No Pain, More Gain: CoolSense pain numbing applicator

Written Improvement Project Submission
Canterbury DHB Quality Improvement and Innovation Awards 2016

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# Table of Contents

Project Information Sheet .................................................................................. 3  
Abstract............................................................................................................... 4  
Introduction and Background ......................................................................... 5  
Needs Assessment ............................................................................................... 5  
Planning ............................................................................................................. 7  
Implementation of Plan ..................................................................................... 8  
Results and Findings ......................................................................................... 10  
Embed and Sustain .............................................................................................. 14  
References .......................................................................................................... 17
Project Information Sheet

Project title
No Pain, More Gain: CoolSense pain numbing applicator

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Children’s Haematology Oncology Centre – CHOC
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Indicate Word Count (limit 3000)

3118 words – not including Abstract + References

Please tick the category you think best fits your project

| Improved quality, safety and experience of care | yes |
| Improved health and equity for all populations |     |
| Best value for public health system resources  |     |

(Please note Assessors make the final decision)
Abstract

Across Child Health, children experience a number of potentially painful procedures including the placement of intravenous (IV) needles, which many children are deeply fearful of. Commonly, topical anaesthetic creams are used to numb the site of injection. This intervention has its own complications and associated anxieties which can lead to ineffective numbing of the skin resulting in a painful experience for the child.

The CoolSense Pain Numbing Applicator is a hand-held device that acts to cool and numb the site of injection. Post application, it takes only ten seconds to work before the injection can then be administered. It is simple, allergen free and immediate.

The Children’s Haematology and Oncology Centre (CHOC) have been trialling the CoolSense device for IV cannulation, blood collection, accessing implantable ports and for subcutaneous and intramuscular injections. A qualitative evaluation survey was designed to capture the CHOC children and families experiences with the CoolSense product with respondents reporting overwhelming positive feedback including more effective numbing of the IV site and reduced waiting times.

The introduction of the CoolSense product has produced a better experience for CHOC patients and families by reducing pain associated with treatment, which is vital in preventing future issues related to needle placement. There is a plan to expand the use of the product to other areas where children have the same/similar type procedures across the Canterbury District Health Board (CDHB). The CoolSense initiative could also potentially represent a significant cost saving to the CDHB operational budget.
Introduction and Background

Across Child Health, children experience a number of painful procedures including the placement of intravenous (IV) needles, which children can find frightening and anxiety provoking (Bray, Snodin & Carter, 2015). Commonly, topical anaesthetic creams are used to numb the site of injection. This intervention has its own complications, is expensive and can take an hour for optimal effect. Additionally the delay is not always clinically appropriate.

The Children’s Haematology and Oncology Centre (CHOC) at Christchurch Hospital has been trialling an alternative device for painful procedures; the CoolSense pain numbing applicator.

CHOC is the tertiary treatment centre for all children diagnosed with cancer from the geographical catchment of the South Island and extending north to the Wairarapa and Wellington districts.

Anecdotal feedback from the children and families had been positive and a patient/parent experience survey was developed to capture retrospective feedback from all families involved in the trial.

Needs Assessment

It is vitally important that children undergoing painful procedures are optimally prepared. Children who are exposed to poorly managed and painful healthcare procedures are more likely to demonstrate increased pain perception and increased pain behaviours and medical fear in later life. It is well documented that trauma/distress in childhood can have an effect on the emotional development of that child, thus affecting how they react to distress in the future (Kennedy and Binns, 2016).

Procedural preparation in Child Health is a combination approach including using the right words to reflect on the necessity of the procedure, engaging the caregiver, utilising play and distraction (Bray, Snodin & Carter, 2015) and appropriate analgesia or sedation.

Until recently anaesthetic creams have been the “go to treatment” to manage topical pain associated with many procedures. However topical anaesthetic creams have their own complications including side effects like rashes, welts or vascular constriction. The time delay for the anaesthetic cream to become effective can provoke further anxiety for children as they have more time to anticipate what is about to happen to them. For many children the most distressing aspect of the procedure is the removal of the film dressing used to hold the cream in place.
Additionally the delay is not always clinically appropriate; children may be very ill requiring fluids or medication intravenously so the cream may only be applied for a short period of time. This can lead to ineffective numbing of the skin resulting in a painful experience for the child.

