The effect of implementing a bundle for anaesthetists to reduce postoperative infections: a stepped wedge cluster randomised multi-site trial.

The Anaesthetists Be Cleaner (ABC) Study

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This is an invitation for you, as an anaesthetist, anaesthetic technician or perfusionist, to take part in a study to determine if a bundle of measures to improve key anaesthetic aseptic practices will reduce postoperative infection after hip or knee arthroplasty or cardiac surgery.

Your participation is voluntary and you may withdraw at any stage if you wish. Participation will have no implications for your anaesthetic current or future employment, or for your training if you are a trainee.

What is it all about?

- Previous research has shown that various aspects of anaesthesia practice, including the way in which IV medications are drawn up, handled and injected, may contribute to the important clinical problem of postoperative infection.
- This study will investigate whether a bundle of measures for improving key anaesthetic practices related to the aseptic drawing up and administering of IV medications, to hand hygiene, and to maintaining a clean work space reduces the rate of post-operative infection.
- The study will be conducted in five clinical sites within three DHBs in Auckland
- Participants will be anaesthetists, (specialists, fellows and registrars but not house officers) anaesthetic technicians and perfusionists.
- The relevant aseptic practices may involve the entire anaesthesia team, notably consultant and trainee anaesthetists and anaesthetic technicians, but also perfusionists to the extent that they administer IV medications. We assume that other aspects of managing perfusion equipment is outside the scope of this study.
- If you agree to be involved in the study your participation will last from the time you sign the consent form for the duration of the study (which will be up to three years) or until you decide to withdraw from the study, which you may do at any time.

What happens during the study?

- The bundle of measures will be implemented in patients undergoing hip or knee arthroplasty or cardiothoracic surgery in a five-site, stepped wedge, cluster randomised quality improvement design.
- We wish to compare at least 5000 patients before implementation of the bundle (i.e. usual practice) with at least 5000 patients after its implementation. These numbers will allow for complexities in our study design.
- The bundle of measures is outlined in detail in the attached two-page guideline. The key elements are (1) wiping the skin with alcohol (with or without chlorhexidine) and allowing it to dry before inserting any IV line; (2) injecting all IV bolus medications except propofol (which cannot be filtered because of its emulsion characteristics) through one or more 0.2µm filters incorporated into each patient's IV line; (3) using meticulous aseptic care with propofol; (4) performing appropriate hand hygiene; and (5) ensuring that clean working surfaces are maintained.
- If you agree to participate you will be asked to attend in particular to those aspects of the bundle most relevant to your own practice as an anaesthetist, perfusionist or anaesthetic technician, but also to participate in being supportive of the adoption of all the elements of the bundle by the whole team.
- The filters will need to be inserted into the patients' IV lines, or into the perfusion set up, at an appropriate time before you need to administer IV medications in each case. They will be supplied with

instructions for their use. They have been donated to the study by Becton-Dickinson so will not be a cost to the hospital. We ask that the filters in the IV lines be removed and discarded at the end of the patients' stay in PACU (hip or knee arthroplasty) or in theatre (cardiothoracic surgery).

- The aseptic practices of the anaesthetic team (including technicians, medical students and nurses who are involved in the anaesthetic) will be observed by non-study staff who have been trained in the use of a behaviourally anchored rating scale designed specifically for this purpose. Observations will be carried out randomly with stratification to ensure coverage of all sites.

Risks & benefits

- You will receive no direct benefit from this study, other than the knowledge that you are contributing to research intended to increase safety for all hospital patients.
- The study involves a small change in your current practice but should not compromise patient safety.
- We do not anticipate any risks or complications with this study.
- All data will be anonymous and your participation in the study will be kept confidential.

Compensation

In the unlikely event of a physical injury as a result of your participation in this study, you may be covered by ACC under the Injury Prevention, Rehabilitation and Compensation Act. ACC cover is not automatic and your case will need to be assessed by ACC according to the provisions of the 2002 Injury Prevention Rehabilitation and Compensation Act. If your claim is accepted by ACC, you still might not get any compensation. This depends on a number of factors such as whether you are an earner or non-earner. ACC usually provides only partial reimbursement of costs and expenses and there may be no lump sum compensation payable. There is no cover for mental injury unless it is a result of physical injury. If you have ACC cover, generally this will affect your right to sue the investigators. For more details, refer http://www.acc.co.nz.

