

## DEMENTIA CARE

# Infection prevention and control challenges of using a therapeutic robot

Dodds P, Martyn K, Brown M (2018) Infection prevention and control challenges of using a therapeutic robot. *Nursing Older People*, 30, 3, 34-40. Date of submission: 7 September 2017; date of acceptance: 13 February 2018. doi: 10.7748/nop.2018.e994

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## Conflict of interest

None declared

## Peer review

This article has been subject to external double-blind peer review and checked for plagiarism using automated software

## Acknowledgements

Thank you to the staff, people with dementia and relatives who participated, Sussex Partnership NHS Foundation Trust's Lived Experience Advisory Forum for Dementia, and Heads On charity, which funded the second PARO for the ward

## Abstract

This work was part of a National Institute for Health Research participatory action research and practice development study, which focused on the use of a therapeutic, robotic baby seal (PARO, for personal assistive robot) in everyday practice in a single-site dementia unit in Sussex.

From the beginning of January 2017 until the end of September 2017, the cleaning and cleanliness of PARO was monitored through a service audit process that focused on the cleaning, amount of use and testing of contamination of PARO being used in everyday clinical practice with individuals and in group sessions. Its use and cleaning followed protocols developed by the study team, which incorporated hand hygiene and standard precaution policies. Its cleanliness was determined using an adenosine triphosphate (ATP) luminometer, with a benchmark of 50 relative light units (RLU). A reading of ATP below 50RLU is the level of cleanliness recommended for social areas in hospital settings. Throughout the study period, monitoring showed that all swab zones on PARO were within the benchmark of the 50RLU threshold for cleanliness.

PARO has an emerging evidence base as a useful therapeutic device. However, introducing such devices into clinical practice may encounter barriers or concerns from an infection prevention and control (IPC) perspective. This study of PARO in clinical practice aims to address the IPC concerns raised and offers cleaning and testing protocols and results.

## Keywords

dementia, gerontology, infection, infection control, older people, technology

PARO (FOR personal assistive robot) is an interactive, therapeutic, robotic device that looks like a furry baby seal (Figure 1), and is used in place of animal therapy to help reduce patient stress. PARO interacts with people through sensors embedded in its body, allowing it to respond to sound and touch, and it moves and makes sounds like an animal. It is designed to promote patients' well-being, mood and communication by building and sustaining their engagement and interaction (Takayanagi et al 2014, Aminuddin et al 2016, Moyle et al 2017a). PARO can also be used to counteract negative experiences such as loneliness and isolation, and help people who need comfort or affection (Jøranson et al 2016, Piatt et al 2016, McGlynn et al 2017). There is an emerging evidence base of the positive effects of using socially assistive robots, including reducing agitation (Moyle et al 2017b, Mervin et al 2018).

A project began in 2014 to introduce PARO to an everyday clinical practice setting in a dementia unit in Sussex, aiming to translate research into practice (Proctor et al 2009, Balasubramanian et al 2015). During the

implementation process, staff encountered an issue not discussed in the literature relating to PARO – that of meeting NHS infection prevention and control (IPC) standards.

The emergent nature of participatory action research meant that this was incorporated into the project (Kemmis et al 2014). The infection control protocol and risk and safety protocol emerged in the initial practice development phase and was then refined during Phase 2, used during Phase 3 and explored as a specific aspect in Phase 4 of the project.

Figure 1. PARO



## Introduction of PARO on a dementia unit

PARO was introduced on a standalone ten-bed unit in Sussex for people with dementia who experience behavioural and emotional distress, and who need a higher level of care. Admissions range from one month to one year. The different phases of the project are summarised in Figure 2.

A preliminary practice development phase (March 2014) prepared the unit for the arrival and introduction of PARO as one of the non-pharmacological approaches used on the unit (McCormack et al 2013). This allowed staff to develop ideas about how best to use PARO with individuals by considering the existing literature and research about its use. In Phase 2, staff began to use PARO; they reflected on their practice and generated experience of using PARO as part of everyday care in their own context. They developed ideas about which patients were suitable for PARO, while refining the risk assessment process and building experience of using PARO.

