Série de webinaires

Réseau-1 Québec 2016-17

A single site RCT on the use of sterile vs. non-sterile gloves for minor procedures in primary care

Clare Heal,FRACGP, Ph. D.

28 octobre 2016

Réseau-1 Québec
Jeannie Haggerty, PhD, Directrice scientifique
Matthew Menear, PhD, Responsable du renforcement des capacités
info@reseau1quebec.ca
http://reseau1quebec.ca/ @reseau1quebec.ca

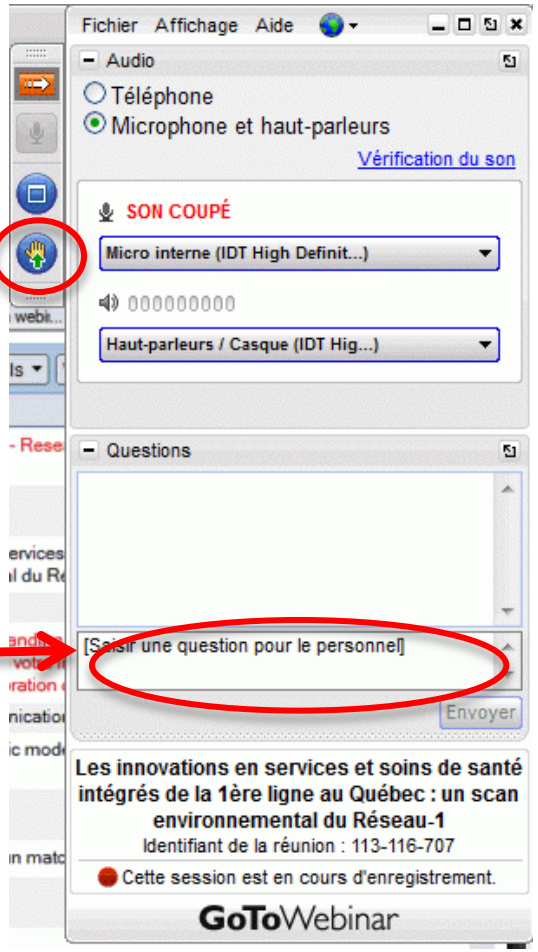
Réseau-1 Québec

Procédure pour les questions

- Vous pouvez **poser vos questions** de deux façons:

  1. ***Lever la main***:
     Nous ouvrirons votre micro et vous inviterons à poser votre question oralement durant la période de questions.

  2. ***Par écrit***:
     Tout au long de la présentation, vous pouvez écrire une question dans la boîte (cliquer sur Questions pour l'ouvrir). Nous répondrons à votre question durant la période de questions.

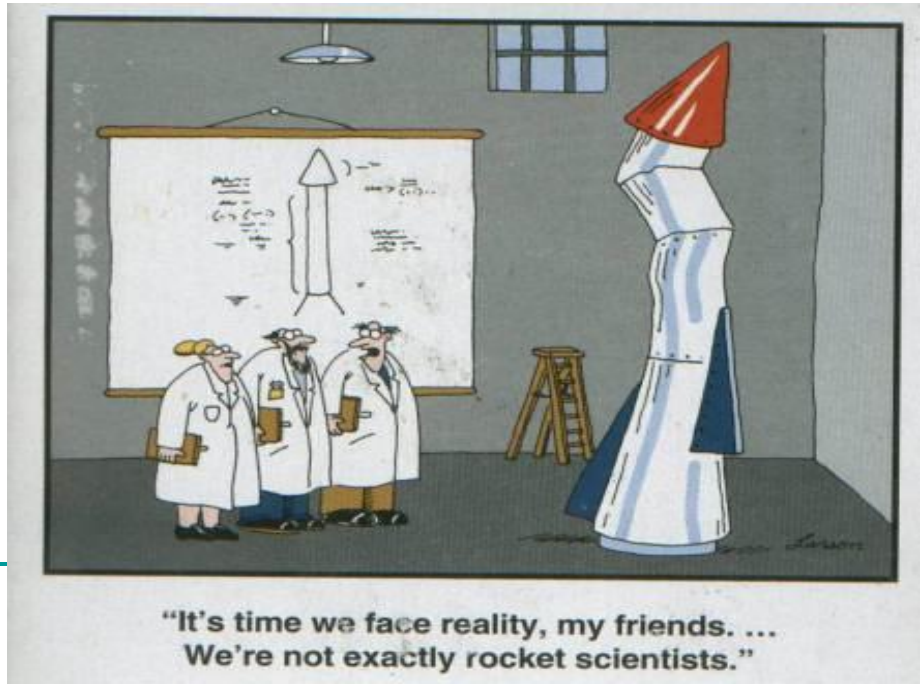


- Nous ferons notre possible pour répondre à toutes vos questions.

Réseau-1 Québec

Sterile v non-sterile clean boxed gloves for minor surgery.

Professor Clare Heal



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  - **Grants/Research Support:** RACGP only
  - **Speakers Bureau/Honoraria:** Nil
  - **Consulting Fees:** Nil
  - **Other:** Employee Qld Health

Disclosure of Commercial Support

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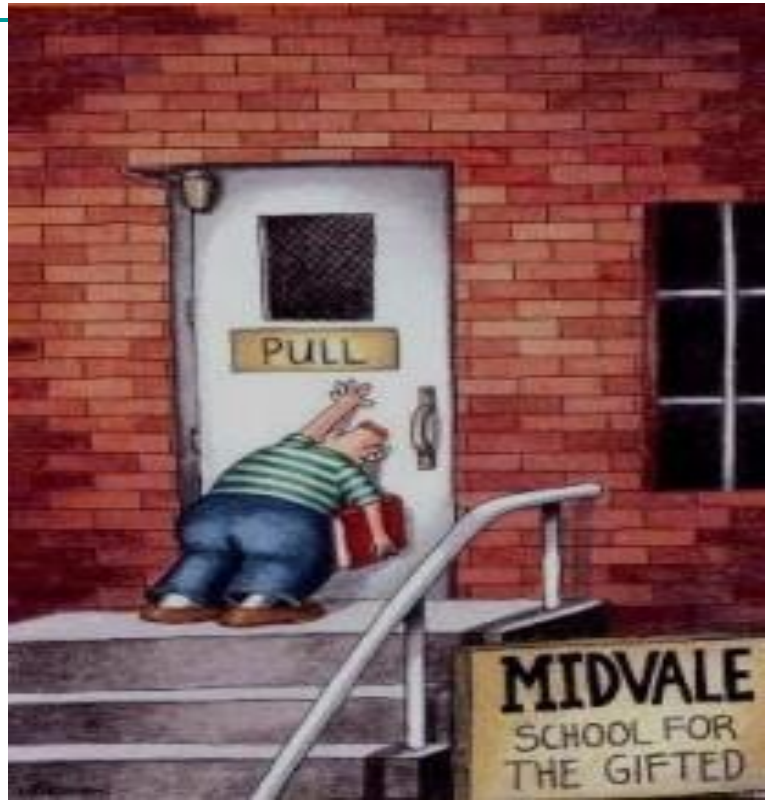
- **Potential for conflict(s) of interest:** Nil

- Background
- Description of ‘Gloves’ trial
- Discussion about practice based research



