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A randomised single-blind comparison of the effectiveness of the high-level disinfectants Tristel Wipes (chlorine dioxide), Cidex OPA (ortho-phthalaldehyde) and Perasafe (peracetic acid/peractyl ions) for use with flexible nasoendoscopes

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Interests to Declare

- This study was funded by Tristel through Tauranga Clinical School
- We have received grants to present at this conference





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Introduction

- Flexible nasoendoscopes in otolaryngology require a high level disinfection that is:
 - Safe
 - Affords rapid turnover
 - Not destructive to nasoendoscopes
 - Cognisant there is no working port in nasoendoscopes

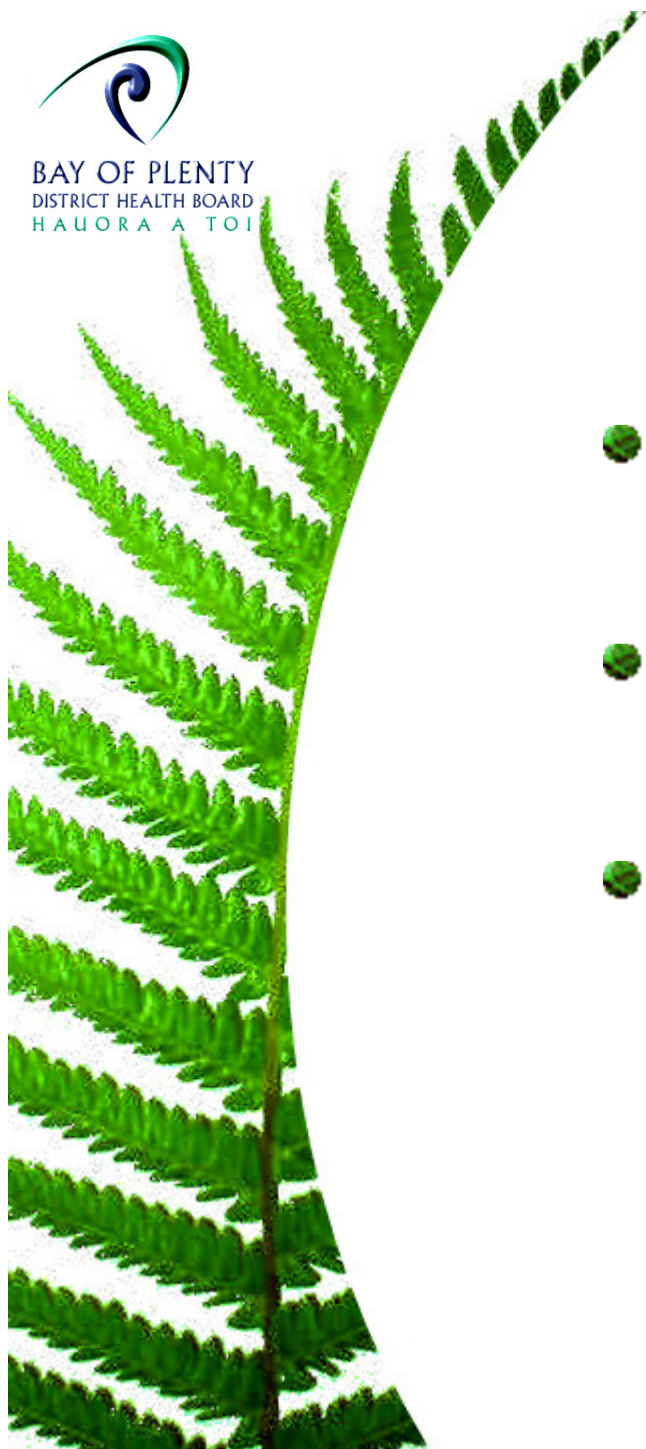




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Introduction

- Currently there is no uniform decontamination system
- Worldwide tendency to eliminate risk of cross infection
- Tendency to opt for central decontamination – the most expensive option





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Hypothesis

- The study hypothesis is that Tristel Wipes and Perasafe are at least as effective and safe as Cidex OPA in clinical use





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High Level Disinfectants - 1

- Cidex OPA (*ortho*-phthalaldehyde)





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High Level Disinfectants - 2

- Tristel 3 part system (Chlorine Dioxide)





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High Level Disinfectants - 3

- Perasafe (peracetic acid/peractyl ions)