The practice development process in Phases 1 and 2 was undertaken while ethics

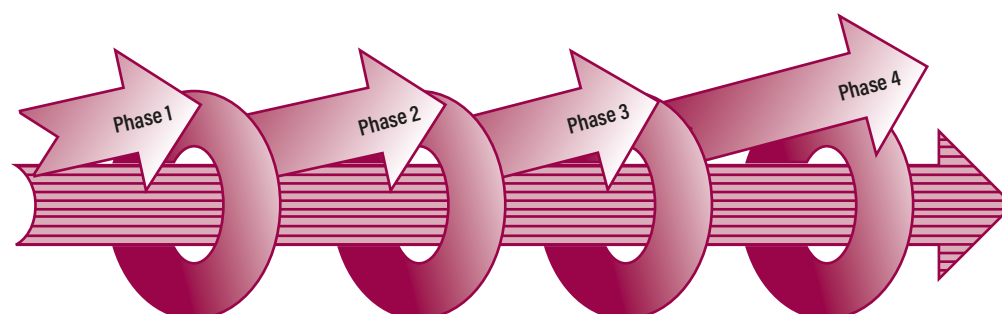
approval was sought for Phase 3, which would capture, more formally, the experiences of staff, patients and relatives who wanted to engage as research participants. This was supported by the National Institute for Health Research participatory action research study (study ID: REC Reference 15/LO/0469; IRAS ID: 164437). The research was designed to be inclusive of people with dementia who are often given no opportunities to participate in research (Shepherd 2016).

The consent process incorporated the mental capacity assessment of people with dementia and consultation with their representatives, consultees and relatives. In this phase, Phase 3, data were generated by observations and interviews with 18 participants (staff, patients and relatives); reflective practice notes; dementia care mapping snapshots; field notes; and observations, which generated themes to aid the implementation of PARO on the unit. These data were synthesised with the reflective notes from the earlier practice development phase. This generated findings about the therapeutic use of PARO, which indicated

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Figure 2. Phases of the PARO project and practice development and action research cycles



that PARO can be used in an acute dementia setting, and that benefits shown in research translated to the everyday clinical setting. A risk and safety protocol and an IPC and cleaning protocol were finalised at the end of Phase 3 (Figures 3 and 4).

Participatory action research and implementation research can generate new areas of development and enquiry, which may be unexpected and unpredictable (Waterman et al 2001, Coghlan and Brannick 2014, McNiff 2017). During Phases 2 and 3, the issue of IPC in the unit arose and this was also noted as an issue more widely in the UK through networking and personal communications during the practice development and research phases. Cleaning protocols were not available for using PARO in health and social care settings that would enable it to comply with IPC standards for hospital settings. Therefore, a subsequent practice development cycle (Phase 4) was overlapped with the end of the research phase to allow further service evaluation and ward-based enquiry to monitor and undertake systematic IPC testing of PARO.

### Technological devices and infection prevention and control

Technological devices have become common in healthcare with the rapid expansion in the use of computerised equipment. Their design and use has been clearly defined as either non-direct patient contact such as tablet computers or direct patient contact, such as the use of robotic devices during surgical procedures. For direct patient contact, national policies and local protocols are in place for cleaning and sterilisation (Department of Health 2015).

