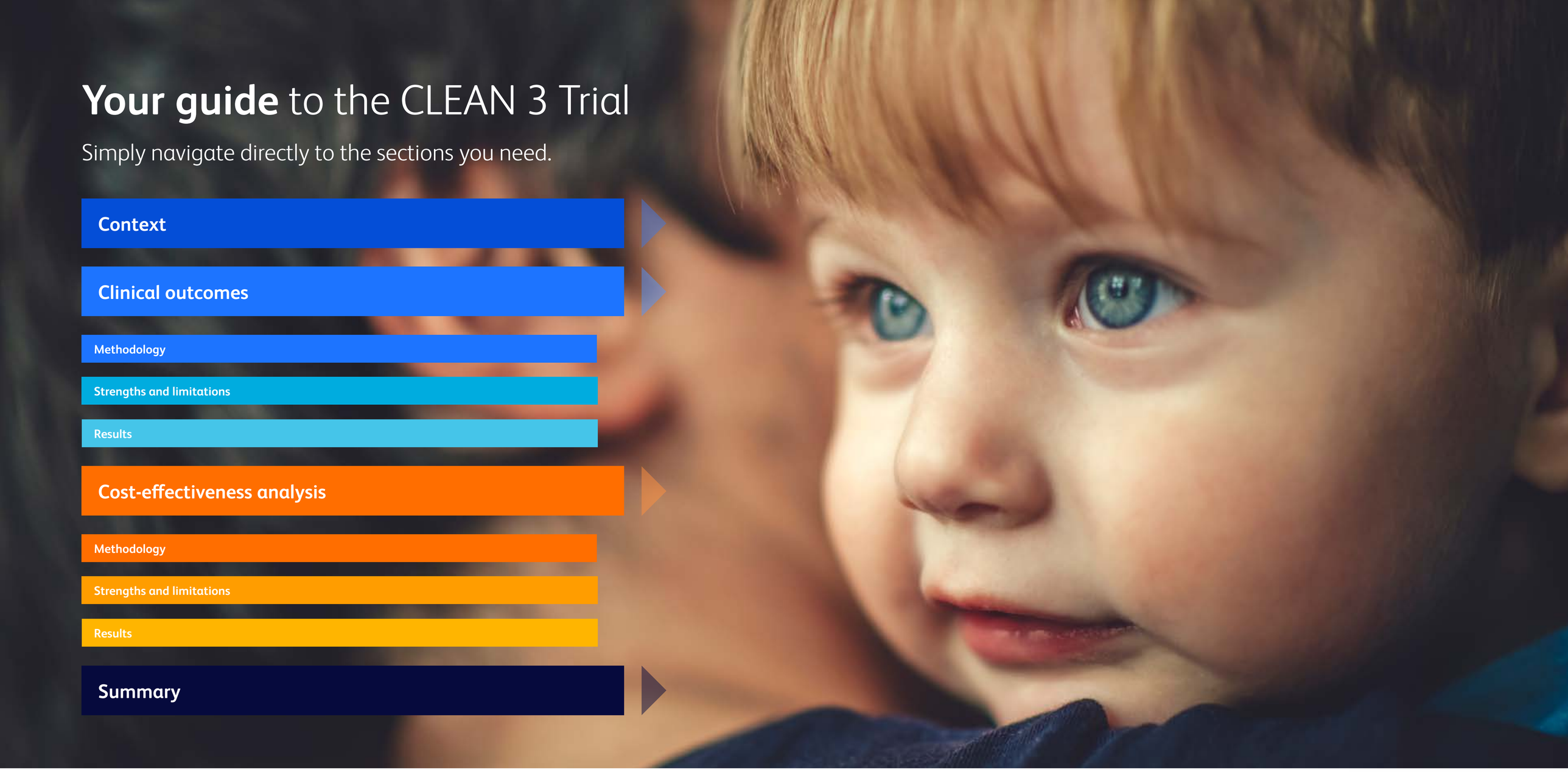
CLEAN 3: A first of its kind trial with cost-effectiveness outcomes for peripheral intravenous access[1, 2]

Find out why you should consider using the BD vascular care solutions for all patients requiring a peripheral intravenous catheter (PIVC) for more than 24 hours.

