

# The PARO seal: weighing up

The PARO robotic seal can improve the wellbeing of people with dementia, but is it safe for use on hospital wards? **Kathy Martyn** and colleagues carried out research and found that it passed hygiene tests. But **Carlene Rowson** and her collaborators claim (opposite) that infection control concerns have not been adequately answered. In this debate, they argue the case for and against PARO on hospital wards

To test whether the PARO robotic seal is sufficiently hygienic to be used by people with dementia on a hospital ward, we introduced it in a stand-alone 10 bedded dementia unit in Sussex NHS mental health services. Patients were experiencing a severity of behaviour that resulted from emotional, psychological and behavioural distress.

The unit uses a range of non-pharmacological approaches where possible to alleviate distress and improve wellbeing. PARO is a socially assistive robot now found in over 35 other countries but relatively new in the UK. Emerging evidence shows that it promotes emotional wellbeing, speech and communication, and mood and social connection (Moyle *et al* 2017).

Translating innovations, such as PARO, from research into everyday practice may be slow, requiring attention to the local context and how to facilitate staff engagement (Wilson *et al* 2017; Rycroft-Malone *et al* 2013; Brooker *et al* 2017; Brownson *et al* 2017). Our Sussex PARO project was attentive to the need to research the process of introduction and be open to any issues that might arise.

Three years ago, we became aware of some hesitancy in the UK and other places (Canada, Australia) about microbiological and hygiene aspects of PARO. In some areas, this led to PARO being blocked by people from an infection prevention control perspective. It is what we have termed a “hard to clean device”, as it cannot be cleaned in the same way as other items of equipment used in the NHS.

There have been four stages to our project, which began in 2014, supported by the National Institute for Health Research and a consultation group of people with dementia and carers. First, we trained and developed staff in good practice with PARO; second, we developed protocols for using it safely and therapeutically; third, we captured data on its use by patients, carers and staff; and fourth, we refined guidance for using the robot, safely cleaning it, and testing levels of contamination of a new PARO under clinical conditions.

As a result of our project the infection prevention control protocols covering the dementia unit were revised in consultation

with the local infection control specialist. In particular, the risk and safety protocol now includes the parameters within which it is considered safe to use PARO and is clear about not using it where people on the unit have transmissible infections such as MRSA, influenza, diarrhoea and vomiting, or open wounds.

We conducted monthly random testing of the cleanliness of PARO, our findings indicating that it remained within the acceptable limits of cleanliness demanded by the Department of Health (2015; Hygiene 2012). The cleaning and testing procedure we devised is in accordance with NICE guidance (2011) and our work adhered to requirements for NHS settings. We invite further work for other settings.

PARO presents an interesting example of a hard to clean device. We were guided by principles of “responsible innovation” (Demers-Payette *et al* 2016), coupled with the “precautionary principle” taken from international environmental law (Stirling 2016). The precautionary principle invites innovators to take steps to demonstrate something new can be used safely and not cause severe harm or death (Weckert & Moor 2006).

Arguably, inhibiting an innovation without exploration is problematic, denies progress in developing new practice, and might be seen as a case of “paralysis without analysis”. It would be a shame if something such as PARO, with apparent clinical therapeutic benefit, was hindered because of speculation about how it might be used and perceptions of hazard and risk

unsupported by evidence from trials.

In our project we employed an ATP luminometer, which detects organic matter on the surface of a device, to measure cleanliness. We recognise the limitations of using ATP (an enzyme found in organic matter) as a surrogate measure for microbial pathogens in hospital and care settings (Shama and Malik 2013). In recognition of this, the University of Brighton is widening its investigation and has begun to undertake analysis in a laboratory-based inquiry into the contagion likelihood and further exploration of cleaning methods.

Finally, it must be emphasised that there have been no reported transmission infections associated with the use of PARO in the UK or worldwide. Based on the findings of our practice-based study, we offer our protocols and report freely to others and would welcome further discussion and evidence on how to use PARO safely in practice in a range of settings. For our report and protocols, please email K.J.Martyn@brighton.ac.uk.

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# the infection risks

So far, the PARO interactive robotic seal has mainly been used as a therapeutic intervention in care homes. Now it has been suggested by researchers at the University of Brighton that it could be extended to NHS inpatient wards.

But the nature of the device generates a number of infection control concerns which we don't feel have been adequately answered. PARO is used in close contact with patients, most commonly in a communal shared setting, and it has an artificial fur covering, making adequate decontamination of the device challenging.

Here in Sheffield, the PARO seal first swam into the infection prevention and control (IPC) spotlight back in early 2015. Infection control implications were raised when the IPC team were approached to sanction and support the purchase of PARO in a local mental health NHS trust which had been trying it out. Staff at the trust were unable to give satisfactory assurances that acceptable and robust cleaning and decontamination standards were in place, so purchase was not authorised.

It is known that common hospital-acquired ("nosocomial") pathogens can survive and persist on inanimate surfaces in the hospital environment for months and can be a source of continuous transmission if surface disinfection is inadequate (Kramer *et al* 2006). Items frequently touched or in close contact with patients can become contaminated by these pathogens.

Contaminated surfaces can serve as a source of transmission of nosocomial pathogens by direct spread to susceptible patients or through hand contamination of health care workers. There is now considerable evidence indicating that environmental transmission plays an important role with these pathogens,

including methicillin-resistant staphylococcus aureus, vancomycin-resistant enterococcus spp, norovirus, clostridium difficile and influenza (Weber *et al* 2010; Otter *et al* 2013, 2016).

For a vulnerable elderly population with dementia and perhaps other conditions, living closely together on a hospital ward, the risks and consequences of transmission are increased. The IPC team has yet to see demonstrable evidence that, once PARO has been exposed to nosocomial pathogens, it can be decontaminated to the extent that these infectious agents cannot be recovered from the artificial fur afterwards. In our view, the University of Brighton's research does not go far enough.

Soft toys are notoriously difficult to decontaminate, with no clear guidelines existing on best practice. The Department of Health guidance for decontaminating used linen recommends a washing process in which the temperature is maintained on a disinfection cycle at 71 °C for three or more minutes or 65 °C for 10 or more minutes (NHS Executive 1995). Data on empathy dolls, evaluated in our unit, has identified that clinically significant organisms can persist on the doll's surface even after a 60 degrees C wash cycle.

In light of the cross-contamination risk, our local protocol for use of empathy dolls in hospital requires that only one patient uses it for the duration of their stay. The doll must then be washed at 80 degrees C before re-use with another patient. If a patient is known to have an infection requiring barrier precautions, the doll is not re-used with another patient at all (Subramanian *et al* 2014).

These practical interventions are not feasible with PARO. The high cost of the device makes single use problematic and it is not suitable for washing at high



temperatures. Chlorine-based wipes could be used to wipe PARO's surface, but they are not licensed for use on soft surfaces and it is unlikely they would adequately penetrate the entire depth of the artificial fur.

There are too few validated decontamination techniques and appropriate cleaning products for use on PARO. Quantitative microbiological evidence is needed to provide assurance of the adequacy of any decontamination procedures. For example, microbial monitoring, with aerobic colony counts before and after cleaning, is an established method of evaluating the efficacy of routine cleaning and disinfection practices (Galvin *et al* 2012).

Before PARO and similar robotic animals are adopted in health care settings, it is vital that potential infection control issues are recognised and proactively addressed. Further enquiry will be necessary to devise an effective decontamination strategy and only then will it be possible to introduce it safely in these settings. ■

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