doesn't offer much that is new but does emphasise the lack of coherence on actioning the guidelines.

Response: Thank you

Please comment on the Methods and analysis presented in this manuscript

Study design

Is the research question and planned outcomes clearly defined?

Was the sample adequate and sufficiently described?

Are the methods adequately described and appropriate to the study objectives?

Statistical considerations

Are simple statistical methods applied appropriately?

Reviewer #1: Yes

Response: Thank you

Please comment on the Results, Discussion and Conclusions presented in this manuscript

Results

Is the population/sample adequately described?

Are the results clearly presented?

Are they credible and do they answer the research question?

Are tables clear and useful, not simply mirroring data discussed in the Results text?

Reviewer #1: Yes

Response: Thank you

Discussion

Are the results well discussed in light of previous evidence and the literature?

Are the limitations of the study sufficiently discussed?/ Are the strengths and weakness discussed?

Is the meaning and relevance of the study discussed?

Reviewer #1: Yes

Response: Thank you

Conclusion

Are the implications of the research summarised?

Do the authors make relevant recommendations for future research or application?

Reviewer #1: Yes

Response: Thank you

Reviewer #1: Well written research that emphasises the problem of poor adherence to preop fasting guidelines!
Would have liked to see more emphasis on last year's consensus statement of reducing fasting period for clear fluids to 1hr.

Response: Thank you.
We have included that in"2018 the Association of Paediatric Anaesthetists of Great Britain and Ireland and the European Society for Paediatric Anaesthesiology released a joint consensus statement,[35] subsequently endorsed by other international paediatric anaesthesia societies,[36-38] recommending that children receive clear liquid up to one hour before elective general anaesthesia."

Response to edits in paper:
Thanks for the edits and revisions, which we have accepted.

Query 1: More recent /up to date preop fasting recommendations have advocated for a 1-4-6hr fasting period. I appreciate that this study was done in 2018, the write up / publication is taking place with these new recommendations. Could they be mentioned in the discussion?

Query 2: Please expand and discuss in more detail (see above comment on current fasting recommendations).

Response:
Thank you for the suggestions. A shorter minimum required preoperative fasting time for clear liquid does seem to be safe and contribute to improving compliance with clear fasting < 4 hours. We have included the consensus statement advocating for a one-hour clear liquid fasting time (see above) and related the findings of studies which found this to be useful to our results. "Two paediatric centres,[23, 41] which adopted this policy, demonstrated a 43% and 53% absolute risk reduction in the proportion of patients fasted for longer than four hours. Based on the one-hour fasting recommendation and the two studies with a number needed to treat of two to three, we would expect to improve compliance from 25.5% to between 51 and 76.5%."

Query 3: Review references

Response: Thank you, all references have been checked and corrected or up dated.

Thank you for giving us the opportunity resubmit our paper. We hope that these revisions are to your satisfaction. Thank you for your interest in our submission.

Regards
Dr Alison Kouvarellis
Registrar
Dept of Anaesthesia and Perioperative Medicine
Groote Schuur Hospital
University of Cape Town

Appendix 8 – Letter of acceptance for publication by the SAMJ

Ref.: SAMJ14814
A prospective study of paediatric preoperative fasting times at Red Cross War Memorial Children's Hospital
South African Medical Journal

Dear Dr Kouvarellis,

We are pleased to tell you that your work has now been accepted for publication in South African Medical Journal.

Please find payment form attached herewith. As soon as proof of payment and the completed form have been received, we will send your article into production. (Please note that we are unable to process American Express card payments). Please send proof of payment to claudian@samedical.org

Thank you for submitting your work to the journal.

Best wishes

Bridget Farham, PhD
Editor
South African Medical Journal