Participation

Your participation is entirely voluntary. You do not have to take part in this study, and if you choose not to take part, this will not affect your employment or your training (if you are a trainee). If you do agree to take part, you are free to withdraw from the study at any time, without having to give a reason and this will in no way affect your employment or your training (if you are a trainee). You will receive no payment for your participation in this study.

General Information

This study is a quality improvement initiative focusing on aspects of the practices of anaesthetists and perfusionists rather than on patients. Adopting the bundle imposes no material risk to patients. Furthermore, it would be impracticable to obtain informed consent from the large number of patients we need in order to answer the study's question. Therefore we are obtaining informed consent from participating anaesthetists, anaesthetic technicians and perfusionists, but not from patients.

Confidentiality

No material that could personally identify you will be used in any reports on this study. All information collected from you will be kept confidential and coded only by a randomly assigned study number. It will be stored in a secure manner by the Department of Anaesthesiology at the University of Auckland for a period of at least 10 years. Only the research staff involved with this study will have access to study data.

Results

The results of this study will be presented at conferences and submitted for publication in peer-reviewed journals. Any presentations or publications resulting from this work will not include identifying data for participants, patients or hospitals. There will be a delay between your participation in the study and the analysis of the results, but once they are to hand we will present them to your departments.

Who should I contact if I have further questions?

If you have any questions or concerns about your rights as a participant in a research study you can contact an independent health and disability advocate. This is a free service provided under the Health and Disability Commissioner Act. Telephone: 0800 555 050 Fax: 0800 2787 7678 (0800 2 SUPPORT) Email: advocacy@hdc.org.nz

This study has received ethical approval from the Northern B Health and Disability Ethics Committee (Ref: 18/NTB/61) and is registered with the Australian and New Zealand Clinical Trials Registry (Ref: ACTRN12618000407291). The Auckland District Health Board Research Review Committee has given their approval for this study to be carried out (Ref: A+8036).

Please feel free to contact us if you have any questions about this study.

On behalf of the ABC study team, thank you for making the time to read about, and consider taking part in this study.

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If you require Māori cultural support, talk to your whānau in the first instance. Alternatively you may contact the administrator for He Kamaka Waiora (Māori Health team) by telephoning 09 486 8324 ext 2324. If you have any questions or complaints about the study you may contact the Auckland and Waitematā District Health Boards Maori Research Committee or Maori Research Advisor by telephoning 09 486 8920 ext 3204.

REQUEST FOR INTERPRETER			
English	I wish to have an interpreter	Yes	No
Deaf	I wish to have a NZ sign language interpreter	Yes	No
Māori	E hiahia ana ahau ki tetahi kaiwhaka Māori/kaiwhaka pakeha korero	Ae	Kao
Cook Island Māori	Ka inangaro au i tetai tangata uri reo	Ae	Kare
Fijian	Au gadreva me dua e vakadewa vosa vei au	Io	Sega
Niuean	Fia manako au ke fakaaoga e taha tagata fakahokohoko kupu	E	Nakai
Sāmoan	Ou te mana'o ia i ai se fa'amatala upu	Ioe	Leai
Tokelaun	Ko au e fofou ki he tino ke fakaliliu te gagana Peletania ki na gagana o na motu o te Pahefika	Ioe	Leai
Tongan	Oku ou fiema'u ha fakatonulea	Io	Ikai

- I have read and understood the information sheet dated 31st August 2018 for anaesthetists. anaesthetic technicians and perfusionists taking part in the study looking at a bundle of measures to reduce post-operative infection.
- I have had time to consider whether I to take part, and to use whanau support or a friend to help me ask questions and understand the study.
- I understand that taking part is voluntary (my choice) and that I may withdraw from the study at any time and this will in no way affect my current or future employment.
- I understand that my participation, and the data collected about me, is confidential.
- I understand the compensation provisions for this study.
- I know who to contact if I have any questions about the study.

Participant Anaesthetist, Anaesthetic Technician, or Perfusionist (please circle one)

I, _____ (full name), hereby consent to take part in this study.