Background: Prof Clare Heal

- Qualified UK (Liverpool) 1990
- Moved Queensland Australia 1992
- JCU senior lecturer 2004
- PhD 2010 – Skin cancer diagnosis and Mx
- Promotional Chair GP 2016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CYCLONES
STINGRAYS
CROCODILES
SHARKS
STEVE IRWIN
ANGRY NATIVES
BACKPACKER MURDERERS
GIANT RATS
POISONOUS SNAKES
NOTHING
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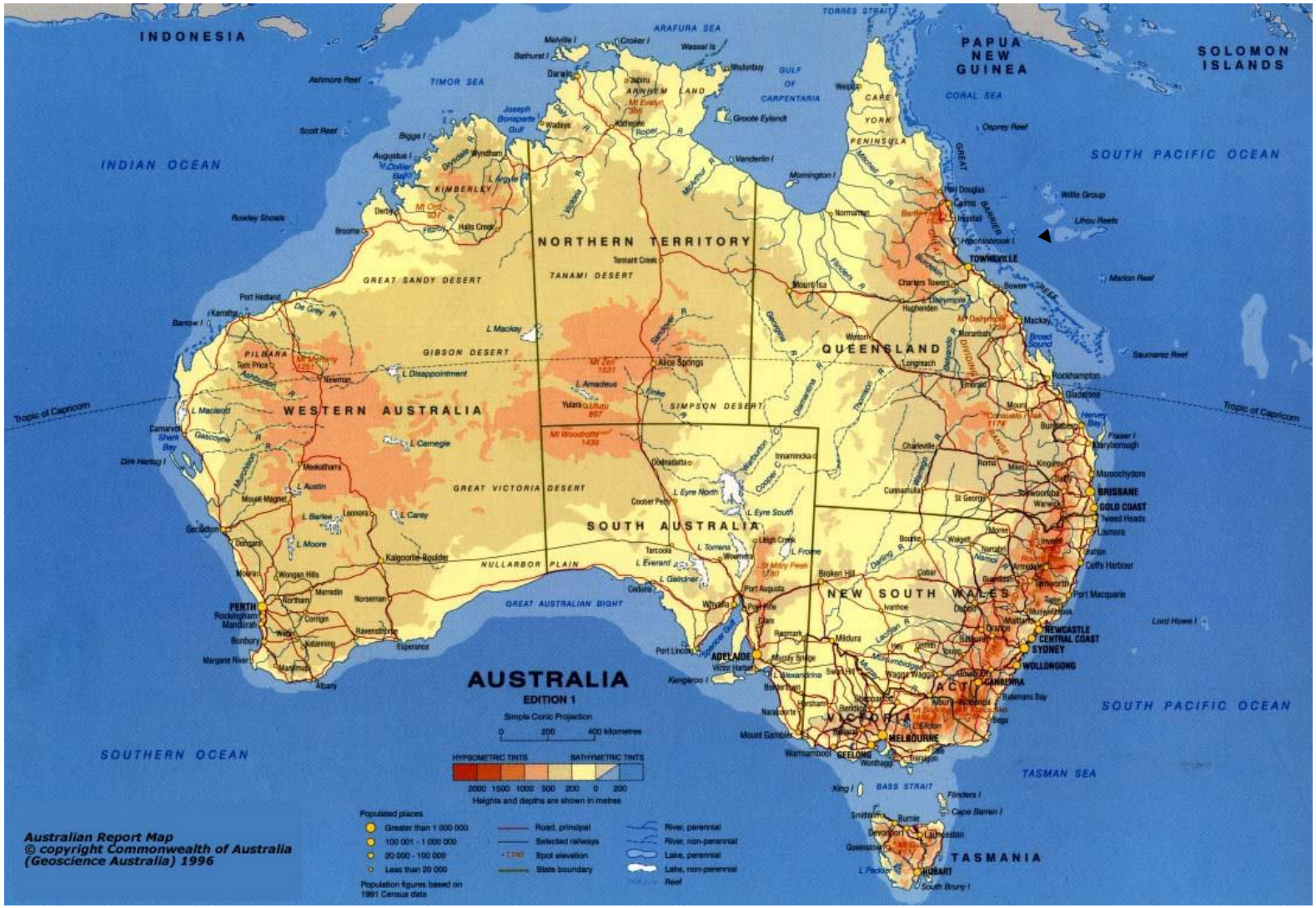
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Spot elevation
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Australian Report Map
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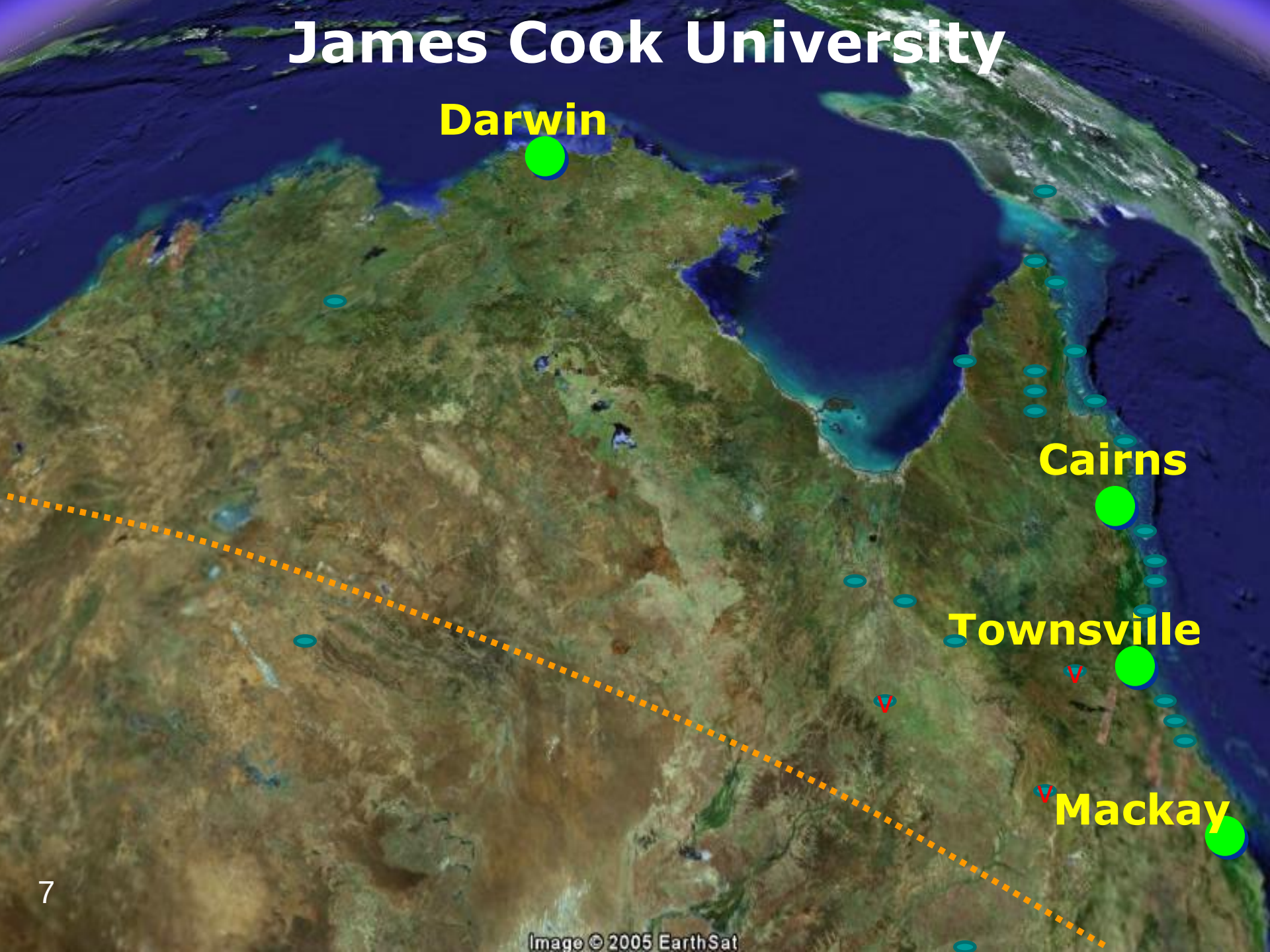