BD

Your guide to the CLEAN 3 Trial

Simply navigate directly to the sections you need.



BD

About two billion peripheral intravenous (IV) catheters are sold annually worldwide.[3]

Peripheral IV catheter placement is the most common invasive hospital procedure performed worldwide.[4]

35–50% of peripheral IVs don't meet their intended dwell time, largely due to complications, such as infection, occlusion, phlebitis, dislodgement and infiltration/extravasation.[4]

Catheter-related complications (CRCs):
Common, costly and impacting care

Peripheral IV catheter failure may cause:

Pain and dissatisfaction[4]

Vein depletion[4]

Extended length of care[4]

Additional costs[5]

You can have a positive impact

Improving peripheral vascular care practices can have a positive impact on patients, healthcare providers, hospitals and, more broadly, healthcare systems:

Implementing best practice policies, may help to reduce complications and improve clinical and economic outcome[6]

Continuous improvements and monitoring may help hospitals to achieve evidence-based best practice standards[6]

May lead to a reduction in excess health care costs[6]

CLEAN 3 Trial: The first large-scale, randomized clinical trial of its kind[1]

Peripheral intravenous catheters (PIVCs) are used extensively within hospitals and sometimes need to be removed prematurely due to complications.

Yet, until recently, there had not been any large clinical trials comparing peripheral vascular care approaches specifically for the prevention of complications, leading to Peripheral Venous Catheter (PIVC) failure, and assessing the efficacy of skin antiseptics for the prevention of catheter-related complications.

CLEAN 3 Trial: Comparing two peripheral vascular care approaches and the efficacy of two skin antiseptics

Could an integrated solution extend the time between catheter insertion and PIVC failure?

BD vascular care solution

Innovative solution

- An integrated peripheral IV catheter (BD® Nexiva™ Closed IV Catheter System)
- A positive displacement needle-free connector (BD® MaxZero™ Needle-free Connector)
- A disinfecting cap (BD PureHub™ Disinfecting Cap)
- A sterile pre-filled flush syringe (BD® PosiFlush™ Pre-filled Saline Syringe)

Standard approach

Standard solution

- Straight safety peripheral IV catheter
- Intravenous fluids and drugs administered through a three-way stopcock, after disinfecting the administration site with sterile gauzes soaked with an alcohol-based antiseptic
- Peripheral IV catheters were continuously infused with saline to prevent catheter occlusion or until catheter removal

+

Could using a different antiseptic prevent infectious complications?

CHG based

Skin preparation with 2% chlorhexidine (CHG) plus 70% isopropyl alcohol (IPA) single use, sterile applicator