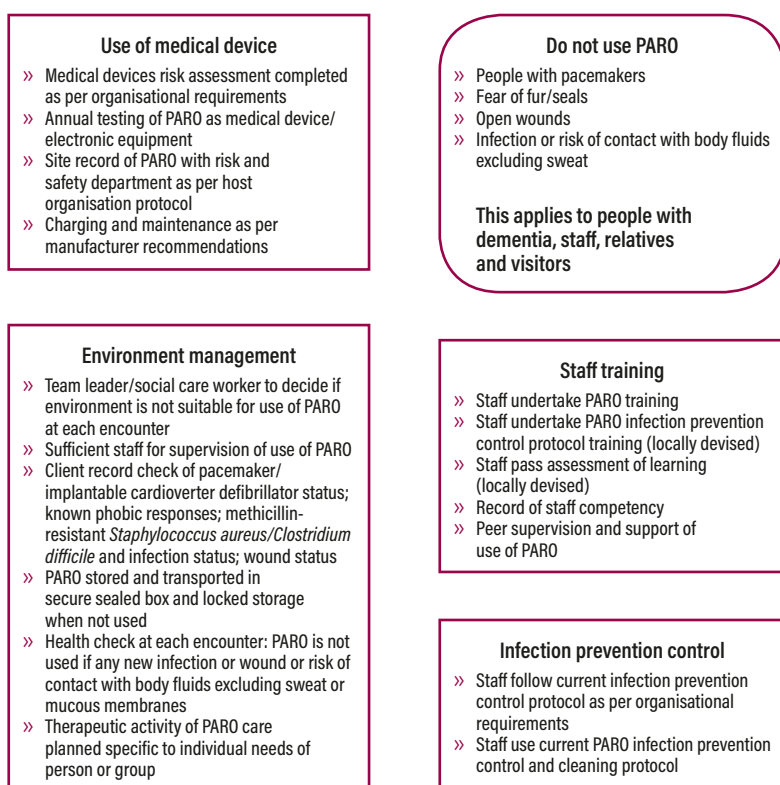
PARO is a novel device in clinical practice like other devices primarily designed for non-clinical use, such as computer game balance boards, which have been used by healthcare practitioners who have recognised their clinical potential with patients who have had a stroke or knee replacement (Negus et al 2015, Lee et al 2016).

Healthcare, nursing, residential and social care settings are required to meet rigorous IPC standards under health and safety legislation (National Institute for Health and Care Excellence (NICE) 2011). This applies to all NHS bodies and independent health and adult social care settings in England (NICE 2012).

Everyday objects, including door furniture, ward fabrics and plastics, can be contaminated with pathogenic micro-organisms (Messina et al 2013, Dancer 2014). Microbial contamination has also been identified on common electronic devices such as mobile phones and tablet computers (Rana et al 2013). However, the continued use of these everyday objects is accepted because they form part of the environmental fabric, or simply because they have been slowly introduced and are now accepted as normal in the workplace (Ventola 2014, Hunter 2015, Turner 2016). IPC concerns have been raised about other devices found in care settings, such as mobile phones (Pal et al 2013) and in the use of empathy dolls in hospitals (Subramanian et al 2014). Scholten et al (2016) discussed the issue of hygiene and robotic animal devices in a review of the literature on children in hospital. They concluded that it is important to gain knowledge about their safe hygienic use, particularly for robots that cannot be cleaned in traditional ways, to avoid them being considered ‘dangerous pals’. They offer opinion about the nature of fabrics, options for cleaning and testing of cleaning procedures and recommend the need for further research to establish best practice to minimise infection risk.

PARO presents a challenge to IPC because it combines robotic technology with a soft fur

**Figure 3.** PARO risk and safety protocol (to be read in conjunction with PARO infection prevention control and cleaning protocol)



covering that is not designed to be removed regularly or to be machine washed, and there is no guidance about how to meet the rigorous IPC standards required of healthcare in the UK.

PARO was not a device familiar in the study unit and presented IPC staff with something they believed may pose a hazard. While PARO has not been implicated with an increased risk of infection, and there have been no documented difficulties with cleanliness reported in the literature in the more than ten years of its use internationally, the absence of any evidence of risk may inhibit the uptake of PARO in practice in the UK.

### Using the precautionary principle

PARO is an example of innovation that may be stifled by caution, that is, 'better safe than sorry'. However, Hathcock (2000) argues that excessive precaution can lead to paralysis of action when, in reality, the risk associated with using the product is safer than not using it. In response to the IPC challenge posed by PARO, the Sussex PARO project formed a collaboration with an IPC nurse specialist, a microbiologist and a life sciences nurse lecturer to explore how these concerns could be addressed (Phase 4).

A framework offered by the precautionary principle (Raffensperger and Tickner 1999) was used to guide the development of a cleaning protocol and associated audit processes. The precautionary principle emerged in the 1980s originating from environmental law and bioethics. It is more commonly applied to technologies or advancements that may be considered to pose severe risk and unknown/uncertain consequences or harm or threat. The emphasis is on the proponent to assume a burden of proof of safety (Walton 1988).