Research Interests

Practice Based research - NQPBRN

Practice Based RCT

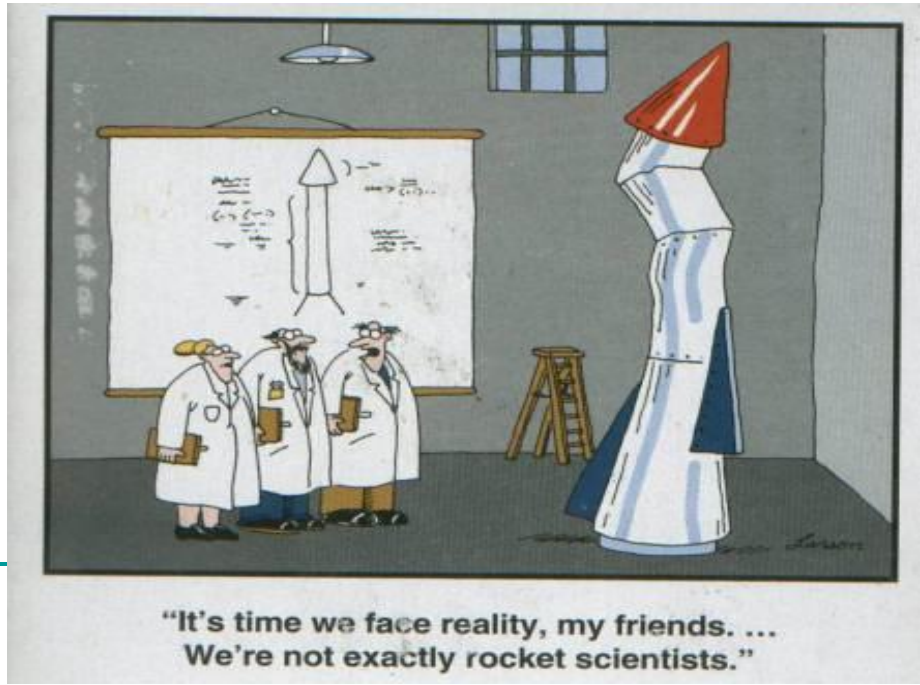
Skin cancer diagnosis and Mx

Sexual Health and Chlamydia

Sterile v non-sterile clean boxed gloves for minor surgery.

A prospective randomised control non-inferiority trial

Clare Heal, Shampavi Sri Haran, Petra Buttner, Debbie Kimber



Background – GP research

- Australia – highest world incidence of skin cancer
- Most cases managed in General Practice
- Minor surgery in Mackay: 8.6% infection rate[1]

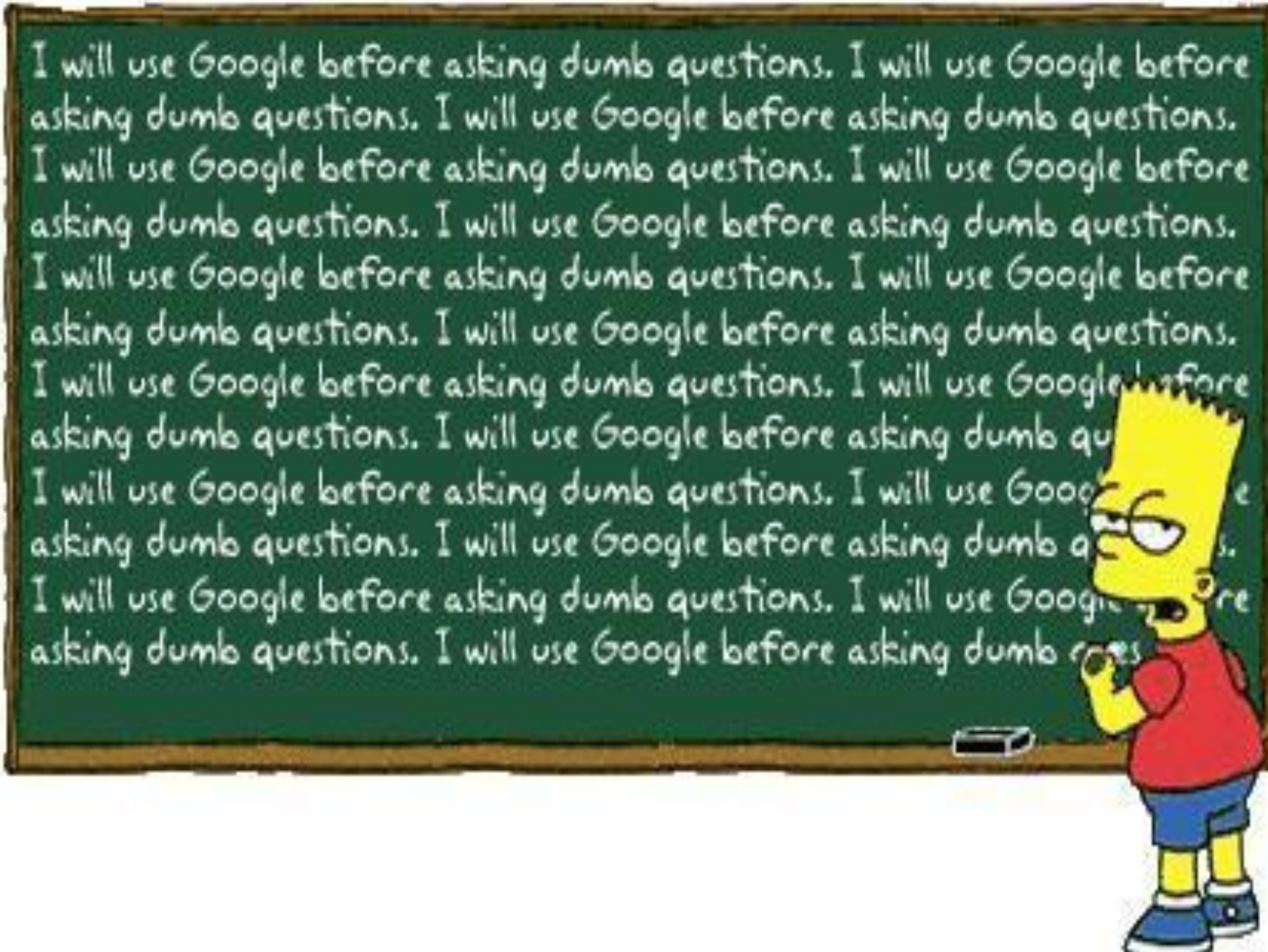
- South Australian GP practice cohort: 1.9%[2]
- Victorian skin cancer clinic: 1.5%[3]
- French dermatology clinic: 2.0%[4]

Background

Audit – glove type made no difference

Doctors disagreed – sterile v non-sterile gloves

GPs and Nurses initiated trial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Literature