PVI based

5% povidone iodine (PVI) plus 69% ethanol

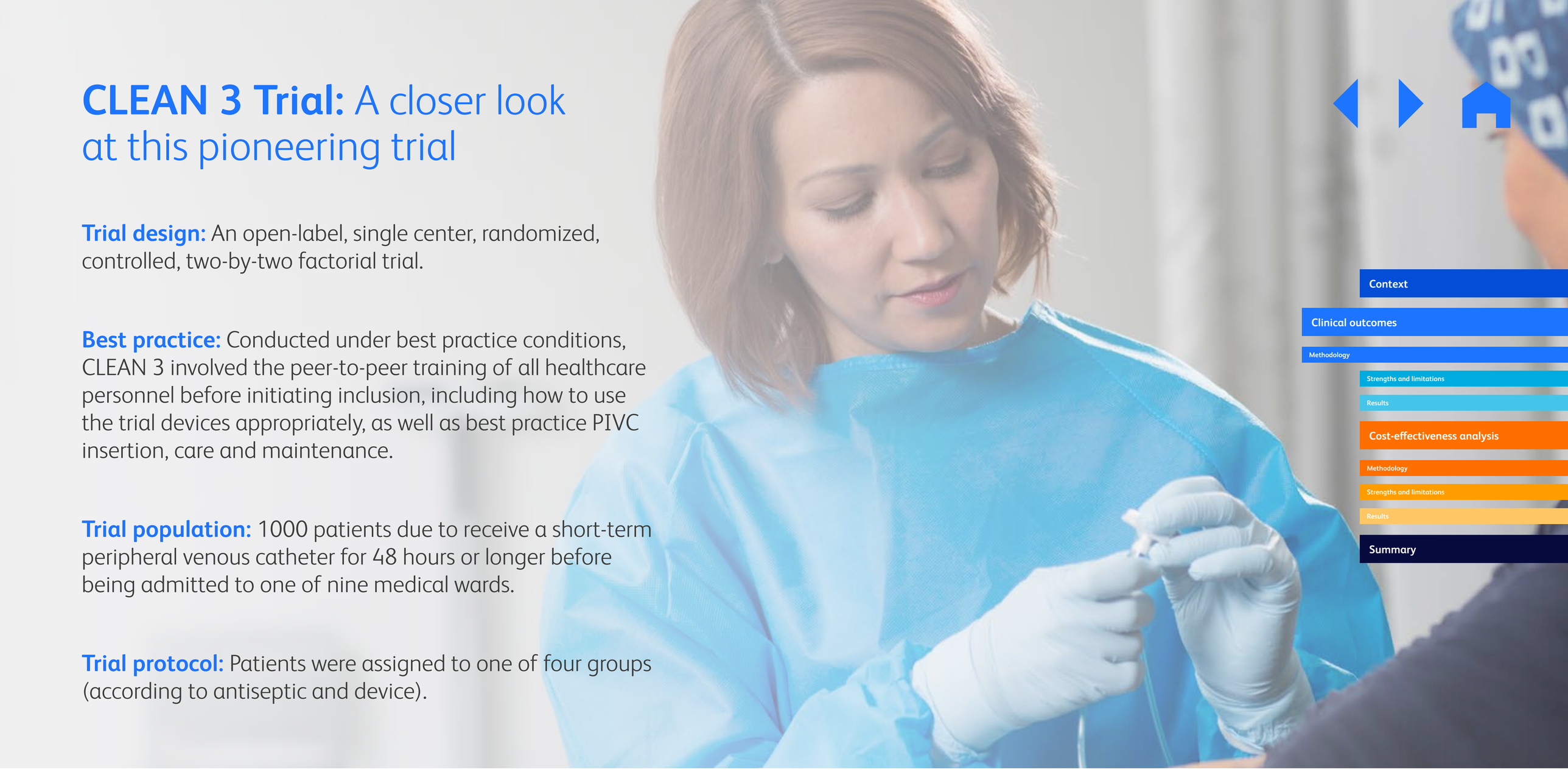
CLEAN 3 Trial: A closer look at this pioneering trial

Trial design: An open-label, single center, randomized, controlled, two-by-two factorial trial.

Best practice: Conducted under best practice conditions, CLEAN 3 involved the peer-to-peer training of all healthcare personnel before initiating inclusion, including how to use the trial devices appropriately, as well as best practice PIVC insertion, care and maintenance.

Trial population: 1000 patients due to receive a short-term peripheral venous catheter for 48 hours or longer before being admitted to one of nine medical wards.

Trial protocol: Patients were assigned to one of four groups (according to antiseptic and device).



CLEAN 3 Trial: How the results were measured

Outcome 1

Incidence of infectious catheter related complications, including local infections, catheter colonization and catheter-related bloodstream infections (CR-BSI).

Outcome 2

The time between PIVC insertion and catheter failure, which was defined as the premature removal of the PIVC related to infection, occlusion, phlebitis, dislodgement and infiltration.

