Feasibility of the antiseptic barrier cap in a NICU and PICU setting aimed to reduce CLABSI

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ABSTRACT

Background Central line associated bloodstream infections (CLABSIs) are a commonly encountered complication in hospitalized infants and result in mortality, morbidity, increased length of stay and cost. The antiseptic barrier cap is developed to improve disinfection procedures and compliance by nurses and helps to prevent CLABSIs by optimizing disinfection through cleaning of the needleless connector entry without active scrubbing.
Aim The purpose of this study was to test the feasibility of the antiseptic barrier cap in a neonatal intensive care unit (NICU) and pediatric intensive care unit (PICU). Feasibility is defined as the initial compliance of nurses and satisfaction of nurses.
Methods In this feasibility study, the Medical Research Council (MRC) guidelines concerning testing feasibility were followed. We used data from daily observations whereby compliance rate was determined and we measured satisfaction with a questionnaire with different closed questions, one open question, and a 10-points rating scale. The results were reported following the Criteria for Reporting the Development and Evaluation of Complex Interventions in healthcare: revised guideline (CReDECI 2).
Results Rate of compliance was 90,5% (361/398) at the NICU and 82,7% (163/197) at the PICU. All of the nurses were satisfied about the use of the antiseptic barrier cap in daily practice and they were intended to use the antiseptic barrier cap in the future.
Conclusion and recommendations This feasibility study shows that the antiseptic barrier cap ensures high compliance rates and satisfied nurses. With this increasing body of knowledge, other departments with a high number of central venous catheters might need to consider that some old methods, which are very time consuming should might be replaced with new product technology which facilitates hygienic procedures.

Keywords: NICU, PICU, CLABSI, Central Venous Catheter

SAMENVATTING

Achtergrond Bloedbaaninfecties zijn een veelvoorkomende complicatie bij kinderen die zijn opgenomen op de afdelingen Neonatologie en IC kinderen en kunnen leiden tot overlijden, morbiditeit, verlengde opnameduur en hoge kosten. De barrier cap is ontwikkeld om desinfectie procedures te verbeteren en de naleving van verpleegkundigen te vergroten. De barrier cap helpt bloedbaaninfecties te voorkomen door het reinigen van het naaldloos bijspuitpunt zonder gebruik te maken van alcoholgaasjes en de gebruikelijke 30 seconden droogtijd.
Doel Het doel van dit onderzoek is om de haalbaarheid van de barrier cap op de afdelingen Neonatologie en IC kinderen te meten. De haalbaarheid wordt bepaald door middel van het meten van naleving van de verpleegkundigen en de tevredenheid van de verpleegkundigen over het gebruik van de barrier cap.
Methode Voor het meten van de haalbaarheid is gebruik gemaakt van de richtlijnen van de Medical Research Council (MRC). Hierbij is gebruik gemaakt van data van dagelijkse observaties waarbij compliance werd gemeten en is tevredenheid van verpleegkundigen gemeten door middel van een vragenlijst met vier gesloten, één open vraag en een 10-punt waarderingsschaal. De resultaten zijn vervolgens gerapporteerd volgens de criteria voor het rapporteren van de ontwikkeling en evaluatie van complexe interventies (CReDECI 2).
Resultaten Mate van naleving op de ICN was 90,5% (361/398) en op de ICK 82,7% (163/197). Alle verpleegkundigen waren zeer tevreden over het gebruik van de barrier cap en staan positief tegenover het gebruik van de barrier cap in de toekomst.
Conclusie en implicatie van de belangrijkste resultaten Deze haalbaarheidsstudie heeft aangetoond dat de barrier cap zorgt voor een hoge mate van naleving en tevreden verpleegkundigen. Met deze kennis zouden andere afdelingen, waar veel bloedbaaninfecties voorkomen, ook kunnen overwegen om nieuwe tijdbesparende interventies, zoals de barrier cap, te gaan gebruiken.