It may seem extreme to adopt a principle usually applied to international biohazards – such as climate change, genetically modified crops and chemical biohazards – to a therapeutic baby seal robotic device that has no known history of posing a risk. However, the principle offers a structure in which to show the conditions under which something is used and the nature of the actual, rather than the assumed, risk.

In responding to the IPC concerns raised, the team also adopted a framework for responsible innovation (Stilgoe et al 2013) that invites thinking beyond risk and regulation by creating discussion about dilemmas, and questions raised by innovation. By applying the framework for responsible innovation and the precautionary principle,

the team aimed to change the knowledge about PARO and hygiene from a position of uncertainty, hesitancy and unknown risk to a better understanding of cleanliness and contamination in a controlled clinical setting.

### Method

To monitor the use, cleaning process and cleanliness testing of PARO under clinical conditions, a new PARO was introduced to the dementia unit in January 2017. A PARO

Figure 4. PARO infection prevention control and cleaning protocol (to be read in conjunction with risk and safety protocol)



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previously in use in the unit had also been used for educational purposes outside this setting, but this new PARO was restricted to the dementia unit and only used in everyday clinical care with individuals and in group sessions from the beginning of January 2017 to the end of September 2017.

During this period a service audit process focused on the cleaning, amount of use and testing of contamination of PARO being used in everyday clinical practice with individuals and in group sessions. Its use and cleaning followed the protocols developed in Phases 2 and 3 of the project. Its cleanliness was monitored using procedures and protocols in the NHS trust that incorporated hand hygiene and standard precaution policies.

PARO was cleaned using the standard equipment available in care settings – biocide wipes, which are commonly used for surface cleaning of non-medical devices. These wipes contain a mixture of biocides that have been tested and demonstrate effectiveness against a range of microbes (Clinell 2017a).

Testing by the manufacturer demonstrated that effectiveness of the biocide depends less on the cleaning technique used and

more on the length of time the biocide is in contact with microbes. The time needed to remove microbes ranged from ten seconds (*Enterococcus faecalis*) to five minutes (*Klebsiella pneumoniae*) (Clinell 2017a).

The cleanliness of PARO was determined using an adenosine triphosphate (ATP) luminometer. ATP is derived from living organisms and it can be measured by detecting relative light units (RLU). It is recognised as a useful benchmark for cleanliness (Alfa et al 2015). This study used the benchmark of 50RLU, because a reading below 50RLU is the level of cleanliness recommended for social areas in hospital settings (Mulvey et al 2011).

### Cleaning and testing stages

The unit used the devised risk and safety protocol and the IPC and cleaning protocol (Figures 3 and 4).

The cleaning protocol was based on guidance on the use of biocide wipes that recommends wiping from clean to dirty, in an S-shaped pattern, and changing wipes if they become dry or soiled (Clinell 2017b). PARO was cleaned using a vigorous action to ensure the fur fibres became covered with the biocide and were damp to touch. The fur was then air dried. The biocide remains active until the fabric is dry. Drying of PARO fur takes eight to 15 minutes in the clinical environment. Staff were taught the cleaning process and a recording system that monitored the use and cleaning of PARO was implemented. Nominated staff took responsibility for routine cleaning.