Signed: _____ Date: _____

Project explained by: _____ Project role: _____

Signed: _____ Date: _____

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1. **Wipe skin with alcohol (with or without chlorhexidine) and allow to dry before inserting any IV line.**
2. **Inject all IV bolus medications except propofol through a 0.2µm filter incorporated into each patient's IV line (see Figure 1 for example configurations).**
   - Use aseptic technique when attaching the filter to the IV and, unless it has been freshly opened from sterile packaging, wipe the IV injection port with alcohol (with or without chlorhexidine) for 15 seconds and allow to dry.
   - If the filter is moved from one access point to another during the case the new access point should first be wiped with alcohol (with or without chlorhexidine) for 15 seconds and allowed to dry.
   - Use more than one filter if necessary or desired (e.g. for cardiac patients, one filter in the peripheral line, one on a central line port where bolus medications may be given, and a third onto the medication injection port on the bypass machine for the perfusionist to use when administering medications).
   - Remove the filter(s) on discharge from the Post Anaesthesia Care Unit or on admission to the Intensive Care Unit.
3. **Use meticulous aseptic technique when drawing up or injecting propofol, and discard syringes, needles or the medication in the event of any suspected contamination:**
   - Note that the rubber bungs on propofol vials are not sterile even with the cap in place, so they should be wiped with alcohol (with or without chlorhexidine) for 15 seconds and allowed to dry before propofol is drawn up. If the medication is supplied in an ampoule, wipe the outside of the neck and surrounding part of the ampoule with alcohol (with or without chlorhexidine) before opening.
   - Use a new needle or spike for each occasion.
   - Cap the syringe with a syringe cap or capped needle.
   - Administer as soon as possible and discard propofol after one hour if not used.
   - Do not reuse syringes or needles for propofol, even for the same patient.
   - Flush IV port with sterile sodium chloride 0.9% after propofol has been administered to ensure no residual propofol remains to support bacterial growth, using meticulous aseptic technique to draw up the flush.
4. **Perform hand hygiene:**
   - Before and after interacting with each new patient (i.e. on entering the operating room and on leaving a patient in the Post Anaesthesia Care Unit).
   - Before and after any procedure creating risk of infection (e.g. IV insertion, airway manipulation, administering propofol, etc).
   - After blood and body fluid exposure (e.g intubation, IV line insertion etc); remove gloves (if they have been worn) and, if practicable, perform hand hygiene before spreading contamination to the work station, computer key board and other surfaces.
5. **Maintain clean working surfaces:**
   - Place used laryngoscopes, masks and other contaminated objects into a tray designated for this exclusive purpose; maintain strict separation of clean and contaminated areas - do not use this tray for clean instruments, swabs or other items even at the start of a procedure.

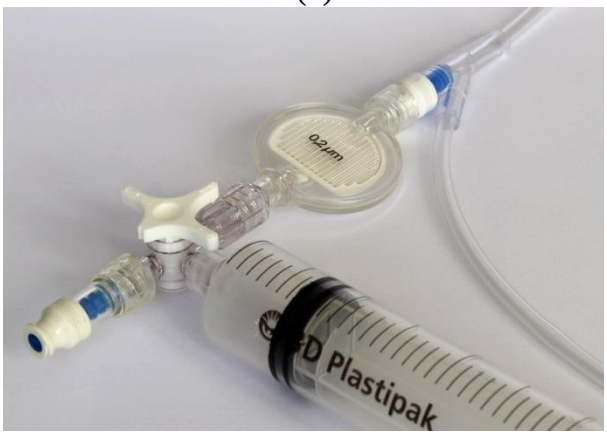
- Wipe the anaesthetic machine bench top and the circuit pressure-relief valve with alcohol (with or without chlorhexidine) once the patient has settled into the maintenance phase of anaesthetic (i.e. after intubation of the trachea if this is done).

NOTES:

- Propofol should not be injected through the filter.
- The filter has a dead space of 0.45 mL and the injection port has a dead space of 0.11 mL (= 0.56 mL in total); therefore, as with any IV setup, it is necessary to prime the filter with sterile sodium chloride 0.9% or sterile water for injection to eliminate air, and it is also necessary to ensure that medications are flushed through.
- Hand hygiene implies either hand washing with medicated soap and water or using alcohol-based hand rub; it is important for hands to dry properly.
- Provided the medications are injected through a 0.2µm filter, the study does not ask for hand hygiene in relation to the injection and drawing up of medications other than propofol.

(a)

(b)



(c)

Figure 1: Three examples of filter configurations for the ABC study: (a) filter and injection port with a 3-way tap to be attached to IV line, (b) filter and injection port attached to a side port on the IV line, and (c) as in b), with a 20mL syringe filled with sterile sodium chloride 0.9% (for easy flushing) attached via a 3 way tap. Any practical approach that permits injection of medications through a filter is acceptable. Note: in these pictures the lines and filter are not primed with fluid.