Kernwoorden Neonatologie, bloedbaaninfecties, centraal veneuze catheters

INTRODUCTION AND RATIONALE

Central line-associated bloodstream infections (CLABSIs) are a commonly encountered complication in neonatal intensive care units (NICU) and paediatric intensive care units (PICU). The reported incidence of CLABSI is between the 3.2 and 20.0 per 1000 central line days among hospitalized infants(1). CLABSIs are a major cause of mortality and morbidity such as brain injury, chronic lung diseases and long-term poor neurodevelopmental outcome(2,3). Furthermore, CLABSIs are very expensive; the hospital costs are 17.000 dollars per infection for a neonate admitted on a NICU and 48.000 dollars per infection for an infant admitted on a PICU(4). Moreover, the mean length of hospital stay for an infant with CLABSI increases with 19 days(5).

Critically ill premature infants are particularly vulnerable for bloodstream infections due to their poor skin integrity, immature immune systems, need for frequent invasive procedures, and exposure to numerous caregivers(6). The chance to survive CLABSI depends on the condition of the infant, the causing microorganism, and the used antibiotics treatment(7). Also, at a NICU, CLABSI in preterm infants frequently occurs due to peripheral infusion, which is caused by their immunocompromised status(8).

There are several proceedings for preventing CLABSI such as s full barrier precaution during the insertion of a central line, cleaning of the skin with chlorhexidine, application of appropriate hand hygiene, and prompt removal when the central line is no longer needed(9). Besides these important components, also disinfection of the needleless connector entry is an important aspect in preventing CLABSI. Following new insights, the right way to disinfect the needleless connector entry is by rubbing the connector for 10 to 15 seconds and a drying time of 30 seconds(10). Although most of the nurses belief that disinfection of the needleless connector entry is an important factor in decreasing CLABSI, compliance in these routines is less than optimum(11). In a previous study is found that mutual collegial feedback improved the rate of compliance during intravenous medication administration from 7,3% to 21,5%. Disinfection of the needleless connector entry with an alcohol swab was complied in approximately 87%. However, the 30 seconds drying time which is necessary for optimal disinfection, was complied in 45% of the cases(12).

Because of the low compliance rates to manual disinfection and the 30 seconds drying time needed to achieve optimal disinfection, the antiseptic barrier cap is developed(13). This novel device contains a sponge with 70% alcohol and the purpose is to prevent CLABSI by optimizing disinfection through cleaning of the needleless connector entry without active scrubbing(14). Another advantage is the direct access to the needleless connector entry

without waiting for the 30 seconds drying time.

The literature suggests that an antiseptic barrier cap placed over the needleless connector entry decreases colonization of microorganisms on the connectors and therefore lowering the risk of CLABSI(15). But only consistent use of the antiseptic barrier cap in combination with strict compliance influences CLABSI rates(16,17). Because of the convenience of the antiseptic barrier cap it is expected that this will improve compliance rates and will motivate nurses to use the antiseptic barrier cap according to protocol. Multiple studies in adults, admitted on oncology or intensive care units showed a significant reduction in number of CLABSI between the 3.0 and 21.0 per 1.000 central line days by using the antiseptic barrier cap(14,15,18-21). Results of the effectiveness of the antiseptic barrier cap in infants and children are lacking.

This feasibility study is part of a larger study, which will provide data about compliance and incidence of CLABSI for one year. The aim of this study was to assess the viability of the larger study and to assess acceptability and practicability of the nurses(22); following phase two of the Medical Research Council (MRC) guidelines(23). Therefore, observing rate of compliance about barrier cap use and measuring satisfaction in daily practice by questionnaires was executed.

OBJECTIVES

Primary objective

To test the feasibility of the antiseptic barrier cap in a NICU and PICU setting.