CLEAN 3 Trial: Strengths

Training

Of all healthcare professionals (HCPs) in the use of medical devices before initiating inclusions

Availability

Some of clinical research nurses to ensure compliance with the protocol 7 days a week

Participation

Of nearly all medical wards of University Hospital Poitiers

Randomized

High number of catheters included

CLEAN 3 Trial: Limitations

- Not all eligible patients were enrolled; emergency room had strain (high demand) periods not suitable for inclusion of patients in study.
- Blinding was not possible because the two antiseptics differed in color and the devices were easily recognizable, however microbiologists and statisticians were blinded from the treatment group.
- Patients requiring surgery were excluded to limit biases related to the higher risk of complications during patient transfers to the OR.
- Only nurses with experience (≥50 PIVC insertions) participated in the trial.
- Despite the relatively high number of catheters, an influence of the type of antiseptic solution used on the comparison of devices, or of the type of devices used on the comparison of skin antiseptics cannot be totally excluded.
- Despite daily presence of research nurses in wards, it was not possible to ensure full compliance by the research nurses in the wards; however, any mistakes, such as flushing would have disadvantaged the innovation group.
- Since the BD peripheral vascular care solution was analyzed as a whole, it is not possible to know the contribution of the individual components.

CLEAN 3 Trial: What it did not show

Not part of the study design:

- Performance/benefit of the individual devices. This study looked at the combination of innovative solutions
- Any benefit relating to combination of 2% CHG plus 70% IPA single use, sterile applicator and the BD vascular care solution (only studied as individual aspects)

Evaluated, but not found significantly to have improved in BD vascular care solution group vs standard approach:

- Patient satisfaction was high overall with no differences between the study groups

This study showed the BD vascular care solution and skin antiseptic* may improve patient outcomes

The BD vascular care solution should be considered to the risk of catheter occlusion and dislodgement and increase dwell times.

27%

Reduction in risk of catheter failure

Compared with the standard approach, the BD vascular care solution reduced the relative risk of peripheral IV catheter failure by 27%, resulting in longer catheter dwell times without complications.

Catheter failure rates were:

- 35% BD vascular care solution
- 48% standard approach

4% vs 9%

Reduced catheter occlusion

The use of the BD vascular care solution reduced catheter occlusion (4% vs 9%) and dislodgement (14% vs 19%), when compared with the standard approach.

92%

Reduction in risk of infectious complications

Compared with 5% PVI 69% ethanol, the use of the 2% CHG 70% IPA single use, sterile applicator skin antiseptic reduced the risk of infectious complications by 92%.

- Catheter colonization: 0.9% versus 16.9%
- Local infection: 0% versus 1.2%
- No CRBSI was reported in either group
- Both skin antiseptics were well tolerated

*2% CHG - 70% IPA single use, sterile applicator.

What this means: The new rules for PIVC care

1. The use of an integrated BD vascular care solution should be the rule when the expected PIVC dwell time exceeds 24 hours.

   This system includes:
   - **i.** A closed integrated peripheral IV catheter
   - **ii.** A positive displacement needle-free connector
   - **iii.** A disinfecting cap
   - **iv.** A sterile prefilled flush syringe

2. The use of a sterile prefilled flush syringe can help to increase flushing compliance by making it easier, saving nursing time and limiting the risk of bacterial contamination.