Guidelines : Sterile gloves for minor procedures

Paucity of literature

No difference sterile v non-sterile gloves

Previous studies

Author, year, country	Setting, procedure type	Study design, Sample size	Non-sterile infection rate	Sterile gloves infection rate	P value
Perelman 2004[9]; Canada	Emergency department, repair of simple lacerations	Prospective randomized controlled trial, 816 patients	17/384 (4.4%) (95%-CI 2.4-6.4)	23/396 (6.1%) (95%-CI 3.5-8.1%)	p=0.295
Chiu 2006[8]; Hong Kong	Outpatient clinic, Wisdom tooth extraction	Prospective, randomized controlled trial, 275 patients	15/134 (10.9%)	12/136 (8.4%).	p=0.31
Rhinehart 2006[33]; Germany	Outpatient clinic, Mohs micrographic surgery	Retrospective cohort, 1810 patients, 2084 procedures	14/766(1.8%)	11/634 (1.7%)	p>0.5
Rogues A.M. 2007[11]; France	Hospital inpatients and outpatients Private dermatology procedures	Retrospective audit, 3491 procedures	1.7% for simple excisions 14.7% for reconstructive procedures Actual numbers not given	1.6% for simple excisions. 3.4% for reconstructive procedures	p<0.001 for reconstructive procedures
Xia 2011[10]; USA	Outpatient clinic,Mohs micrographic surgery	Pilot Prospective randomised controlled trial, 60 patients	1/30 (3.3%)	2/30(6.6%)	p=0.99

Clinical Question

Are non-sterile gloves worse than sterile gloves for minor skin excisions?

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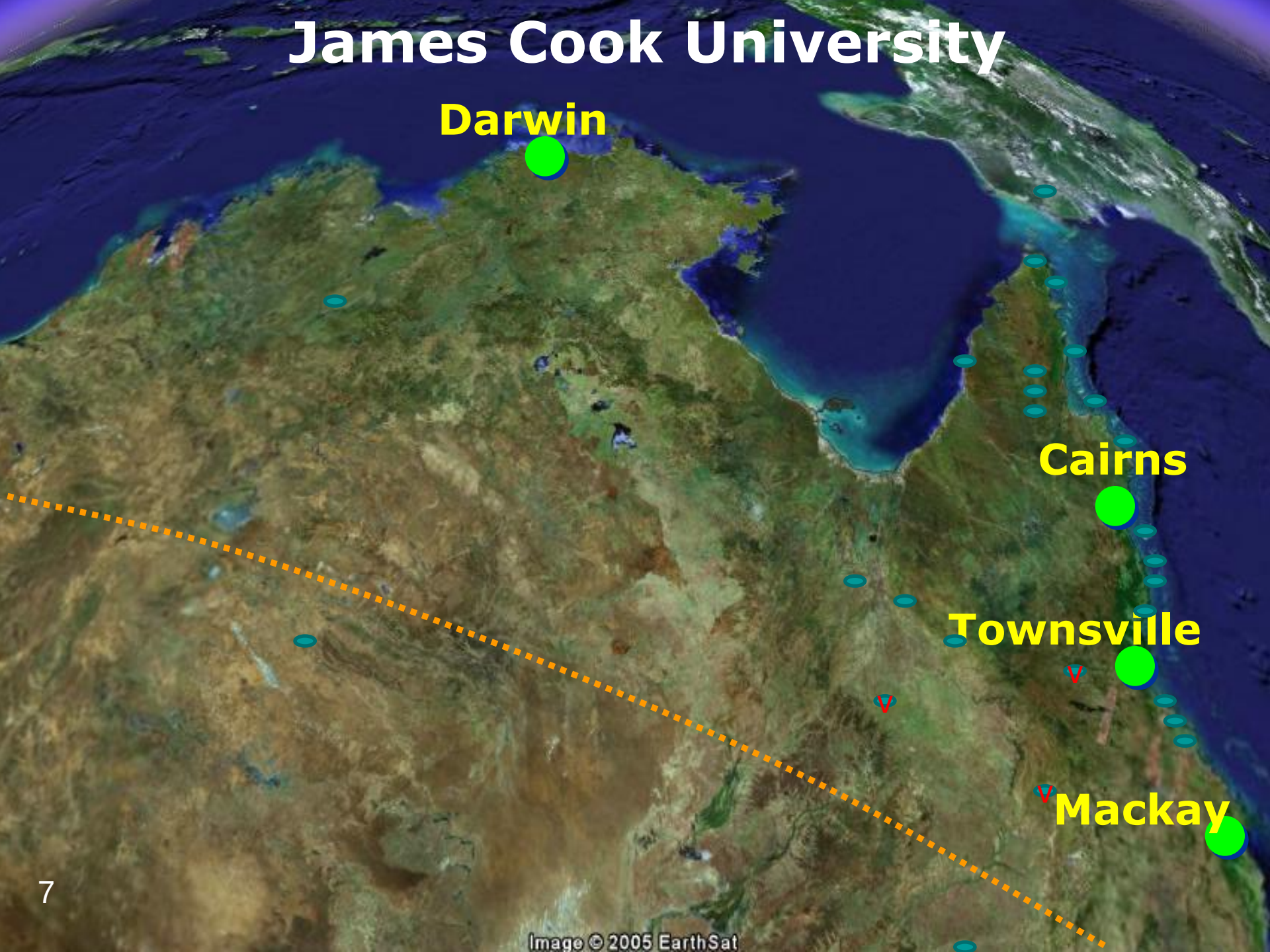


Setting

JCU - Mackay Rural Clinical School

Mackay's population about 80,000

104 practicing GPs

No dermatologist or plastic surgeon

Design

- Prospective randomised controlled non-inferiority trial
- No attempt made to blind

Participants and Recruitment

- Single General Practice Clinic
- Consecutive skin surgery patients
- Surgical excision protocol
- Practice nurse - recruitment

Eligibility Criteria

Inclusion

- Excision of minor skin lesions
- All body sites including face

Exclusion

- Taking oral antibiotics
- Immunocompromised
- Lacerations
- Excision of sebaceous cyst
- Latex allergies
- Needing shave biopsies

Data Collection

Demographics

- Age
- Sex

Surgical information

- Excision site – body map
- Excision size
- Suture used
- Histology

Social

- Occupation
- Smoking status

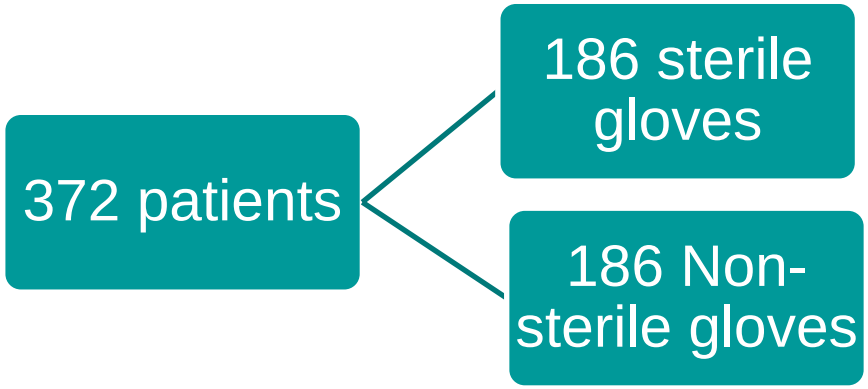
- **Other Medical conditions**

- **Other**
  - Diabetes Mellitus

- **Medications**
  - Oral/inhaled steroids
  - Warfarin
  - Aspirin/Clopidogrel
  - Disease Modifying Anti rheumatic drugs (DMARDS)

Sample Size

- Non-inferiority trial
  Pre-set margin of non-inferiority
- Baseline infection rate: 8.0%→ 15% considered clinically significant
- 372 patients; 186 in each group
- 80% power to detect a non-inferiority margin difference of 7%