METHOD

Study design

A quantitative observational feasibility study was performed from May 2nd until June 17th at the NICU and PICU of the Sophia Children's Hospital in the Netherlands. A feasibility study is a small-scale test to assess viability of a larger study(24). The MRC defines phase-two feasibility testing as follows: testing procedures, estimating recruitment and retention and determining the sample size(23).

Because the antiseptic barrier cap is a new intervention, the focus is on determining whether this intervention is appropriate for further testing. It could be helpful to identify what needs modification but also how changes might occur(25). Sample size calculations were not applicable because the antiseptic barrier will be eventually implemented as usual care.

For testing the feasibility there are two important parameters: rate of compliance and satisfaction of the nurses regarding barrier cap use.

An observational design was chosen, in order to assess the compliance of nurses. This design seems suitable because it provides information on "real world" use and practice(26).

Setting and participants

The Sophia Children's Hospital is the greatest Children's Hospital of the Netherlands.

At the NICU all admitted infants with tunneled, non-tunneled central venous catheters, and peripheral catheters were included. The Sophia Children's Hospital NICU is a 34-bed level IIID NICU, divided over four units. This NICU takes care for newborn infants with extreme prematurity (gestational age from 24 weeks), infants who are critically ill or require surgical intervention(27).

The Sophia Children's Hospital PICU is a 28-bed PICU, which is the largest PICU department of the Netherlands. This PICU is specialised in craniofacial surgery, trachea surgery, Extra Corporeal Membrane Oxygenation (ECMO) and paediatric heart transplants.

At the PICU all admitted infants with tunneled and non-tunneled central venous catheters were included. In contrast to the NICU, infants admitted on the PICU with only peripheral catheters were excluded. These infants were excluded because they are less vulnerable than infants admitted at the NICU and the chance that they will develop CLABSI from peripheral catheter regard considerably smaller(8).

The intervention

The Curos® antiseptic barrier cap is developed to improve disinfection procedures by nurses and helps to prevent CLABSIs by optimizing disinfection through cleaning of the needleless connector entry without active scrubbing(14). To apply, a nurse twists the antiseptic barrier cap onto the needleless connector entry after the catheter is placed, bathing the connector in 70% alcohol. The cap remains in place until the next catheter access. No drying time is needed when it is removed. This makes direct access possible without 30 seconds delay time(28).

For diagnosing CLABSI, the following criteria should occur: "A laboratory-confirmed bloodstream infection (LCBI) where central line (CL) or umbilical catheter (UC) was in place for >2 calendar days on the date of event, with day of device placement being day 1, AND the line was also in place on the date of event or the day before. If a CL or UC was in place for >2 calendar days and then removed, the date of event of the LCBI must be the day of discontinuation or the next day to be a CLABSI."(29)

Variables

Primary parameter

The primary parameter was feasibility. Defined by rate of compliance and satisfaction of nurses.

Procedures

Implementation

To achieve maximum rate of compliance and satisfied nurses, it is important in which way implementation takes place. The implementation of the antiseptic barrier cap is done according the model of Grol and Wensing(30). This model consists out of five phases: *orientation, insight, acceptance, change,* and *preservation of change*. Each phase got specific activities and goals. The goal of the *orientation* phase was to made the nurses aware of the new innovation and to create interest and commitment. Teaching sessions and an online newsletter were used to create this. In the teaching sessions, the use of the antiseptic barrier cap was explained and some points of interest were featured. Nurses were able to ask questions. The goal of the phase *insight* was to create knowledge and understanding, this was reached by distributing specially designed instruction forms. These forms were NICU and PICU specific and explained how the antiseptic barrier cap should be used and is illustrated with images of the different sort of needleless connector entries. The phase *acceptance* was designed to create positive attitude and motivation, but also the intention to change. This was reached by distribution of the protocol and a special note on the website. Followed by the phase of *change*, consisted of introduction of the antiseptic barrier cap in

practice and confirmation of utility. This was accomplished by ensuring sufficient stock and specially designed screensavers with tips and compliance rates per week. The final phase was *preservation of change*. In this phase the specific activities were evaluation rounds.