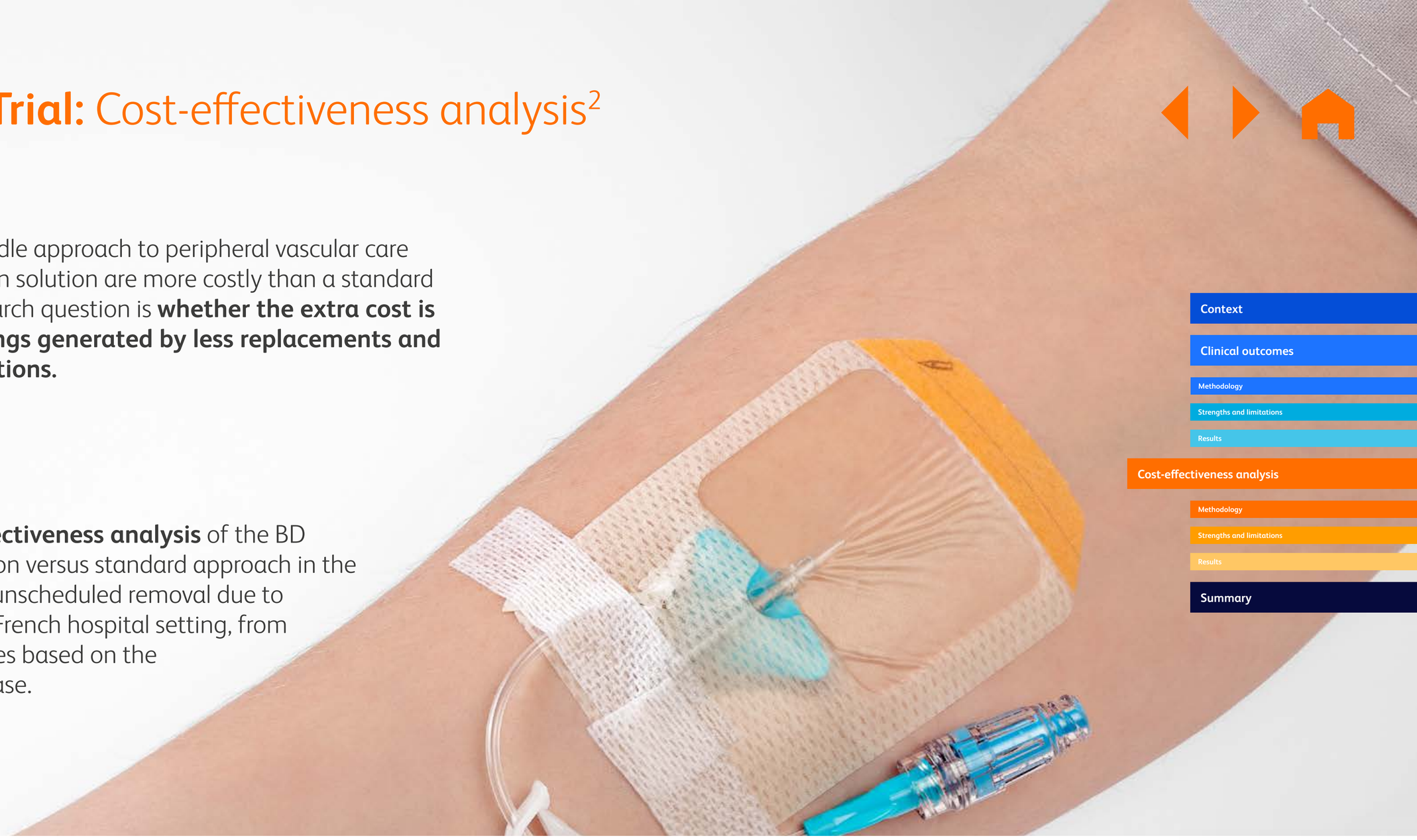
3. A 2% CHG 70% IPA single use, sterile applicator should become the first-line antiseptic for skin disinfection prior to the insertion of a short-term PIVC.

CLEAN 3 Trial: Cost-effectiveness analysis[2]

The innovative bundle approach to peripheral vascular care and skin disinfection solution are more costly than a standard approach, the research question is **whether the extra cost is offset by the savings generated by less replacements and reduced complications.**

Objective:

Perform a **cost-effectiveness analysis** of the BD vascular care solution versus standard approach in the prevention of PVC unscheduled removal due to complications in a French hospital setting, from modeling techniques based on the Clean 3 trial database.



CLEAN 3 Trial: Cost-effectiveness analysis

Methodology:

A 14-day time **model based on observed data from CLEAN-3 study** considering 5 health states (or conditions) and 8 transitional events* (or probabilities of a PIVC to be removed) over cycles of 1.4 days and within the following scenarios:

Base case scenario

Time horizon of 0-14 days considering the whole cohort of patients, the most conservative case and the most representative of real life.