Skin Excision Protocol

Skin preparation	Use chlorhexidine solution
Follow aseptic non-touch technique:	➢ Complete usual hand washing technique using either aseptic soap and water and/or alcohol rub ➢ Use sterile operating equipment ➢ Use regular aseptic technique for preparation of excision site regardless of glove type being used ➢ **APPLICATION OF STERILE GLOVES OR NON-STERILE GLOVES**
Local anaesthesia	Subcutaneous injection of excision 1% lignocaine with or without adrenaline
Excision closure	Close the excision site with nylon sutures

Intervention Process

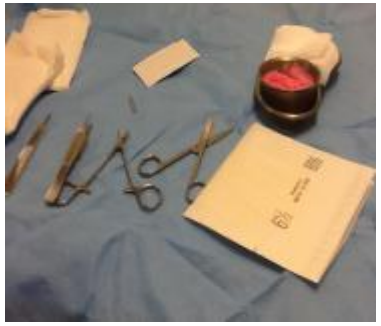
SINGLE CENTRED RANDOMISED CONTROLLED TRIAL

Mackay, QLD, GP practice

Between June 7th 2012- March 31st 2013

CONTROL

Sterile gloves for minor skin excision



INTERVENTION

Non-sterile clean boxed gloves for minor skin excision

Clinical outcome measure

CDC definition of superficial surgical site infection

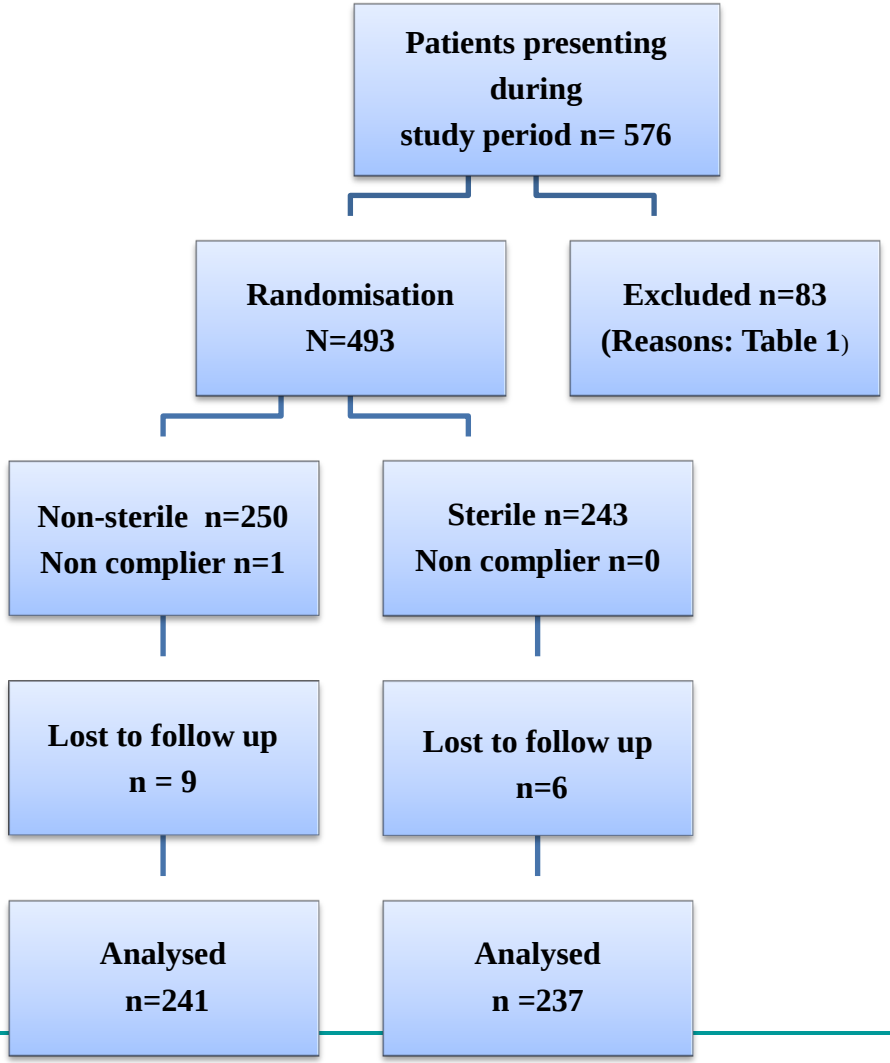
1. *Infection within 30 days*

2. *a. Purulent discharge from wound, or*
   b. Positive culture, or
   c. Doctor diagnoses infection

3. *Stitch abscess does not count as infection*

Rather vague – but "gold standard"

Results- Participants



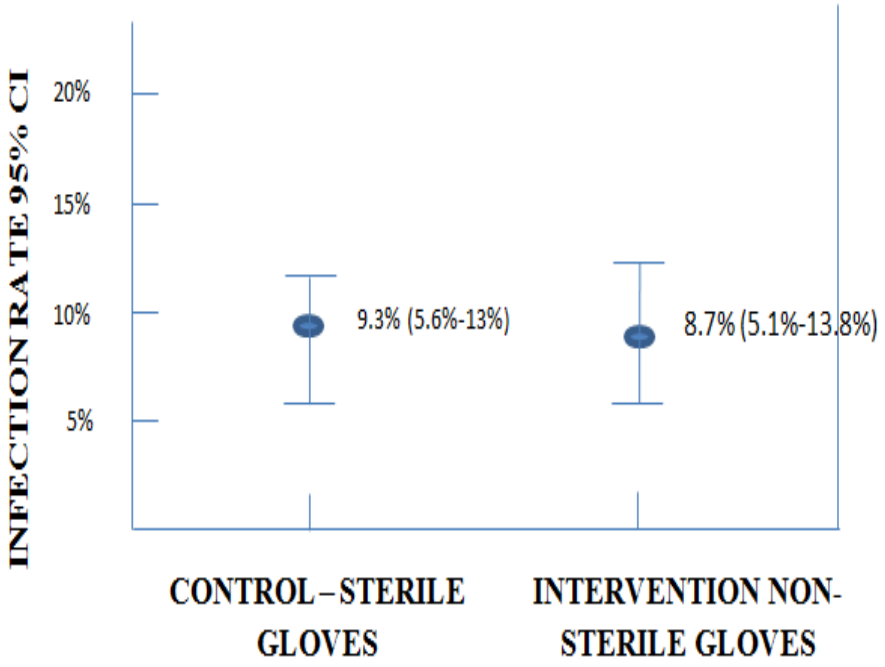
Baseline Data

	Control group(sterile gloves) n=237	Intervention group (non-sterile gloves) n=241
Characteristics of patients		
Mean age (SD)*	65.7 (15.3)	64.9 (15.8))
% Male	60.3%	58.9%
Smoking status		
% Never smoked	52.7%	57.7%
% Ex-smoker	35.9%	30.7%
% Current smoker	11.4%	11.6%
% Diabetes mellitus	12.7%	10.0%
% With medical condition**	35.9%	38.1%
Medications		
Warfarin	5.1%	4.1%
Clopidogrel/aspirin	27.0%	28.6%
Steroids oral or inhaled	8.1%	6.3%
Characteristics of lesions		
Body site		
% Neck and face	31.2%	35.3%
% Upper extremities	30.4%	26.9%
% Trunk	19.8%	19.1%
% Lower limb above knee	1.6%	4.6%
% Lower limb below knee	16.9%	14.5%
Histology		
% Naevus or Seborrheic Keratosis	13.0%	15.3%
% Skin cancer and precursor***	70.5%	66.4%
% Other#	16.5%	18.3%
Skin Integrity		
Normal	74.7%	75.9%
Ulcerated	19.0%	19.1%
Characteristics of procedures		
Mean length of excision (SD)	20.0 (13.5-27))	20.0 (14-27)
Median number of days until removal of sutures (IQR) ##	9 (7, 10)	8 (7, 10)
% With two-level procedure	0.8%	0%