Compliance

In this feasibility study, total compliance was defined as 1) using the antiseptic barrier cap according to protocol, i.e. on every needleless connector entry for intravenous medication administration an antiseptic barrier cap for up to seven days and 2) consumption of the antiseptic barrier cap according to the 'patient data management system' (PDMS) file. In the PDMS file all medication administration moments are registered. If a child for example receives six times antibiotics per day, than the expected use is six antiseptic barrier caps. Because of the fact that each child has a personal stockpile of ten antiseptic barrier caps, the researcher will count the number of medication administration per day and compare this number with the number of antiseptic barrier caps left in the personal stockpile. After that, the personal stockpile is replenished to ten antiseptic barrier caps. If the antiseptic barrier cap is used in a different way or not at all, this will be considered as noncompliance. To help nurses find the right needleless connector entry, a special "needleless connector entry" sticker is developed to twist on the medication administration line.

The method that was used for observation is called "systematic observation". This means that the researcher will observe and record occurrence of certain specific proceedings, in this case the use of the antiseptic barrier cap. Systematic observation is often used for gathering quantitative data and is the usable for investigating a new area or intervention. The first step was to develop a coding system (31). For this study a specially designed observation form was used (appendix A). The researcher of this study (LS) was the observer and made a daily round on both departments in order to measure the use of the barrier cap and to fill in the observation form.

The check up round took place at random times so the nurses did not know at what time the researcher visited the unit. The data was aggregated to the department (NICU or PICU) and reported to each manager as a weekly nursing department compliance rate. With specific department screen savers, the nurses were informed about the rate of compliance. Except for the use of screensavers there were no further measures taken in order not to affect the use of the antiseptic barrier cap.

Satisfaction

For this study satisfaction was defined as: **"**The fulfilment or gratification of a desire or need" (32). The satisfaction questionnaire was distributed to fifteen nurses from the NICU and fifteen nurses from the PICU. There is sought to maximum variety between the nurses, based on age, gender, and years working experiences. A small quantitative questionnaire was used. The main goal of this questionnaire was to get insight whether the antiseptic barrier cap fulfilled them expectations and whether the antiseptic barrier cap was an improvement compared with the alcohol swabs. Four questions could be answered with "yes" or "no", one subquestion was an open question, and the last question was to assess the antiseptic barrier cap with a number from one to ten. The complete questionnaire can be found in appendix B.

Analysis

All of the collected data about compliance and satisfaction were presented with descriptive statistics. Rate of compliance was presented in percentages, which represents the ratio between the number of needleless connector entries whereby a barrier cap should be used and the number of needleless connector entries where the barrier cap were actually used. Analysis was completed, using the Statistical Package for the Social Sciences (SPSS), Version 2.

Ethical considerations:

This study was conducted according to the principles of the declaration of Helsinki (version 2008 (Seoul), and in accordance with the Medical Research Involving Human Subjects Act (WMO). By signing this protocol the investigators committed themselves to conduct the study according to Good Clincal Practice (GCP). An Institutional Review Board approved the study protocol. This study falls not under the WMO because all infants underwent identical treatment, and there was no randomization.

RESULTS

At the NICU there were a total of 398 needleless connector entries where an antiseptic barrier cap was supposed to be confirmed between May the 2nd and June the 17th, at the PICU were 197 needleless connector entries where an antiseptic barrier cap was supposed to be confirmed.

Findings

Compliance

NICU

Total compliance at the NICU was 90.5% (361/398). In 97.7% (389/398) was the antiseptic barrier cap confirmed at the needleless connector entry. Consumption according PDMS was correct in 92.7% (369/398) of the cases. The lowest total compliance score was 78.8% in the first week after implementation. The highest score was 96,4% in the fourth and sixth week after implementation.