Scenario 1

Time horizon of 2-14 days considering a subgroup of patients with a catheter duration >24 hours or <24 hours but with unscheduled removal due to a complication. This scenario excludes the catheters inserted for a short foreseeable period, for which the benefit of the BD vascular care solution is low.

Scenario 2

Time horizon of 0-14 days without PVCs complication costs. This scenario removes the cost of complications, for which management is not standardized between hospitals, potentially favoring the BD vascular care solution group.

Costs included

Average costs of catheter first placement, removal, replacement, daily maintenance, and cost of complications.** These costs have been calculated including material used, nurse time, and waste management. Resources and unit costs were estimated using hospital observations***.

Endpoints:

- Number of patients with unscheduled PVC removal avoided (per 100 patients)
- Cost per patient with unscheduled PVC removal avoided resulting from the BD vascular care solution versus standard approach

*See Figure 1 of the publication

**See Table 3 of the publication

***Available in the Supplement 1 of the publication

CLEAN 3 Trial: Strengths and limitations

Strengths:

This study used the data base from Clean 3 trial, which was randomized and included a high number of catheters.

A strong statistical model structure was developed including 3 scenarios. Even the least favorable scenario demonstrated significant cost-savings.

Limitations

- The model has been built on a single clinical study because it was the only Randomized Controlled Trial (RCT) available with the BD vascular care solution.
- The cost-effectiveness analysis was based on a scenario specific to French medical wards, with their own protocol to treat complications. So, the NH-SMC model cannot be directly transposed to other settings or other countries with different settings. This transposition would require local individual data on time-dependent probabilities of transition among health states at the daily level.
- This study has been sponsored by industry (the BD Company). However, an external research organization was hired by the University Hospital of Poitiers to handle independently the development of the cost-effectiveness model and the data analysis to remove any possible bias.

This cost-effectiveness analysis showed that the BD vascular care solution strategy is significantly more effective to prevent PVC-complications, with significant savings for the hospital

In all scenarios BD vascular care solution is the dominant solution (less costly and more effective).

In the base case scenario 12.65 PVC removal are avoided with BD vascular care solution every 100 patients, saving €42 per patient on average or €31 per patient-PVC-day.

Results

Main results, per patient*:

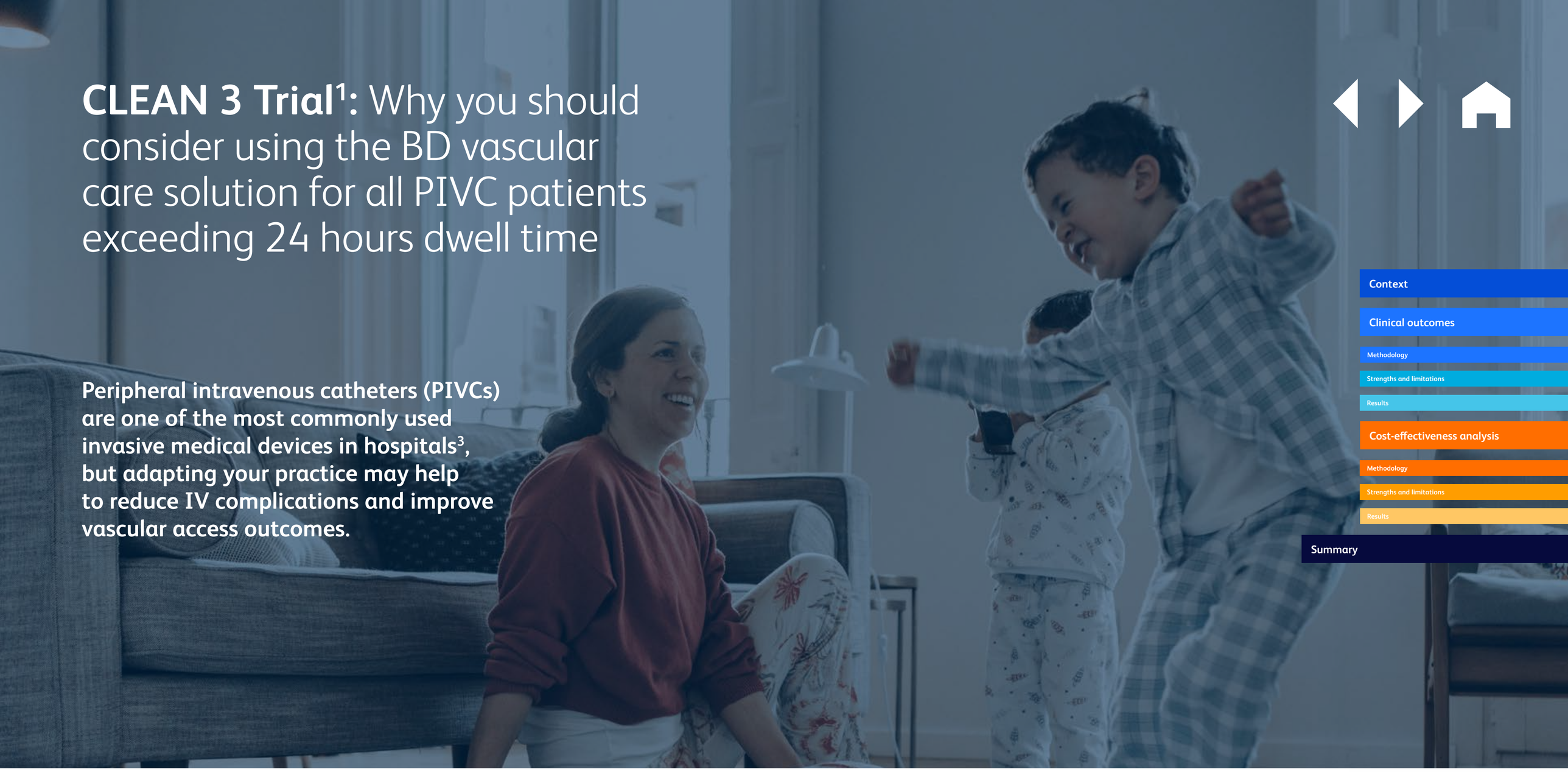
RESULTS PER PATIENT	Standard approach	BD vascular care solution	Difference
Patients with unscheduled PIVC removal	47.5%	34.8%	**12.65%**
Base case scenario	€144 (€135-€154)	€102 (€95-€109)	**€42 (€32-€54)**
Scenario 1	€169 (€160-€179)	€118 (€110-€126)	**€52 (€40-€65)**
Scenario 2	€131 (€124-€139)	€94 (€89-€100)	**€37 (€28-€48)**

Sensitivity analysis

The probabilistic sensitivity analysis for all the scenarios confirmed that the BD vascular care solution strategy is more effective and less costly versus the standard approach strategy in 100% of all the 1'000 iterations.

*We are only summarizing here the results per patient, however the study also has results per patient-PVC-day showing saving of €31 for base case scenario.

CLEAN 3 Trial[1]**:** Why you should consider using the BD vascular care solution for all PIVC patients exceeding 24 hours dwell time



Peripheral intravenous catheters (PIVCs) are one of the most commonly used invasive medical devices in hospitals[3]**, but adapting your practice may help to reduce IV complications and improve vascular access outcomes.**

CLEAN 3 Trial aimed to find out whether:

- The use of an integrated BD vascular care solution extends the time between catheter insertion and PIVC failure, compared with a standard approach.
- Skin preparation with 2% CHG 70% isopropyl alcohol (IPA) decreases the risk of PIVC colonization when compared with 5% povidone iodine (PVI) 69% ethanol.
- The extra cost at purchasing of the BD vascular care solution is offset by the savings generated by less replacements and reduced complications.