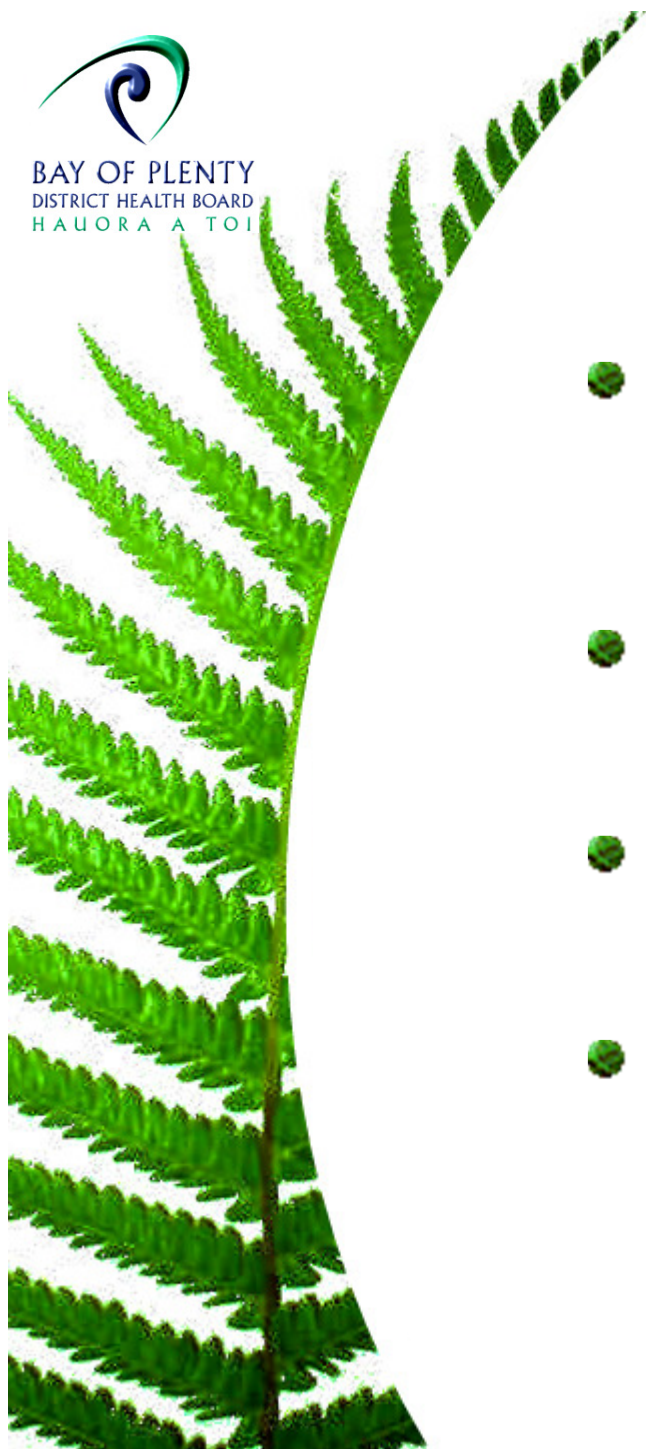




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Study Design

- This was a randomised, single-blind study comparing the high level disinfectants Tristel Wipes, PeraSafe and Cidex OPA.
- Clinics were randomly allocated to 1 of the 3 disinfectants
- Participants were blinded to the disinfectant used
- Evaluation of efficacy was determined by assessing microbiology samples, patient perception, cost-effectiveness, ease of use and safety.





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Inclusion/Exclusion

INCLUSION:

- Required diagnostic flexible nasoendoscopy
- Provided written informed consent
- Were 18 years old on the day of consent

EXCLUSION:

- Known to be allergic to topical cophenylcaine spray or any of the disinfectants to be used in the study
- Current or recent treatment with antibiotics
- Nasal surgery in the last 6 months