The CoolSense pain numbing applicator is a device originally developed for use with cosmetic procedures. CoolSense works almost immediately upon application to cool and numb the site of injection and is chemical free reducing the likelihood of localised reactions sometimes seen with topical anaesthetics. The 10 second application time and the simplicity in using the applicator were seen as positive attributes to improving the experience of children undergoing needle insertion.

The product gained our attention via a Child Health Australasia (CHA) newsletter where we were informed The Royal Children’s Hospital Melbourne Medical Imaging team have successfully performed over 5000 cannulations using the device with overwhelming positive feedback from patients who reported radically reduced sensations of pain with IV insertion (The Royal Children’s Hospital Melbourne, 2015).

The topical anaesthetic cream (Emla®) takes an hour for optimal effect at a cost of $9.00 per 5g single use tube. The pharmacy department has recently introduced a comparable product to Emla® in an effort to reduce costs to the CDHB, LMX4® – Lignocaine 4% at $6.75 per 5g tube. The current year to date (July 2015 – April 2016) financial data from across Child Health indicates that the cost of local anaesthetic creams (Emla®, LMX4®), Gels (Amethocaine 4%) and patches (Emla®) is at $59,468.57.

The cost of the CoolSense device is $160 NZD which comes with an alcohol cartridge that yields 350+ uses. Replacement cartridges are $60 NZD for a box of 2, again each cartridge yields 350+ uses. Using the device as an alternative to Emla cream will potentially result in a saving of $8,780 per 1000+ applications. The introduction of the CoolSense pain numbing applicator could represent significant cost savings to the Canterbury District Health Board (CDHB).

After discussion between the CHOC Charge Nurse Manager and Clinical Nurse Specialist, the Nursing Director, Women’s and Children’s Health, the Clinical Director Paediatric Medicine, the Service Manager Child Health and the Child Health Quality Co-ordinator, it was decided to undertake a trial of the CoolSense device in the Children’s Haematology and Oncology Centre. A patient/parent experience survey would be designed to capture retrospective feedback from the families involved in the trial.

This quality initiative is closely aligned to the CDHB’s vision to deliver better outcomes both for the patient and for the system (Canterbury District Health Board, 2016). This supports the overarching commitment of the regional alliance partners and central government policies for improved quality, safety and experience of care while ensuring best value from public health system resources (Ministry of Health, 2014; South Island Alliance, 2015).
Planning

The CoolSense devices are manufactured in Israel and our initial contact was through the Australasian distributor, Balance Medical, who provided an on-loan device for the proposed trial. The company director also offered to provide in-service education to the CHOC nursing team who would be the core users of the device during the trial period.

With mounting interest from the Christchurch Hospital Child Health network the CoolSense device was presented to the Child Health Senior Medical Officer’s meeting and highlighted in the newsletter from the Child Health Nurse Educators “Hot Tips” June 2016 issue as a new initiative.

Despite the obvious potential for the CoolSense device it was made very clear to the wider Child Health teams that the initial trial would be confined to the CHOC unit until all protocols and procedures for use were in place and then would be rolled out to the other Child Health wards/units in a controlled manner with education and support.

We contacted the Nurse Unit Manager from the oncology ward at the Children’s Hospital at Westmead, Sydney, Australia, where they have been successfully using the CoolSense device for 12 months. Following their experience we expanded the trial to include using the CoolSense device for intravenous (IV) cannulation, blood collection (venepuncture), accessing implantable ports (central venous access devices), and intramuscular (IM) injections like immunisations and for subcutaneous (SC) injections like G-CSF and Clexane.

The trial was conducted over the month of May 2016 and all children receiving treatment on CHOC over this time period were eligible to participate. Verbal consent was obtained from either the child or caregiver whichever was age and developmentally appropriate prior to using the device.

We predicted that the CoolSense device would provide a better experience for the child and family by providing more effective numbing of the IV site and by reducing waiting times. Anecdotal feedback was very positive and the CoolSense device was fast becoming known as the ‘Magic Wand’ for a lot of the children who frequent CHOC for treatment.

Figure 1. “The Magic Wand worked really well on me because it numbed the area straight away which meant I didn’t need to remember to put cream on an hour before, it was also really good when the needle went in because it didn’t hurt as much as it usually would” - Nikhita
We chose to measure the effectiveness of the introduction of the CoolSense device by developing an eight question Survey Monkey evaluation survey to gauge parent/child experiences with the product, its effectiveness and if it was preferred over tropical anaesthetic creams. Parents were encouraged to involve their child in answering the questions where their age and condition permitted.