Results: Primary Outcome Measure

Surgical Site Infection

	Number	% ; (95% CI)
Sterile gloves	22/237	**9.3% (5.6-13.0)**
Non-sterile gloves	21/241	**8.7% (5.1-13.8)**
Total infection	43/478	**8.9%**

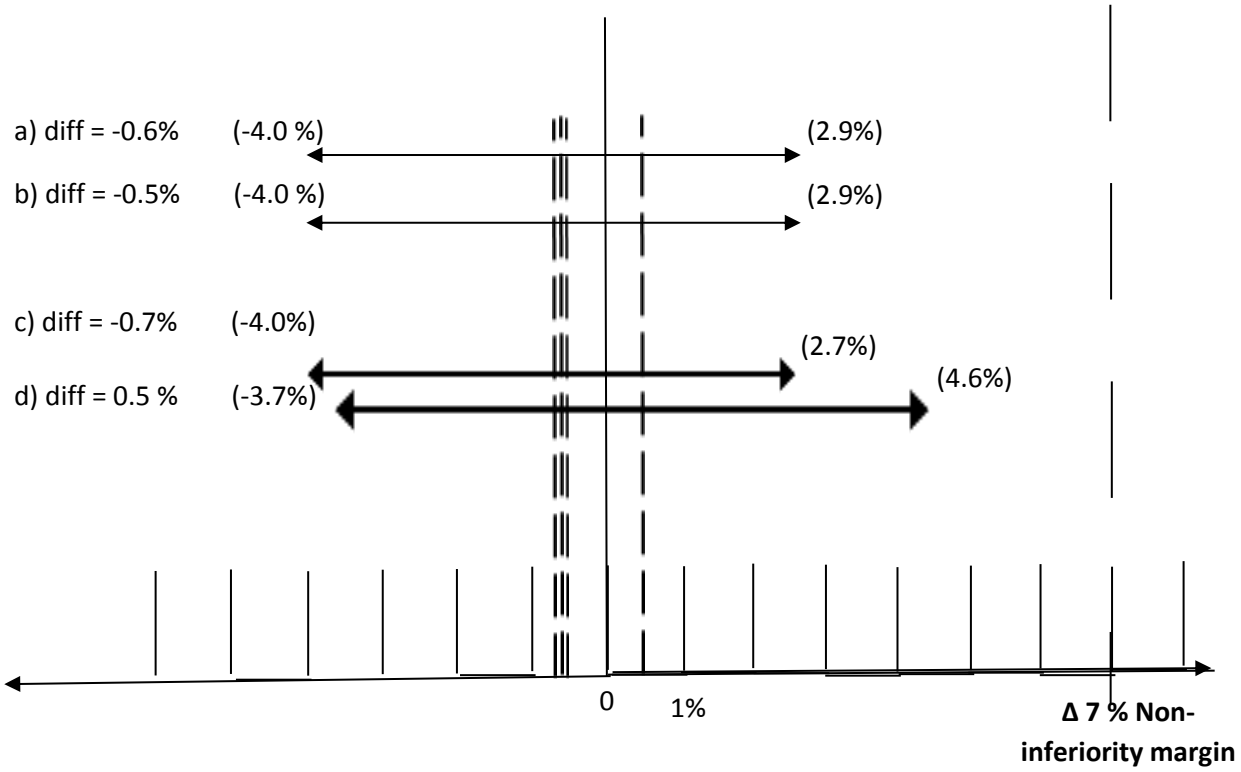


Difference in Infection

- Sterile gloves 9.3% (22/237)
- Non sterile gloves 8.7% (21/241)
- Difference in Infection -0.6% (95% CI
- -4.0 to +2.9)

Sensitivity analysis

	Intervention	Control	Difference (95% CI)
Intention to treat (available case analysis)	21/241 (8.7%)	22/237 (9.3%)	**-0.6%** (-4.0, 2.9)
Per protocol	21/240 (8.8%)	22/237 (9.3%)	**-0.5%** (-4.0, 2.9)
Sensitivity analysis: lost to follow up assumed without infection	21/250 (8.4%)	22/243 (9.1%)	**-0.7%** (-4.0, 2.7)
Sensitivity analysis: lost to follow up assumed with infection	30/250 (12%)	28/243 (11.5%)	**0.5%** (-3.7, 4.6)



a) Intention to treat analysis
b) per protocol analysis
c) sensitivity analysis: lost to follow up assumed without infection
d) sensitivity analysis: Lost to follow up assumed with infection

Discussion

- Use of non-sterile gloves is not worse than use of sterile gloves in terms of infection rates
- Reason for choice of gloves
- Limitations
- Cost saving

Discussion: Limitations

- Diagnosis of infection subjective
- Surgical training and techniques of GPs
- High baseline infection rate
- Generalisability might be limited
- Single Centre
- Preset margin non-inferiority too liberal

Discussion: Cost Saving

Glove	Cost of one box	Cost of one pair	Cost for 576 Patients	Incidence of infection
Sterile	$43.75 + 4.37 GST 40	**$1.203**	= $692.928	9.3%
Non-sterile	$13.95 +$1.39 GST – 100	**$0.1534**	= $88.35	8.7%
Difference In cost		**$1.0496**		

10 MONTHS PERIOD SAVING = $604.60

Conclusion

Use of non-sterile gloves is **NOT WORSE** than use of sterile gloves in terms of infection rates in minor skin procedures in a GP setting

Acknowledgements - Thank you!

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6 May 2006

BMJ

332:1043–1102 No 7549 6 MAY 2006 *International* ISSN 0959-8146

Can sutures get wet without risk of infection?

Yes, after minor skin excisions p1053

Better diagnosis of pneumonia in primary care p1045, p1077
Is inhaled insulin good enough? p1043
Banking on the human genome p1052
Who controls the medical research agenda? p1061, p1063
The case for greater access to trial protocols p1086

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RESEARCH

Does single application of topical chloramphenicol to high risk sutured wounds reduce incidence of wound infection after minor surgery? Prospective randomised placebo controlled double blind trial

BMJ 2009; 338 doi: http://dx.doi.org.ezp.lib.unimelb.edu.au/10.1136/bmj.a2812 (Published 15 January 2009)
Cite this as: *BMJ* 2009;338:a2812
Infectious diseases Injury Trauma General practice / family medicine

Clare F Heal, *senior lecturer*[1] , Petra G Buettner, *senior lecturer*[2] , Robert Cruickshank, *general practitioner*[3] , David Graham, *general practitioner*[3] , Sheldon Browning, *general practitioner*[4] , Jayne Pendergast, *practice nurse*[3] , Herwig Drobetz, *staff orthopaedic surgeon*[5] , Robert Gluer, *medical student*[1] , Carl Lisec, *surgical registrar*[6]

BMJ Open

Prevention of surgical site infection in lower limb skin lesion excisions with single dose oral antibiotic prophylaxis: a prospective randomised placebo-controlled double-blind trial

Samuel C Smith,[1] Clare F Heal,[2] Petra G Buttner[3]

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[1]The Townsville Hospital, Townsville, Queensland, Australia
[2]School of Medicine and Dentistry, James Cook University, Mackay, Queensland, Australia
[3]School of Public Health, Tropical Medicine and Rehabilitation Sciences, James Cook University, Townsville, Queensland, Australia

Correspondence to
Dr Samuel C Smith;
Samuel_Smith1@health.qld.gov.au

ABSTRACT

Objectives: To determine the effectiveness of a single perioperative prophylactic 2 g dose of cephalexin in preventing surgical site infection (SSI) following excision of skin lesions from the lower limb.