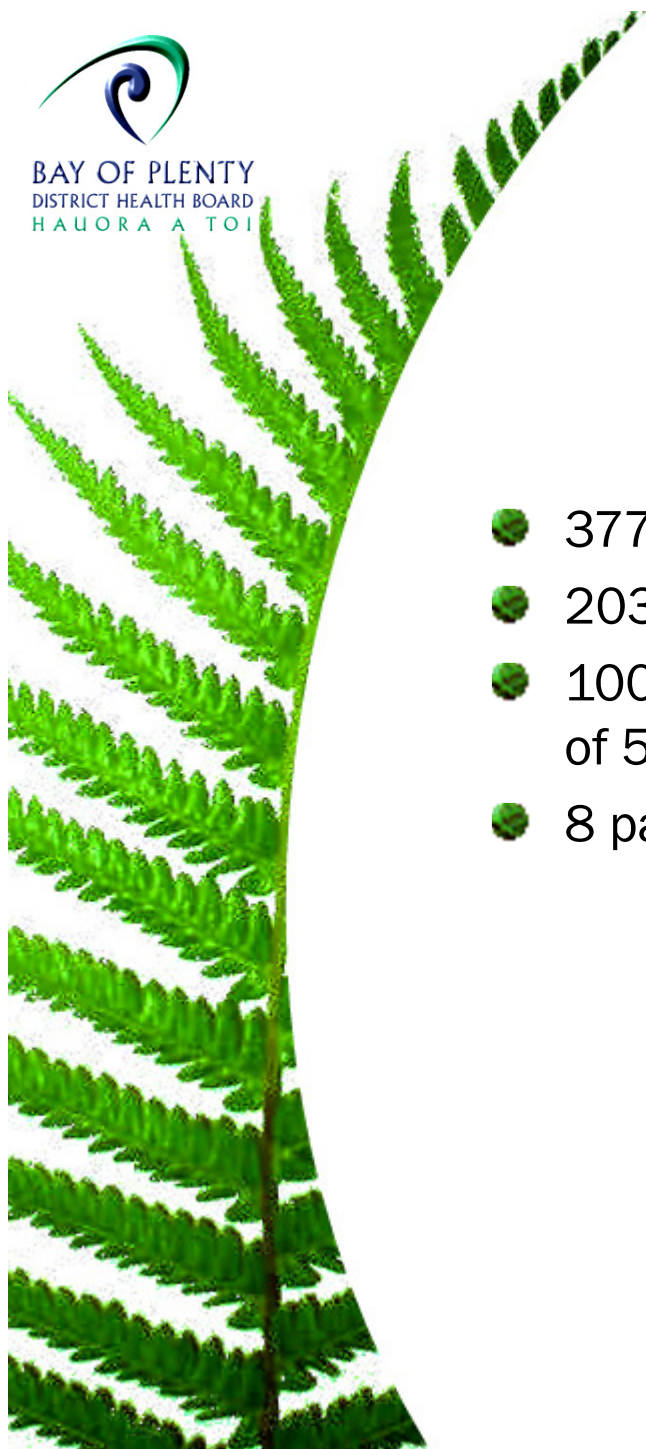




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Patient Population

- 377 participants screened
- 203 participants randomised
- 100 males and 103 females with a mean age of 57.1 years
- 8 participants incomplete



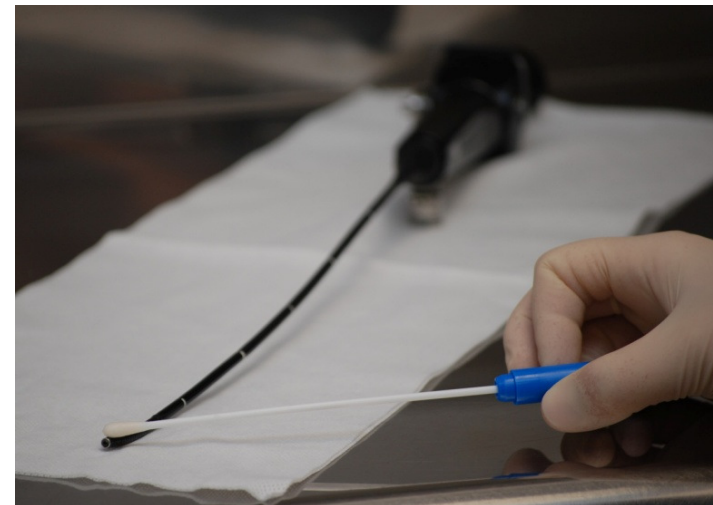


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Microbiology Protocol

All Scopes:

- Immediately after disinfection prior to use of the nasoendoscope on a study participant the tip and the shoulder of the nasoendoscope was swabbed and sent for culture.



Microbiology Protocol

Cidex Equipment Process:

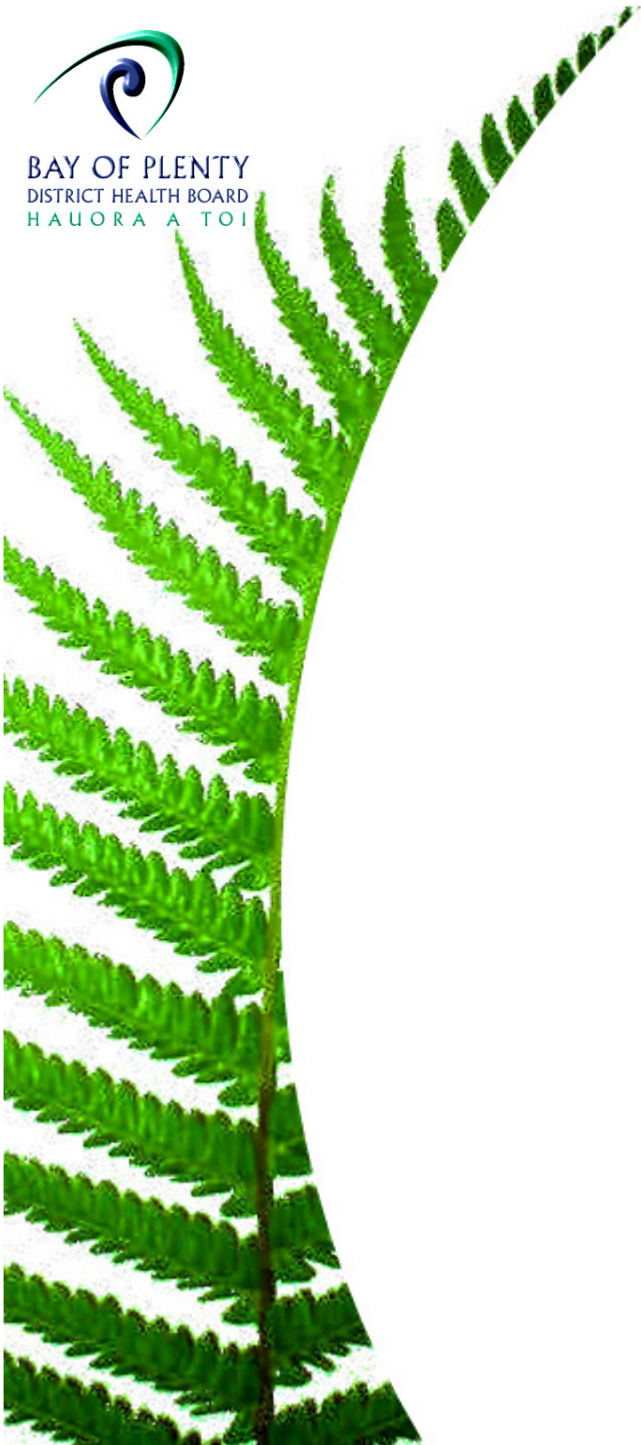
- Pre and post clinic swabs of the Cidex OPA Medivator were taken from the exit port and from the inner rim of the lid.

Perasafe Equipment Process:

- Post clinic swabs were taken from the bottom of the cylinder when the solution was emptied at the end of the clinic.



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Results

Microbiology Efficacy Endpoints

- In total 541 samples [203x2 + 4x27 + 27] swabs and samples were taken for microbiology

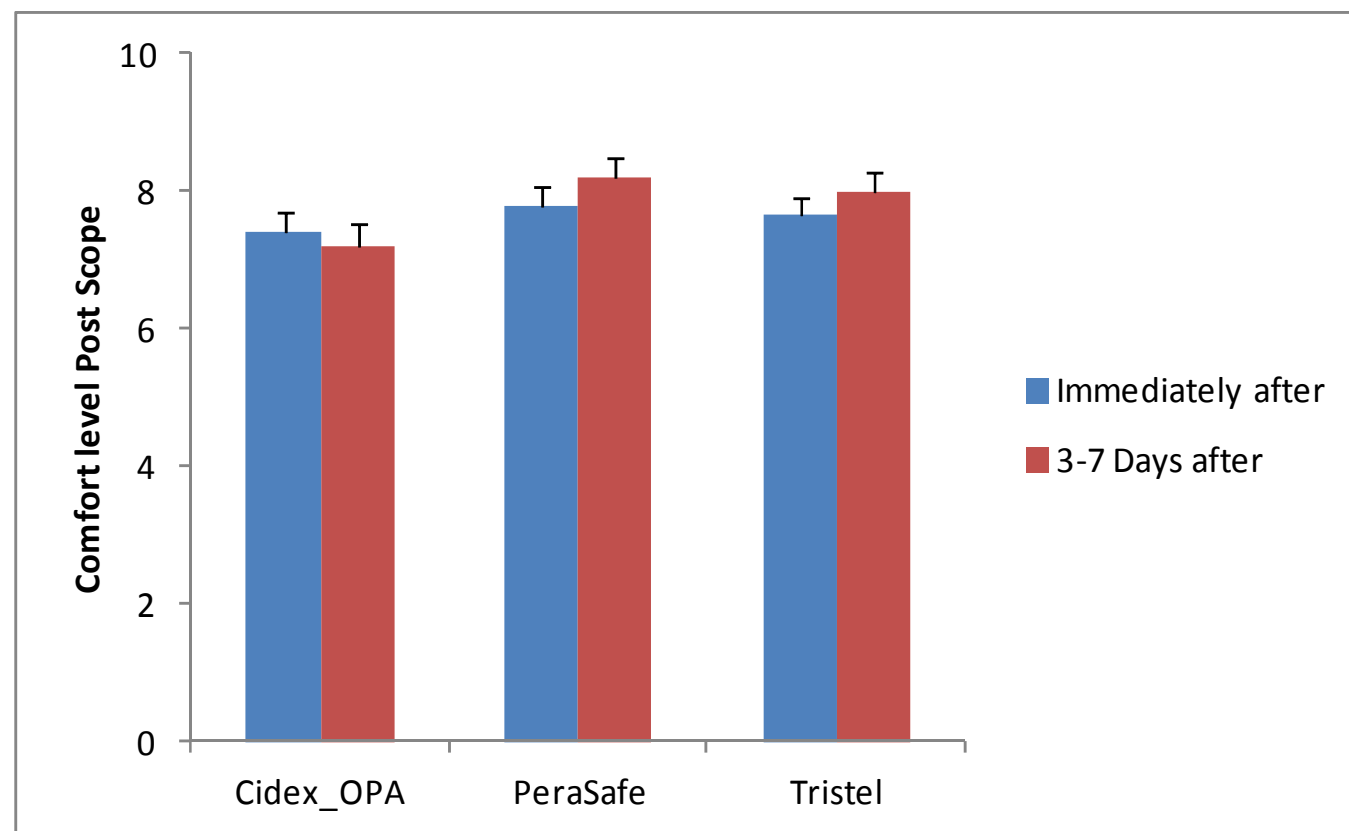
Chemistry Used	Sample Description	Organism Grown	Relevance
Tristel	Tip & Shoulder of Nasoendoscope	No Growth	
Cidex	Inner rim of Medivator Lid	Pseudomonas species isolated	Likely environmental organism of low pathogenic potential.
Cidex	Tip of Nasoendoscope	Light growth of Coagulase negative staphylococcus	Skin commensal of low pathogenic potential
Cidex	Inner rim of Medivator Lid	Light growth of Coagulase negative staphylococcus	Skin commensal of low pathogenic potential Possibly due to inadequate exposure to disinfectant at this site of the medivator.
Perasafe	Shoulder of Nasoendoscope	Light growth of Stenotrophomonas maltophilia	Environmental organism of low pathogenic potential, except in immunocompromised patients. Inherently quite a resistant organism to Antibiotics.