Implementation of Plan

Prior to purchasing we had the CoolSense device assessed by the Christchurch Hospital Medical Physics and Bioengineering Department to ensure that it had all of the appropriate documentation for use in the New Zealand health sector.

The following information was provided by the manufacturer. The CoolSense is a TGA (Therapeutic Goods Administration) licenced device that temporarily cools and numbs the skin on application. The small handheld device consists of an alloy metal core enveloped in an alcohol solution. It is cooled in a standard freezer obtaining operating temperatures of between -2 to -6 degrees Celsius. It is applied to the area to be numbed for approximately 10 seconds and provides topical numbing of the area for up to a minute, with peak effectiveness in the first 30 seconds.

The risk of using this technology was assessed as minimal with the greatest risk to patients being localised burns if the device is operated at too low a temperature, or with insufficient coverage of alcohol solution on the device tip. The Medical Physics and Bioengineering Department recommended that we replace the devices on an annual basis as the battery powered aluminium core block could not be accessed to replace the batteries.

The device was assessed by the Infection Prevention and Control team to provide guidance for cleaning the product to prevent cross contamination between patients.

Two CoolSense units were purchased with each device contained in an individual hard plastic ‘Click Clack’ box with the operating instructions clearly displayed. The units were to be stowed in the CHOC staff freezer until a dedicated freezer was sourced. The devices were still restricted for use only on CHOC with experienced users until a clear roll out strategy was in place for the other Child Health areas.
<table>
<thead>
<tr>
<th>CoolSense Steps to Use</th>
<th>CoolSense Infection Control Cleaning Guide</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Once removed from freezer, check light temperature indicator is flashing GREEN. Do this by pressing the button once. If the light flashes RED, return to the freezer. If the light flashes BLUE, leave out until flashes GREEN.</td>
<td>The CoolSense cartridges contains 70% isopropyl alcohol in a gel form. This prevents causing a cold burn and does provide a level of aseptic cover. However, further cleaning precautions are required to prevent cross-contamination across multiple patients.</td>
</tr>
<tr>
<td>2. Check that the CoolSense cartridge contains alcohol before using the device; failure to do so may cause a cold burn. Gently press upon the centre of the alcohol cartridge to push out the gel through to the metal pin of device; remove the top cap with a twisting motion and put it aside.</td>
<td>1. Clean the skin using CDHB procedural guidelines.</td>
</tr>
<tr>
<td>3. For vascular access applications place the surface of the metal pin to the site of injection for 10 seconds. The device can be used up to 8 minutes after being removed from the freezer, for as many times needed (within this timeframe).</td>
<td>2. Following use, wipe the metal pin and the entire device down with either a chlorhexidine /alcohol wipe or an isopropyl alcohol wipe (Azowipe).</td>
</tr>
<tr>
<td>4. After cooling the site of injection, immediately complete the injection procedure and not longer than 5 seconds after removing it from the spot of injection.</td>
<td>3. The CoolSense is <strong>NOT</strong> to be used on patients with a known <em>Clostridium difficile</em> infection.</td>
</tr>
<tr>
<td>5. Ensure that the CoolSense device is cleaned as per Infection Control Policy.</td>
<td></td>
</tr>
<tr>
<td>6. Return the device to the freezer, storing it on its side or cap down.</td>
<td></td>
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</table>

**Figure 2.** The CDHB operating instructions for safe use of the CoolSense device
Results and Findings

Methodology
An eight question Survey Monkey was designed to capture the parent/child experiences with the CoolSense product, its effectiveness and if it was preferred over topical anaesthetic creams. The survey ran from 30th May 2016 to the 18th July 2016 (49 days) returning an 80% response rate (n=31) with children who are currently actively receiving treatment. The survey was a mixture of Likert style, yes/no and open questions. Respondents enter their survey answers via a tablet device.

Question 1. CoolSense saved us time at our last appointment compared to previous appointments where Emla cream or similar was used.

28 respondents answered positively to this statement (90.3%); 15 agreed and 13 strongly agreed that the device did save them time at their last appointment. 3 respondents disagreed with the statement; 2 disagreed and 1 strongly disagreed (9.7%).

Question 2. CoolSense works well in numbing my child’s skin before needle insertion.
26 respondents answered positively to this statement (83.8%); 17 agreed and 9 strongly agreed the device worked well in numbing their child’s skin prior to needle insertion. 2 respondents disagreed that CoolSense worked well (6.5%) and 3 respondents did not know if the product worked well.