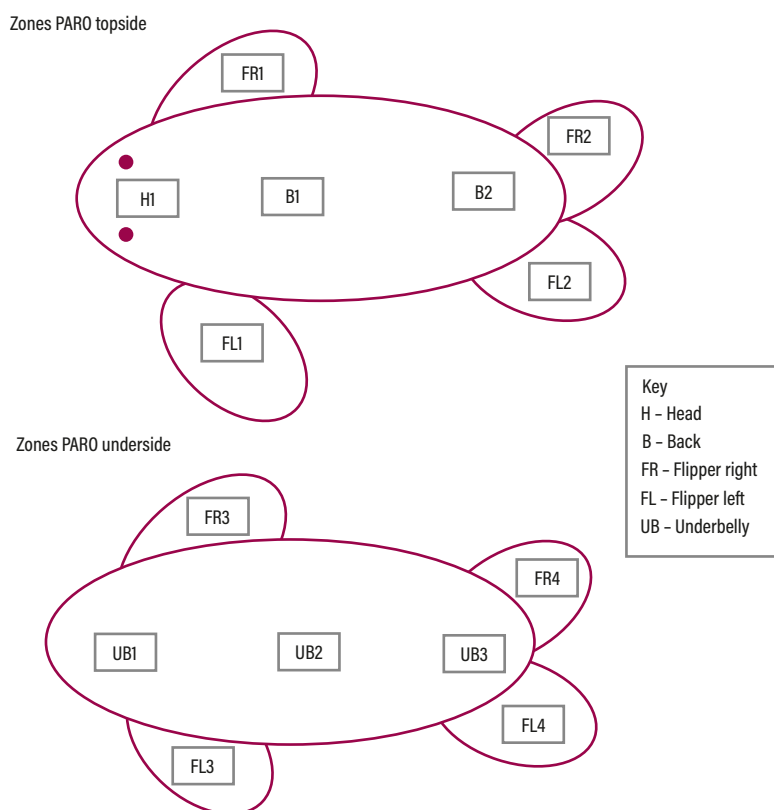
To test levels of contamination on the PARO, it was divided into zones as shown in Figure 5. These were swabbed using the ATP luminometer to measure ATP levels. The PARO was tested on its introduction to the unit and a baseline RLU was obtained in all testing zones. Testing then occurred at four-weekly intervals and visits were not planned with unit staff but were unannounced.

### Results

Throughout the period January 2017 to September 2017 all swab zones on PARO were found to be within the benchmark of the 50RLU threshold for cleanliness.

Figure 6 shows ATP levels of each area of the PARO tested after use. Areas shown in red were found to be below 40RLU and those shown in pink were between 40 and 50RLU. Although readings were below 50RLU, those areas shown in pink were on the threshold of acceptable levels. These areas were identified and staff were instructed to pay attention

Figure 5. PARO swab zones



to ensuring all areas of PARO were cleaned effectively. In particular:

- » The head (H1) was below 40RLU 73% of the time and 40-50RLU 27% of the time.
- » The underside of the front right flipper (FR3) was below 40RLU 50% of the time and 40-50RLU 50% of the time.
- » The top of the rear right flipper (FR2) was below 40RLU 78% of the time and 40-50RLU 22% of the time.

It is not clear why different zones demonstrated different levels of contamination. It is possible that the variations in levels of RLU reflected how PARO was handled. Anecdotal observations suggested that most patients stroked the head or the front flippers of PARO. Staff touched the back flippers more often because this is where the on/off switch is located. An example of this is the difference between the underside of the left rear flipper (FL4) and the top side of the front left flipper (FL1). This suggests that those areas in direct contact with the patient, or likely to be stroked or handled, recorded higher levels of ATP. These results indicate that the recommended cleaning protocol using biocide wipes maintained PARO at below 50RLU over the nine-month period.

### Further research

The findings indicate that PARO can be cleaned with biocide wipes using the protocol devised with cleanliness maintained below the threshold of 50RLU. However, during this study the time allowed for cleaning in the cleaning protocol was considered by the staff to be long and onerous. This had the potential to limit the use of PARO by affecting perceived workload.