PICU

Total compliance at the PICU was 82.7% (163/197). In 87.8% (173/197) was the antiseptic barrier cap confirmed at the needleless connector entry. Consumption according PDMS was correct in 85.3% (168/197) of the cases. The lowest total compliance score was 65.2% in the first week after implementation. The highest score was 92.1% in the fifth week after implementation.

The complete rate of compliance aggregated per week can be found in figure 1.

-- figure 1 –

Satisfaction

NICU

All of the nurses of the NICU were satisfied about the use of the antiseptic barrier cap, found the antiseptic barrier cap easier to use than the alcohol swabs, and found them supporting in working more hygienic. All of the nurses were intended to use the antiseptic barrier cap in the future. The mean grade the nurses gave on the NICU was a 9,2 (SD 0,86). The open question about which part of the antiseptic barrier cap specific made them satisfied, answered ten of the nurses they found it easy to use, eight found it less time-consuming, six

found it much cleaner to work with, and three found it pleasant that the antiseptic barrier cap also functions as a physical barrier. The mean age of the nurses who filled in the questionnaire was 37.1 years. The younger nurses (until the age of 35) appreciated the barrier cap slightly more than the older nurses and gave more often a rate of ten than there older colleagues.

PICU

Also at the PICU, all the nurses were satisfied about the use of the antiseptic barrier cap, found the antiseptic barrier cap easier to use than the alcohol swabs, and found them supporting in working more hygienic. They were intended to use the antiseptic barrier cap in the future too. The nurses of the PICU gave a mean rate of 8,6 (SD 0,99). The answers given to the open question were eight times easy to use, seven times less time-consuming, five times cleaner to work with, and two of the nurses found it an advantage that the antiseptic barrier is visible. The mean age of the nurses was 36.2 years. There we no notable differences between gender, age, or working experience.

Age, gender, and years of working experience of both the NICU and the PICU are presented in table 2.

-- Table 2 --

DISCUSSION

With this study we showed that the antiseptic barrier cap was feasible to use in large scale in the NICU and PICU setting. The MRC framework was used as a theoretical guide. We tested the acceptability and practicability by daily observations and through questionnaires.
In reporting this feasibility study we followed the revised Criteria for Reporting the Development and Evaluation of Complex Interventions in healthcare (CReDECI2). For this study, we followed the second stage item five criteria concerning description of the feasibility study and its impact on the definite intervention(33). Regarding this criteria, there are some things we learned in how to implement the antiseptic barrier cap in large scale.

We implemented the antiseptic barrier cap according the model of Wensing and Grol. By following the five phases, we reached a high degree of adaptation. Most important was to create a shared vision; a consensus on the goal of the implementation an how that goal needs to be achieved(34). We realized this by teaching sessions. By listening to the nurses about what they needed and what could help them to make them work easier, we structured our implementation. The nurses of the NICU and PICU are characterized by them motivated attitude. Because the need of reducing CLABSI and the willingness of nurses, the antiseptic barrier cap is well adapted and resulted in high compliance rates and satisfied nurses. Although the implementation worked out well, there are some phases that need to be reconsidered. Before the large-scale implementation will start it is important to pay attention to the phase insight. In this phase we distributed instruction forms about how to use the antiseptic barrier cap, but in particular the PICU found it unclear which needleless connector entry to use. Another phase that needs some extra attention is the preservation of change phase. With evaluation rounds we asked the nurses about their experiences and what could be modified. However, this was asked to a small number of nurses while it is important to know the opinion of all of the nurses. For a large-scale study it is advised to organize evaluation rounds continuously with different nurses.