**Question 3.** My Child’s anxiety about the procedure appeared less using CoolSense than the topical creams.

![Question 3 Graph](image)

Comparatively less respondents answered positively to this statement (n=17, 54.8%); 8 agreed and 9 strongly agreed that their child’s anxiety appeared less using CoolSense than with topical creams. 5 respondents disagreed and 2 strongly disagreed that their child’s anxiety appeared to be reduced (22.6%). 7 respondents responded they did not know if their child’s anxiety was less when CoolSense was used instead of topical anaesthetic cream.

**Question 4.** The CoolSense device did not cause any discomfort to my child.

![Question 4 Graph](image)
22 respondents answered positively to this statement (70.9%), 13 agreeing and 9 strongly agreeing that CoolSense did not cause their child any discomfort when used. 2 respondents disagreed and 3 strongly disagreed that no discomfort occurred. (16.2%). 4 respondents did not know if any discomfort had been experienced by their child when CoolSense was used.

**Question 5.** My child appeared more cooperative with the procedure being performed when CoolSense was used compared with topical cream.

![Chart showing responses to Question 5](chart1.png)

21 respondents answered positively to this statement (67.7%), 12 agreeing and 9 strongly agreeing that CoolSense enabled their child to be more cooperative with a procedure than when topical cream was used. 5 respondents disagreed and 2 strongly disagreed with this statement. (22.6%). 3 respondents did not know if the use of CoolSense translated to their child being more cooperative.

**Question 6.** Comparing CoolSense with topical numbing creams used on my child I believe.....

![Chart showing responses to Question 6](chart2.png)

25 (83.3%) respondents answered they believed CoolSense was more effective than topical anaesthetic cream whereas 5 respondents (16.7%) believed the cream to be more effective. 1 respondent skipped this question.
Question 7. Would you recommend CoolSense to other parents/children?

27 (87.1%) respondents answered they would recommend CoolSense to other parents/children where 4 respondents (12.9%) would not.

Question 8. We would appreciate any other comments you may have about you/your child's experience with CoolSense

This question saw 19 responses being submitted from a total of 31 who commenced the survey (61.3%). The majority of positive responses described CoolSense as easier, faster/quicker to use than the topical anaesthetic alternative. Some respondents did comment on CoolSense being better but did not necessarily quantify how. Some respondents did mention how their child’s stress levels were reduced with the use of CoolSense. Other comments indicated that CoolSense was not effective for their child or that they are distressed at anyone touching their port area.

The overall results from the evaluation survey were consistent with our initial prediction that the CoolSense device would produce a better experience for CHOC patients and families by reducing pain associated with treatment which is vital to preventing future issues related to needle placement. In younger children it was often difficult to measure the effectiveness of the device as just the requirement to take their t-shirt off to access the Portacath can cause great distress. The majority of the feedback indicated that using the CoolSense was quicker, and not having to remember to put the cream on or wait for up to an hour for the cream to be effective was an important outcome especially for the parents/caregivers.

A number of families chose not to participate in the trial with CoolSense as they felt that the ritual using local anaesthetic cream established in the initial stages of treatment meant that their child was in a ‘good place’ and they did not want to jeopardise this.
In the week following the introduction of the two new CoolSense devices there were reported incidents of the device causing superficial burns to 4 patients. The CoolSense units were immediately removed from practice pending an investigation.

Email contact with the author of the initial Melbourne Royal Children’s Hospital quality of care report indicated that they had two cases of skin colour change that had persisted beyond 24 hours and one of these was thought to be a first degree burn. They believe that the device had not been used appropriately in this instance with the device being left on for >20 seconds and the rod not covered in the alcohol gel. They have just completed an audit of 100 patients with low complication rates with only minor skin discolouration that did not persist beyond a few minutes. They planned to continue reviewing the device and are developing a formal controlled study.

The two devices were examined by the Medical Physics and Bioengineering team. Their findings indicated the one of the devices was damaged as the aluminium block was loose within the housing which meant that the block was not protruding enough to touch the foam pad containing the alcohol gel. This defective unit was determined to be the likely cause of the identified burns cases.