Adverse Events

Participant	Agent	Event	Outcome	Intensity	Frequency	Relationship to Agent
124	Perasafe	Rhinorrhoea	Resolved	Mild	Single	Possible
	Perasafe	Epiphora	Resolved	Mild	Single	Possible
	Perasafe	Head pressure	Resolved	Mild	Single	Unrelated
	Perasafe	Epistaxis	Resolved	Mild	Continuous	Unrelated
146	Perasafe	Metastatic Carcinoma	Death*			Unrelated
158	Perasafe	Nasal discharge	Resolved	Mild	Continuous	Unrelated
186	Perasafe	Dysphagia	Lost F/U	Mild	Continuous	Unrelated
012	Tristel	Rhinorrhoea	Resolved	Mild	Single	Possible
013	Tristel	Rhinorrhoea	Resolved	Mild	Single	Unrelated
104	Tristel	Post nasal discharge	Resolved	Mild	Continuous	Possible
177	Tristel	Nasal discomfort	Resolved	Mild	Single	Unrelated

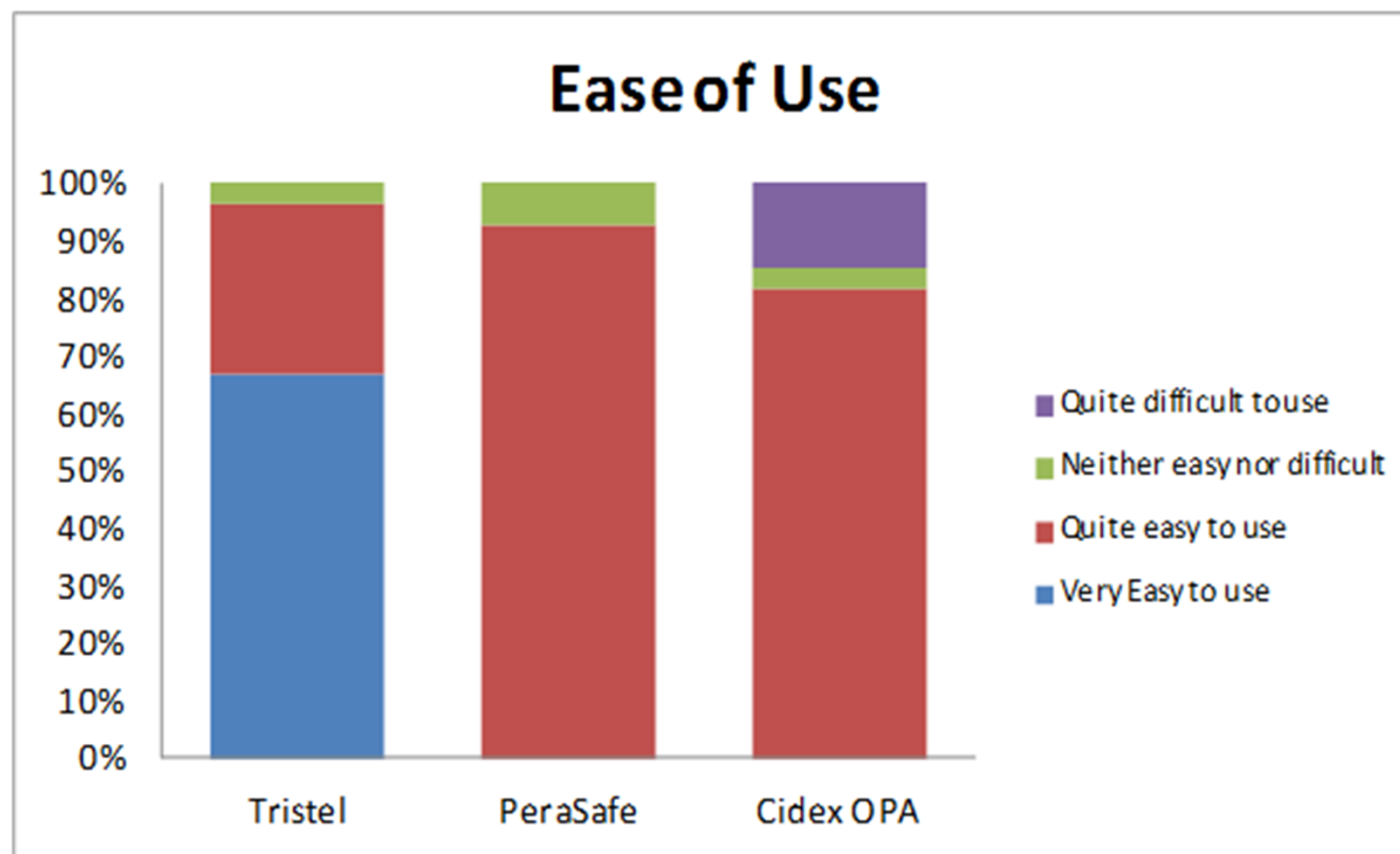
Patient Comfort

- Patient Perception of the comfort of the procedure, using a 10cm visual analogue scale (VAS)
 - Immediately following nasoendoscopy
 - 3-7 days post nasoendoscopy