This study showed that the BD vascular care solution and skin antiseptic* may improve patient outcomes compared with the standard group

27%

Reduction in risk of catheter failure

The BD vascular care solution reduced the relative risk of peripheral IV catheter failure by 27%, resulting in longer catheter dwell times without complications.

4% vs 9%

Reduced catheter occlusion

The use of the BD vascular care solution reduced catheter occlusion (4% vs 9%) and dislodgement (14% vs 19%).

92%

Reduction in risk of infectious complications

The use of the 2% CHG plus 70% IPA single use, sterile applicator skin antiseptic reduced the risk of infectious complications by 92% when compared with 5% PVI plus alcohol.

€42

Cost-savings

The use of the BD vascular care solution reduced on average cost of €42 per patient or €31 per patient-PIVC-day, in the base case scenario.

*2% CHG - 70% IPA single use sterile applicator

The new rules for PIVCs

1. **Consider using a BD vascular care solution,** when the expected PIVC dwell time exceeds 24 hours.

2. A 2% CHG plus 70% IPA single use, sterile applicator should become the first-line antiseptic for skin disinfection prior to the insertion of a short-term PIVC.

3. From a cost-effectiveness point of view, **the routine use of these bundled devices for patients in medical wards can be recommended.**

We're here for fewer complications

As a global leader in vascular access solutions, we're on a mission to make sure every healthcare professional is able to use the right catheter for the right patient at the right time, every time.

BD Vascular Access Management is an integrated approach designed to identify and address gaps in the vascular access process that may result in improved clinical outcomes, better patient experience, and process and economic efficiencies.

We hope that you have found this study enlightening. To find out how we can help you to implement the necessary changes within your healthcare setting, please speak to your BD representative.

References

1. Guenezan J, Marjanovic N, Drugeon B, et al. Chlorhexidine plus alcohol versus povidone iodine plus alcohol, combined or not with innovative devices, for prevention of short-term peripheral venous catheter infection and failure (CLEAN 3 study): an investigator-initiated, open-label, single centre, randomised-controlled, two-by-two factorial trial. *Lancent Infect Dis*. 2021. https://doi.org/10.1016/S1473-3099(20)30738-6.

2. Maunoury F, Drugeon B, Boisson M, et al. Cost-effectiveness analysis of bundled innovative devices versus standard approach in the prevention of unscheduled peripheral venous catheters removal due to complications in France. PLoS One 2022 Jun. 14;17(6):e0269750. doi: 10.1371/journal.pone.0269750.

3. Rickard CM, Marsh N, Webster J, et al. Dressings and securements for the prevention of peripheral intravenous catheter failure in adults (SAVE): a pragmatic, randomised controlled, superiority trial. *The Lancet* 2018; 392: 419–30.

4. Helm RE, Klausner JD, Klemperer JD, Flint LM, Huang E. Accepted but unacceptable: peripheral IV catheter failure. *J Infus Nurs* 2015; 38: 189– 203.

5. Tuffaha HW, Rickard CM, Webster J, et al. Cost-effectiveness analysis of clinically indicated versus routine replacement of peripheral intravenous catheters. *Appl Health Econ Health Policy* 2014; 12: 51–8.

6. Lim S, Gangoli G, Adams E, et al. Increased clinical and economic burden associated with peripheral intravenous catheter-related complications: Analysis of a US hospital discharge database. *Inquiry* 2019; 56: 46958019875562.

Context

Clinical outcomes

Methodology

Strengths and limitations

Results

Cost-effectiveness analysis

Methodology

Strengths and limitations

Results

Summary

BD provided an unrestricted grant.

CE 2797 CE 0050 CE 0086

BD Switzerland Sàrl, Terre Bonne Park – A4 Route de Crassier 17, 1262 Eysins, Switzerland

BD, the BD Logo, MaxZero, Nexiva, Posiflush and BD PureHub are trademarks of Becton, Dickinson and Company or its affiliates © 2026 BD. All rights reserved. BD-80105 (02/26)

BD