Design: Prospective double-blinded placebo-controlled trial testing for difference in infection rates.

Setting: Primary care in regional North Queensland, Australia.

Participants: 52 patients undergoing lower limb skin lesion excision.

Interventions: 2 g dose of cephalexin 30–60 min before excision.

Main outcome measures: Incidence of SSI.

Results: Incidence of SSI was 12.5% (95% CI 2.7% to 32.4%) in the cephalexin group compared with 35.7% (95% CI 18.6% to 55.9%) in the placebo group (p=0.064). This represented an absolute reduction of 23.21% (95% CI −0.39% to 46.82%), relative reduction of 65.00% (95% CI −12.70% to 89.13%) and number-needed-to-treat of 4.3.

Conclusions: Administration of a single 2 g dose of cephalexin 30–60 min before skin lesion excision from the lower limb may produce a reduction in the incidence of infection; however, this study was underpowered to statistically determine this.

Trial registration number: ACTRN12611000595910.

Strengths and limitations of this study

- Blinded randomised design with placebo control.
- Standardised protocol for excision and follow-up.
- Collection of a large amount of demographic, medical and excision-related data for comparison of groups.
- Underpowered study due to small sample size.
- Higher than anticipated infection rate with no clear underlying reason.

INTRODUCTION

Skin cancer causes a significant burden of disease in many developed countries.[1 2] The majority of skin cancers are treated by surgical excision[3 4] which is increasingly being performed in outpatient and primary care settings.[5 6] As the majority of skin cancer surgery takes place in general practice in Australia,[5] it is important to study infection rates in this setting. Skin lesion excisions form a large proportion of a typical Australian general practitioner's (GPs) workload, and this proportion is even greater for Queensland GPs, given that this State has the highest incidence of skin cancer.[6] General practice dermatological surgery may differ from a hospital setting, with most procedures taking place in treatment rooms rather than in formal operating theatres.

Surgical site infection (SSI) is one of the few complications of this relatively minor surgery. These infections often require antibiotics and repeat consultations to assess wound healing. They can potentially lead to significant bacteraemic complications and impair cosmetic outcome.[7] The acceptable rate of infection following clean minor surgery (class 1) is less than 5%.[8–12] This is reflected in skin lesion excisions, with a rate of between 1% and 3% in most studies.[13–18] The exceptions are studies conducted by the present authors in 2005 and 2009 which reported infection rates of 8.6% and 11.7%.[19 20] The reason for this higher infection rate remains unclear, but might be related to tropical humidity. Even within cohorts with a low overall incidence of infection, some procedures may be at higher risk because of the body site, pathology or patient factors and infection rates may be greater than 5% in these high-risk groups. Previously identified risk factors include

Comparing non-sterile with sterile gloves for minor surgery: a prospective randomised controlled non-inferiority trial

in regard to wound infection, non-sterile clean boxed gloves are not inferior to sterile gloves for minor skin excisions in general practice

Abstract

Objective: To compare the incidence of infection after minor surgery conducted using non-sterile clean boxed gloves with surgery conducted using sterile gloves.

Design: Prospective randomised controlled single-centre trial testing for non-inferiority in infection rates.

Setting: Primary care regional centre, Queensland, Australia.

Participants: Consecutive patients presenting to participating general practitioners for a minor skin excision, between 30 June 2012 and 28 March 2013, were eligible to participate.

Intervention: The use of non-sterile clean boxed gloves was compared with normal treatment using sterile gloves in the control group.

Main outcome measures: Wound infection, assessed at the time of removal of sutures, and other adverse events.

Results: Four hundred and ninety-three consecutive patients presenting for minor skin excisions were randomly allocated to the two treatment groups: non-sterile clean boxed gloves ($n = 250$) or sterile gloves ($n = 243$). Four hundred and seventy-eight patients contributed data for analysis (241 non-sterile, 237 sterile gloves). The incidence of infection in the non-sterile gloves group (8.7%; 95% CI, 4.9%–12.6%) was significantly non-inferior compared with the incidence in the control group (9.3%; 95% CI, 7.4%–11.1%). The two-sided 95% CI for the difference in infection rate (− 0.6%) was − 4.0% to 2.9%, and did not reach the predetermined margin of 7% which had been assumed as the non-inferiority limit. Results of the intention-to-treat analysis were confirmed by per-protocol and sensitivity analyses. There were no important adverse effects.

Conclusion: Our study suggests that in regard to wound infection, non-sterile clean boxed gloves are not inferior to sterile gloves for minor skin excisions in general practice.

Trial registration: ACTRN12612000698875.

Minor surgery is an important aspect of general practice. This is particularly the case in Australia, where the incidence of skin cancer is reported to be the highest in the world,[1] and where general practitioners perform most surgical excisions for skin cancer.[2]

When the use of gloves for surgery was first implemented by William Stewart Halsted in 1890, it was in an attempt to protect his surgical scrub nurse from dermatitis as a result of contact with mercuric chloride — which was used for sterilisation processes — rather than to prevent infection.[3] Nowadays, several guidelines exist in Australia and internationally, which recommend that GPs use sterile gloves for small procedures such as minor surgery in general practice.[4-6] However, these guidelines are based on expert opinion rather than on medical evidence.

Before our study, about half of the participating GPs used non-sterile clean boxed gloves when conducting minor skin excisions in general practice, while the other half used sterile gloves. A comprehensive Medline search found few studies relating to the use of sterile versus non-sterile gloves (Appendix 1). Randomised trials looking at lacerations in an emergency department,[7] wisdom tooth extraction in an outpatient setting[8] and Mohs micrographic surgery[9] all showed no significant difference between infection rates. However, these studies looked for superiority of the sterile gloves rather than non-inferiority of the non-sterile gloves, resulting in negative trials, and the latter two studies were statistically underpowered. An observational study in a private dermatology setting showed no difference in infection rate for minor procedures; however, sterile gloves were shown to result in a significantly lower infection rate than non-sterile gloves for a subgroup of more complicated reconstructive procedures, which comprised flaps and skin grafts.[10] Another observational study of Mohs surgery showed no statistical difference in infection rates.[11] The only study conducted in a general practice setting was an audit of 126 patients where non-sterile gloves had been used for minor surgery, which showed an infection rate of 2.4%.[12]

Prior studies of wound infection after minor surgery involving GPs in Mackay, Queensland, showed overall incidences of wound infection of 8.6% and 8.9%.[13-16] This incidence was higher than expected based on published results of a similar Australian general practice cohort (1.9%),[17] a skin cancer clinic cohort (1.5%)[18] and a European dermatology clinic cohort (2%).[19] A suggested acceptable rate of infection after clean minor surgery is less than 5%.[20] The reason for our high infection rate is unclear, but may be related to the hot, humid environment, or to patient behaviour in our rural setting. A low risk of infection after clean surgery means that studies of more than 1000 procedures (sometimes many more) are required, under normal circumstances, to detect a clinically relevant difference in infection from an intervention with statistical confidence.[21] Because of the high incidence of infection in our patient cohort, and the high minor surgery workload,[22] we decided to use this capacity to investigate the

Clare Heal FRACGP, PhD[1]