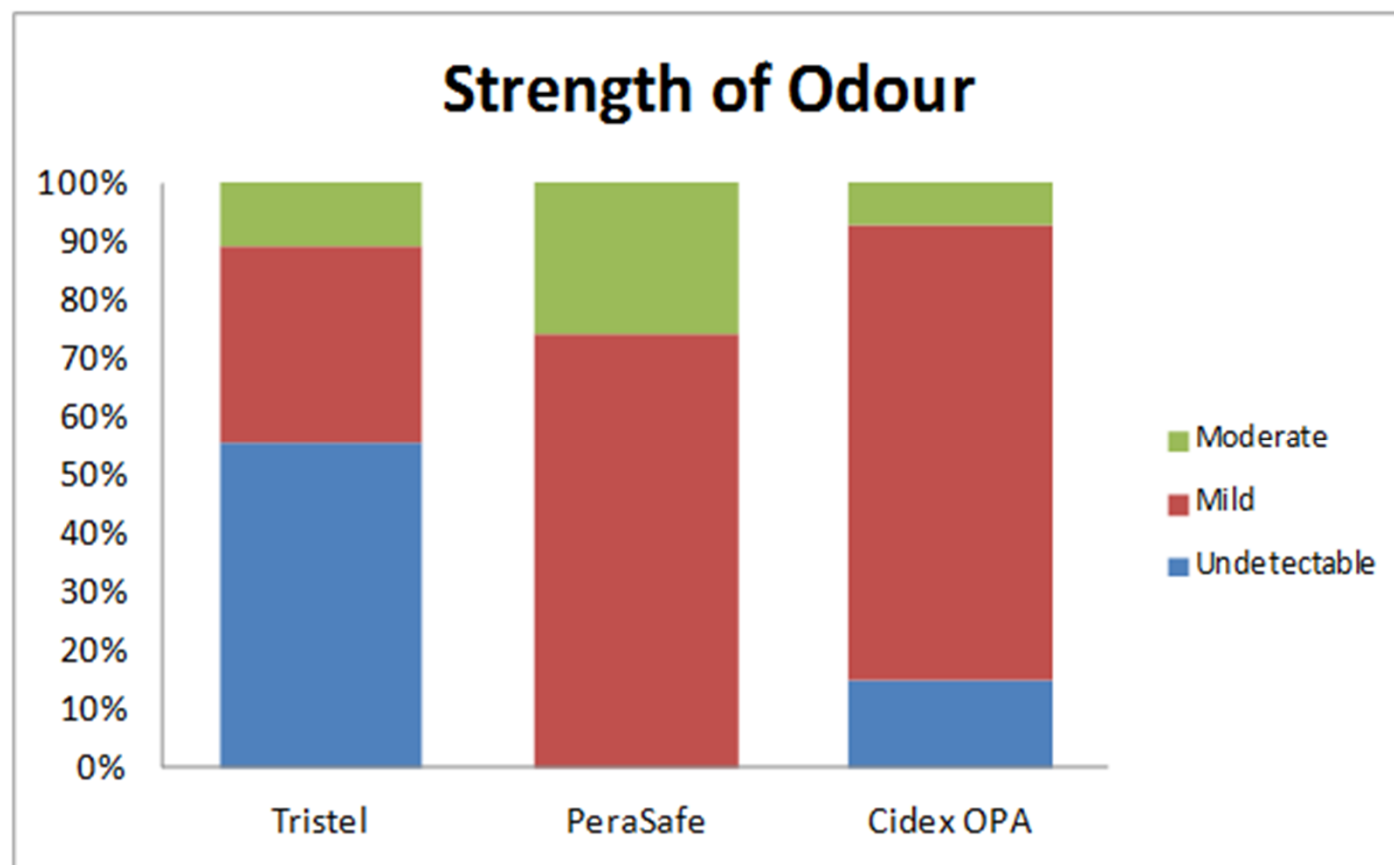
Ease of disinfection

- A 5 - point Likert rating scale was used by the nurses to rate the ease of use of the disinfection system on each study day.



Strength of Odour

- The strength of any odour detected during the disinfection



Capital Cost

- This is the one off purchase cost this does not include any equipment maintenance.

Agent	Equipment	Cost
Cidex	Medivator	\$76,106.25
Perasafe	Cyclinder & Jug	\$227.00
Tristel	Nil	\$0.00