For this feasibility study we have chosen for determining rate of compliance and satisfaction of nurses because it represents the acceptability, adaptation, and practicality in daily practice. We found a rate of compliance of 90.5% (NICU) and 82.7% (PICU), which is very high compared with earlier research whereby the rate of compliance is measured between the 73% and 85% (16,21,35). The questionnaire revealed that all of the nurses were very satisfied about the use of the antiseptic barrier cap and they found it all an improvement compared with the alcohol swabs, and were intended to use the antiseptic barrier cap in the

future. The nurses found the antiseptic barrier cap easy to use, less time-consuming, a physical barrier, and much cleaner to work with.

In this study is the incidence of CLABSI not calculated but is has to be notified that earlier research found promising results with a reduction of CLABSI between the three and 55 per 1.000 central line days (15,16,18,21,35-37). It is a notable finding that studies whereby both compliance and incidence of CLABSI is measured, the studies with the highest rate of compliance also found the highest reduction in number of CLABSI (35). This shows that only consistent use of the antiseptic barrier cap, in tandem with strict compliance does influence the number of CLABSI (11,38).

A strength of this study was the fact that observations took place every day and this results in a lot of data to give a complete overview about rate of compliance. A disadvantage of daily observations is that nurses might felt pushed or forced to use the antiseptic barrier cap. In order to obviate this, we decided to hand out satisfaction questionnaires. Another strength of this study is the fact that compliance is defined as using the antiseptic barrier cap according to protocol and consumption of the antiseptic barrier cap according to the PDMS file. In this way, the nurses were not tempted to re use the barrier caps. This way of testing compliance is not described in earlier research. A disadvantage of measuring consumption according to the PDMS file is if the number of barrier caps in the personal stock file not correspondents, this is might considered as non-compliance wrongly. It could happen for example that a barrier cap is fallen on the floor and thrown away or medication was given consecutively.

There are some limitations in this study. One problem which occur during this feasibility study was the fact that a some infants received more than ten times per day medication so the personal pile stock of ten barrier caps run out and barrier caps were caught from other infants or were used again. When it appeared that this was more often the case, a patients sticker were pasted on the personal pile stock so that no exchange could take place anymore. When infants went for weekend leave the consumption of the barrier cap was hard to ascertain. In this case, parents were asked to collect the used barrier caps but this proved difficult to measure. Although, satisfaction of parents was not asked, it has to be mentioned that they were also very enthusiastic about the use of the antiseptic barrier cap. They found it much easier to use than alcohol swabs and had also the feeling they were able to provide optimal care to their child. Furthermore, a limitation in the implementation phase was a delay in delivery of the antiseptic barrier cap, which resulted in a time period of three months between the first teaching session and the start of the intervention. Because of this, many

nurses had to be reminded again and this could be the reason of the relative low compliance rates in the first week.

CONCLUSION

We found that it was feasible to implement the antiseptic barrier cap in a NICU and PICU setting and there is viability and acceptance for a larger study. We found that if the implementation strategic is performed correctly this results in a good adaptation. The implementation model of Wensing and Grol was found to be suitable for implementation of the antiseptic barrier cap. We used compliance and satisfaction, which seems a fair reflection of the feasibility.

RECOMMENDATIONS

This study found the antiseptic barrier cap feasible in a NICU and PICU setting but could also be feasible in other sort departments, especially where central venous catheters are often used and CLABSI rates are high. We found that when a new technique or device is implemented it should meet the expectations of the nurses to makes adaptation easier. It need to fits in what nurses need and what makes them work more efficient. Especially timesaving interventions are a success because of the heavy workload that nurses have to deal with it.