Shampavi Sriharan MB BS(Hons), DCH[1]

Petra G Buttner PhD, MSc[2]

Deborah Kimber RN, BN, CDE[3]

1 James Cook University, Mackay, QLD.

2 Tropical Health Solutions, Townsville, QLD.

3 Paul Hopkins Medical Clinic, Mackay, QLD.

clare.heal@jcu.edu.au

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Top 20 Research Studies of 2015 for Primary Care Physicians

MARK H. EBELL, MD, MS, *University of Georgia, Athens, Georgia*
ROLAND GRAD, MD, MSc, *McGill University, Montreal, Quebec, Canada*

In 2015, a group of primary care clinicians with expertise in evidence-based practice performed monthly surveillance of more than 110 English-language clinical research journals. They identified 251 studies that addressed a primary care question and had the potential to change practice if valid (patient-oriented evidence that matters, or POEMs). Each study was critically appraised and disseminated to subscribers via e-mail, including members of the Canadian Medical Association who had the option to use a validated tool to assess the clinical relevance of each POEM and the benefits they expect for their practice. This article, the fifth installment in this annual series, summarizes the 20 POEMs based on original research studies judged to have the greatest clinical relevance for family physicians. Key recommendations include questioning the need for backup throat cultures; avoiding early imaging and not adding cyclobenzaprine or oxycodone to naproxen for patients with acute low back pain; and encouraging patients with chronic or recurrent low back pain to walk. Other studies showed that using a nicotine patch for more than eight weeks has little benefit; that exercise can prevent falls that cause injury in at-risk older women; and that prostate cancer screening provides a very small benefit, which is outweighed by significant potential harms of screening and associated follow-up treatment. Additional highly rated studies found that tight glycemic control provides only a small cardiovascular benefit in patients with type 2 diabetes mellitus at the expense of hypoglycemic episodes; that treating mild hypertension can provide a modest reduction in stroke and all-cause mortality; that sterile gloves are not needed for minor uncomplicated skin procedures; that vasomotor symptoms last a mean of 7.4 years; and that three regimens have been shown to provide the best eradication rates for *Helicobacter pylori* infection. (*Am Fam Physician*. 2016;ePub ahead of print. **)**

RESEARCH

Clare F Heal
MBChB, DRANZCOG, DipGUMed, FRACGP, MPHTM, is Senior Lecturer, General Practice and Rural Medicine, James Cook University, Mackay, Queensland. clare.heal@jcu.edu.au

Craig Veitch
PhD, BA(Hons), DipAppSc(RT), is Professor of Rural Health, James Cook University, Townsville, Queensland.

Robyn Preston
BA(DevS) (Hons) MHSc(HealthProm), is Primary Health Care Research Evaluation and Development (PHCRED) Coordinator, James Cook University, Townsville, Queensland.

AFP

Practice based research

Lessons from the field

Background
The authors sought to describe the process of conducting a successful randomised controlled trial in a primary care setting and identify enabling factors and barriers.

Methods
Descriptive report of methods used to conduct a randomised controlled trial investigating the effect of allowing sutures to be wet and uncovered in the first 48 hours following minor excisions.

Results
The trial identified several enabling factors and barriers to conducting research in a primary care setting. The project described in this article was successful because a group of general practitioners sought to answer an interesting question which was relevant to their clinical practice and which had not been answered by current evidence.

Primary care research has been described as 'a lost cause',[1] and Australian general practice has been advised there is some 'catching up' to do in the area of research performance.[2,3] Australian general practitioners publish less research than their public health physician colleagues, both nationally and internationally.[4]

Primary care and general practice research in Australia has been criticised for conducting mainly small descriptive and survey based studies.[5] Only 13% of all 248 General Practice Evaluation Program (GPEP) projects funded from 1990–1999 were intervention studies.[5] This is partly because many of these studies were conducted in single practices, with numbers insufficient to produce results of high statistical power. General Practice Evaluation Program grants were generally limited to 1 year, with insufficient time to conduct large scale

GP Research in Australia

- Very few RCTs in primary care
- Methodologically and practically difficult
- GP – informed by primary care evidence
- Funding – 2% of NHMRC grants

Enablers for GP research

- Choose questions from GPs- “grass-roots”
- Personal relationship with practice
- Keep GP workload to minimum
- Engage Practice Nurses

Barriers to GP research

- Funding
- Ethics – takes time
- Ensuring randomisation and quality data collection

Sterile Gloves Project – Recruitment

- Experienced research nurses
- Simple intervention and outcome
- Recruitment easy
- Retention 97%

Tips for GP research

- Look for strengths in your region
- What is unique to your setting?

Tips for GP research

- GPs have to ‘own’ the project for it to be successful
- Keep things as simple as possible
- Engage practice nurses – excellent researchers, recruiters and data collectors

Research on a shoestring

Stick to one primary outcome

Randomise at home – cheaper

Find friendly pharmacist

Pay practice nurses

Questions?

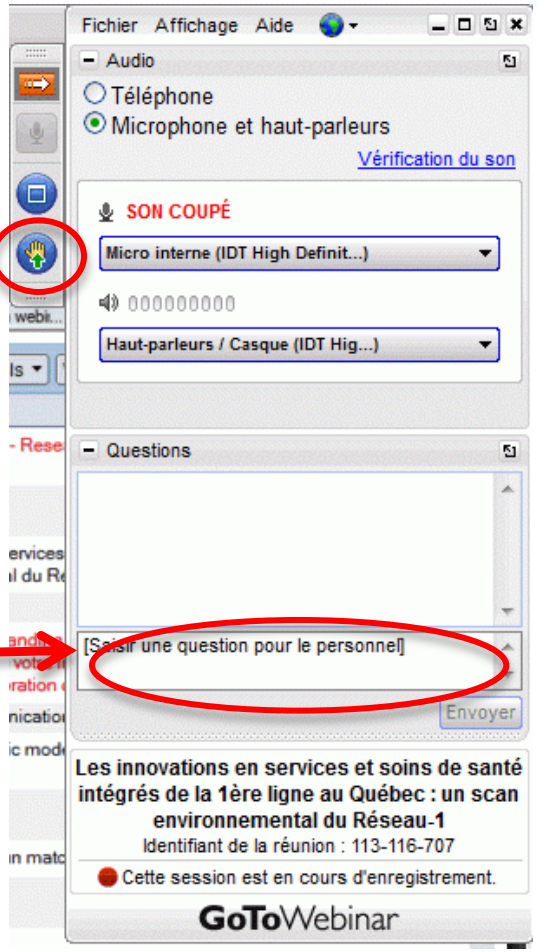
Thank you very much

Procédure pour les questions

- Vous pouvez **poser vos questions** de deux façons:

  1. ***Lever la main***:
     Nous ouvrirons votre micro et vous inviterons à poser votre question oralement durant la période de questions.

  2. ***Par écrit***:
     Tout au long de la présentation, vous pouvez écrire une question dans la boîte (cliquer sur Questions pour l'ouvrir). Nous répondrons à votre question durant la période de questions.



- Nous ferons notre possible pour répondre à toutes vos questions.

Réseau-1 Québec

À venir….

- **Prochain webinaire :**
  - Date : **vendredi 25 novembre 2016** de 12h à 13h
  - « Analyse transversale HEC des projets lauréats R1Q » **Philippe Tamba et Karim Skiredj**

- Devenez membres! http://reseau1quebec.ca/membres-et-partenaires/membres/

- Si vous avez des idées pour des webinaires à venir, contactez-nous : info@reseau1quebec.ca

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