<table>
<thead>
<tr>
<th>Aluminium Block Height</th>
<th>Red</th>
<th>Yellow</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>14mm</td>
<td>8.5mm</td>
</tr>
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</table>

**Figure 3.** Aluminium block height of the CoolSense units.

**Figure 4.** Showing the gap between the end of the metal block and the alcohol gel pad in the defective unit.
Subsequent to the physical examination of the devices the temperatures of both devices was also captured as it changes from Blue to Green and from Green to Red repeated again for both devices as a comparison once they had been in the freezer for >30 minutes and their LED is blue.

Table 1.

<table>
<thead>
<tr>
<th></th>
<th>Red 1</th>
<th>Red 2</th>
<th>Yellow 1</th>
<th>Yellow 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial Temperature</td>
<td>-12.3°C</td>
<td>-12.1°C</td>
<td>-12.7°C</td>
<td></td>
</tr>
<tr>
<td>BLUE to GREEN Temperature</td>
<td>-11.9°C</td>
<td>-11.8°C</td>
<td>-11.1°C</td>
<td></td>
</tr>
<tr>
<td>GREEN to RED Temperature</td>
<td>-5.3°C</td>
<td>0.4°C</td>
<td>-4.9°C</td>
<td></td>
</tr>
</tbody>
</table>

Both devices were in the freezer (-22.8°C) for 30 minutes and both came out with the blue LED flashing. Both devices changed from blue to green between -11.1°C and -11.9°C. There was a significant difference in the temperature that the green LED changed to red between the two devices. The damaged CoolSense had a green LED until 0.1°C whereas the other device turned off at -4.9°C.

The manufacturer indicates the following temperature parameters for the LED light indicators
- BLUE < -6°C
- GREEN -2 to -6°C
- RED > -2°C

This represents a significant difference in the actual operating temperatures compared to the manufacturers guide. They have been notified of this discrepancy.

The investigation led to the following recommendations

- Sending the defective unit back to the supplier for replacement.
- Placing some form of identification on the CoolSense devices to identify individual units. This would allow tracking of specific devices which can be marked against a patient to ensure that they have a history of treatment if a problem occurs.
- To notify Medsafe to capture the event in case it is not an isolated incident.
- To consider the recommended time that the CoolSense is placed against the skin – the longer it is applied, the colder the skin is going to get. This in the context of the skin thickness in younger patients where it is possible to deliver the cold temperature more quickly. The manufacturer suggests a 3-5 second application time in the context of cosmetic procedures, predominantly on the face. The experience of both Melbourne and Westmead for venepuncture is 10-15 seconds.
Embed and Sustain

The CoolSense device is already a popular alternative for CHOC children requiring topical anaesthesia for painful procedures. The use of the CoolSense device is still on hold following the formal investigation into the adverse events as we await the replacement of the defective unit and to ensure that all our processes and training are lined up before we rollout CoolSense further.

The governance of the use of the CoolSense device is very important and we have put several steps in place to ensure safe usage. A hospital wide policy is being developed based on the Royal Children’s Hospital Melbourne’s draft document. The instructions for use will be edited to include a step that instructs the user to inspect the device for any damage and that there is no visible gap between the metal block and the alcohol gel pad.

We are also recommending that the CoolSense devices are stored in a freezer that is maintained at a temperature >-10 ºC. With most domestic fridge/freezer compartments designed to maintain a temperature of approximately -20ºC this will mean a dedicated freezer is required for purpose.

We have ordered a number of new CoolSense devices for use across the wider Child Health division. There will be a controlled roll out with education and supervision of inexperienced users utilising the expertise of the Child Health Nurse Educator team. Consideration will be given to the timing of the rollout as there are a number of significant new projects being undertaken across Child Health including E-Meds which will need to be embedded into practice before introducing a new initiative.

The Radiology Department have expressed an interest in the device and will be the first department outside of Child Health to introduce the product into practice with ongoing guidance and support from the CHOC team. There is also scope for the CoolSense device to be utilised across other CDHB specialties such as the Emergency and Anaesthetic Departments where children are subjected to painful procedures.

With the return of many CHOC children to their local shared care centres there is also an opportunity to introduce the CoolSense device across other DHBs. The CoolSense initiative has also been put forward to present at the College of Child and Youth Nurses annual conference in November.

To measure the financial benefits of the CoolSense initiative, we intend to monitor the use of topical anaesthetic creams across Child Health over the next 6-8 months to calculate the actual cost savings.

The CHOC experience has proven the CoolSense pain numbing applicator to be a very effective tool for preparing children for painful procedures. When used appropriately and with the right education support this initiative has the potential to deliver improved health experience outcomes with significant cost savings.
References