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TABLES AND FIGURES

Figure 1
Rate of compliance per week

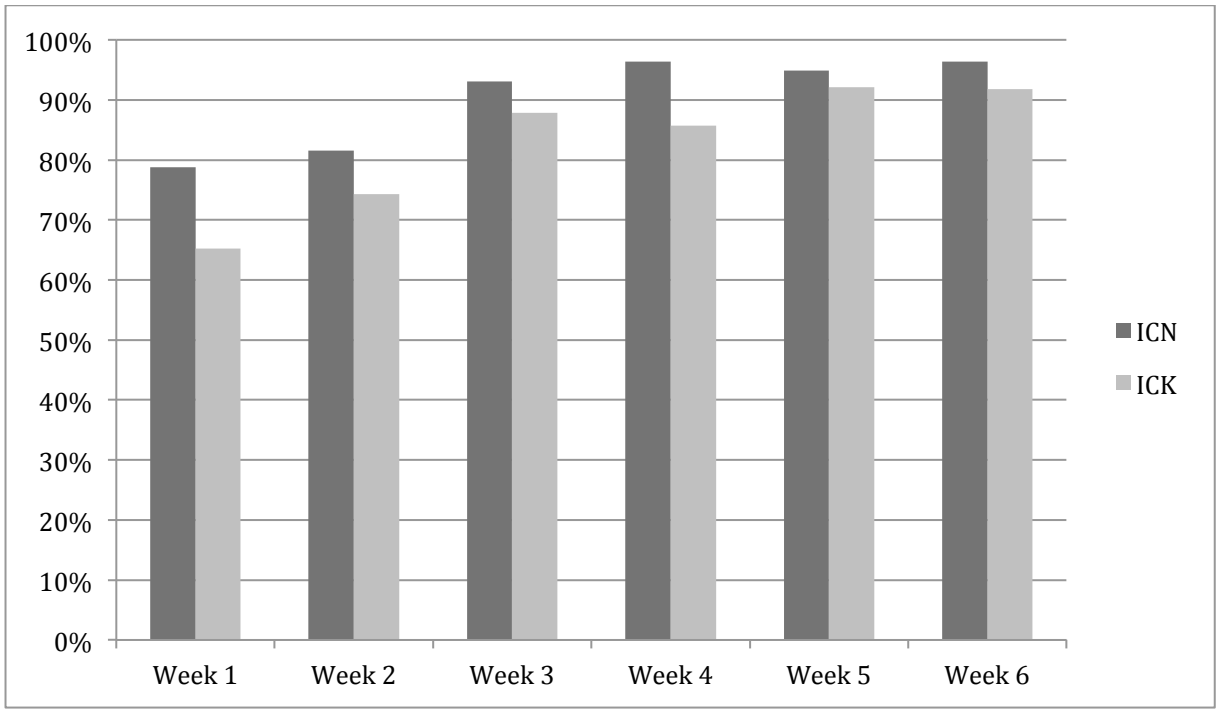

Table 2
Characteristics of the nurses

	NICU	PICU
Female (%)	14 (93.3)	14 (93.3)
Age in years	31.0 (28.0-53.0)	34.0 (28.0-43.0)
Working experience in years	10.0 (7.0-16.0)	13.0 (10.0-24.0)

Data are expressed as median (IQR) unless specified otherwise

APPENDICES

Appendix A

Barrier cap observation form

Observator:…………………………………………………………
Date:……………………………………………………………..
Time:………………………………………………………………

Unit	Bed	Number of barrier caps used according to PDMS	Barrier cap present on needleless connector entry	Consumption corresponds according to PDMS

Appendix B

Nurses' satisfaction questionnaire

1. Are you satisfied about the use of the antiseptic barrier cap? □ Yes □ No

If yes, about which part are you satisfied?
……

2. Do you think the antiseptic barrier cap is easier to use than the traditional alcohol swabs? □ Yes □ No

3. Do you want to use the antiseptic barrier cap in the future? □ Yes □ No

4. Do you think the antiseptic barrier cap supports you to work more hygienic compared with the traditional alcohol swabs? □ Yes □ No

5. Which grade would you give the antiseptic barrier cap? (1=extreme dissatisfied, 10=extreme satisfied)

O	O	O	O	O	O	O	O	O	O
1	2	3	4	5	6	7	8	9	10

Please fill in the final questions below

Gender	M/F
Age	….
Years of working exeperience	….