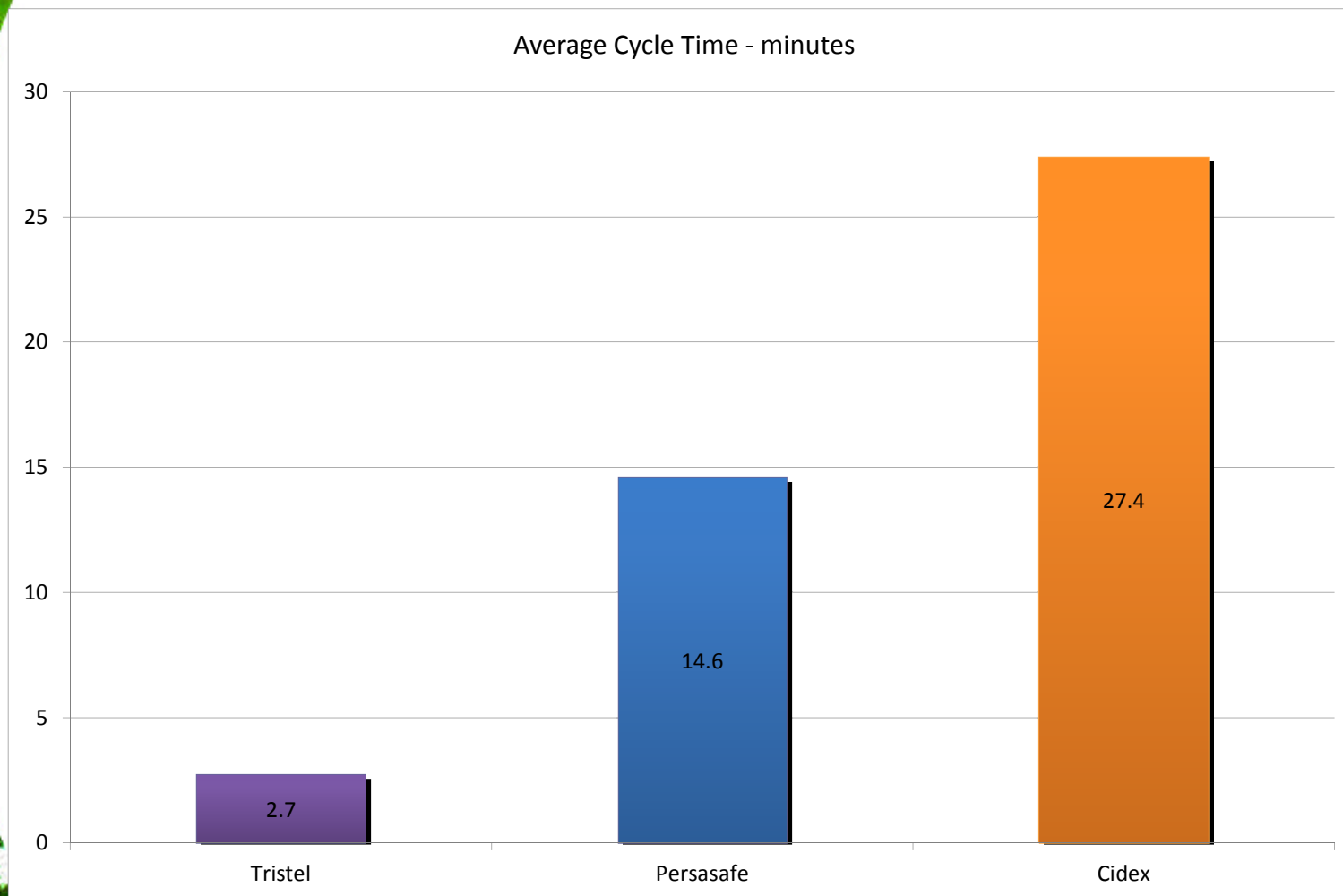
Cost for Disinfectant Cycles

- The cost for Cidex and Perasafe are set regardless of how many scopes are reprocessed due to the expiry of the product as noted in frequency.
- The Tristel cost is only as required as this product has a long shelf life.

Disinfectant	Frequency	Cost \$NZ
Cidex	Every 14 days	\$578.62
Perasafe	Every 24 hours	\$3.79
Tristel	Each Disinfection	\$9.50

Average Time for Disinfection Cycle

● The mean cycle time includes preparation time.

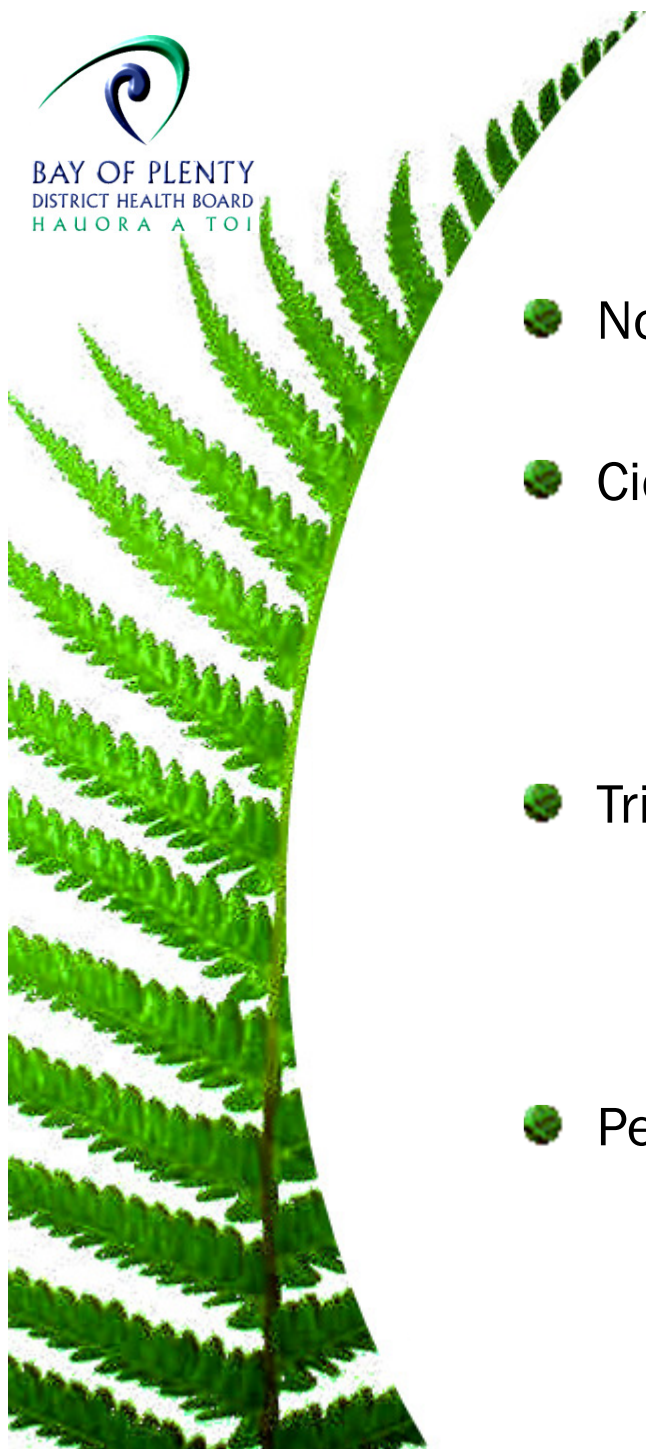




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Conclusion

- No agent proved harmful to patients
- Cidex in an automated endoscopic reprocessor
 - Significantly most expensive agent
 - Slowest to recycle nasoendoscopes
- Tristel Wipes
 - Fastest to recycle nasoendoscopes
 - Low running costs
- Perasafe - soak
 - Intermediate recycling of nasoendoscopes
 - Low running costs





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Final conclusion

- A rationalisation of the method of flexible nasoendoscope disinfection is warranted





Danke