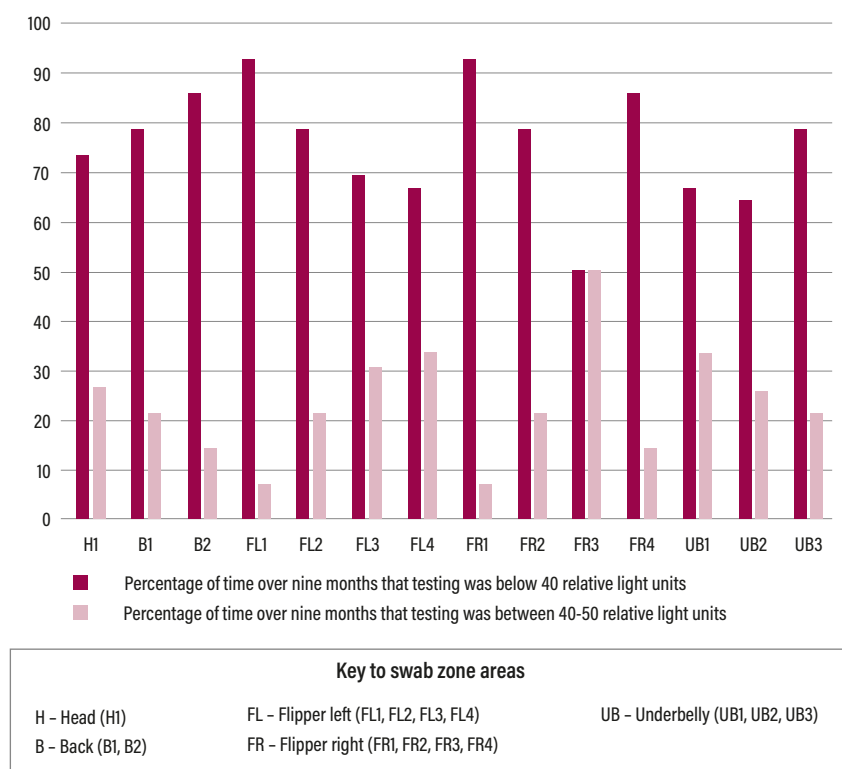
To address these issues, and to add to our understanding of the effective use of biocide wipes to clean PARO effectively in the clinical setting, a second study has been identified and is being undertaken in collaboration with the School of Pharmacy and Biomolecular Sciences at the University of Brighton. A microbiologist will measure the effectiveness of biocide wipes cleaning PARO fur samples in a controlled environment. Fur samples will be inoculated with a measured number of common microbes identified in the healthcare environment. It is hoped that this study will measure the effectiveness of cleaning soft fur coverings using biocide wipes; validate the use of measuring ATP on soft fur coverings; and establish the optimum cleaning time required to ensure PARO meets the threshold of 50RLU or less during its use therapeutically in clinical settings.

### Conclusion

PARO is an interactive, therapeutic, robotic device that looks like a furry baby seal and its use has been shown to help reduce patient stress. It has an emerging evidence base demonstrating its therapeutic benefits with older people in a range of physical, social and psychological domains. It has the potential to be used in a wide range of services that offer support to older people and people with dementia. However, its uptake may be hampered by worries of infection control. This article offers insight into how a project team introduced PARO into a unit for patients with dementia and embraced the challenge posed by IPC concerns.

Over a nine-month period of using PARO in everyday clinical practice, using the cleaning and monitoring protocols developed in collaboration with the unit, PARO remained within IPC levels of contamination and complied with local and national IPC requirements. This study was carried out in a specialist secondary mental health unit for people with dementia with severe emotional and behavioural distress. However, the IPC findings apply to a wide range of care settings, which include NHS acute hospital

Figure 6. Percentage of time PARO measured below 50 relative light units



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settings, nursing and care homes, community and private dwellings. It is disappointing if innovation is inhibited in the absence of any evidence of risk or exploration of how to overcome IPC issues. This applies to other less conventional objects used in practice and devices that are difficult to clean.

This article offers a template of practice development for those considering using PARO in other clinical settings or who are considering introducing other novel devices to clinical practice but are concerned about IPC. This study offers risk and safety and cleaning protocols, testing methods and results that may reduce concerns and invite wider discussion rather than blocking innovation.



**Implications for practice**

- » The use of interactive, therapeutic, robotic animals such as the PARO baby seal can help reduce patient stress and has been shown to have positive effects with older people and people with dementia, including improving mood and reducing agitation.
- » IPC protocols and monitoring can ensure that socially assistive robots can be maintained at an acceptable level of cleanliness for use in hospitals and other care settings with patients with dementia.
- » Innovative ways of improving the lives of older people and people with dementia should not be ruled out because of infection control worries.

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