Risk assessment and reuse of placebo respiratory equipment

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Risk assessment of devices is needed to assess if reuse causes cross-infection

Abstract


Placebo respiratory devices, such as inhalers, large volume spacers (spacers) and peak-flow meters (PFMs) provide reliable methods of teaching patients effective drug delivery techniques, monitoring compliance and assessing treatment progress (British Thoracic Society and Scottish Intercollegiate Guideline Network, 2008; Asthma UK, 2006; nice.org.uk/NICE, 2002). While healthcare professionals have traditionally recycled these items of placebo equipment between patients, concerns have been raised regarding the lack of guidance relating to their reuse, the wide variation in decontamination practice across the country and the risk of cross-infection (Weller, 2005; Clancy, 2003; Weller and Levy, 2002). This article describes the risk assessment one hospital conducted in response to these concerns and the actions taken to safeguard patients.

Keywords: Placebo inhalers, risk assessment, infection prevention, infection control

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Risk assessment is a process that identifies potential hazards that could cause harm to individuals and organisations, and informs the implementation of reasonable actions to control them. While risk assessment may not remove the hazard altogether, it can modify it so that harm will not occur or is reduced as far as is reasonably practical.

To quantify the potential hazards associated with reusing placebo respiratory equipment, we convened a committee comprising an infection prevention nurse, a microbiologist and two adult/paediatric respiratory nurses. Using a trust-approved risk assessment tool, we examined:

- Current controls - the systems and processes in place to minimise the risk of cross-infection from respiratory devices;
- Guidance and legislation surrounding respiratory devices;
Likelihood and consequence of cross-infection to staff and patients.

Controls identified by the risk assessment

All respiratory devices were thoroughly manually cleaned between patient use, but variations in decontamination practice were evident. Some devices received additional treatment with low or high-level chemical disinfection, which was confusing, expensive and time-consuming for staff. No clear guidance existed to identify patients at high risk of carrying or acquiring respiratory pathogens and no device tracing was possible.

Regulation

PFMs and spacers are designated single-patient use by manufacturers and are subject to regulation by the Medicines and Healthcare products Regulatory Agency, being intended for diagnostic or monitoring purposes.

There is a question as to whether, in certain circumstances, such single-patient-use devices can be converted to multi-patient-use instruments. Verbal advice from the MHRA indicates that the principles concerning single-use items apply to single-patient-use items, namely that the use of devices against manufacturers’ recommendations has legal implications for organisations, as responsibility for the safe and effective functioning of the device transfer from the manufacturer to the user (MHRA, 2006).

Although many manufacturers now designate placebo inhalers as single use, placebo inhalers cannot be classified as medical devices, as they contain no active drug and are used for the purpose of assessment, rather than treatment. Consequently, they are not covered by MHRA legislation.

Likelihood and consequence of cross-infection

Some patients attending respiratory clinics may harbour potentially pathogenic micro-organisms in their respiratory tract and possibly introduce them into respiratory devices.

A literature review was conducted to establish the likelihood and consequence of this. Few studies examine contamination and infection from inhalers.

Levesque and Johnson (1984) cultured inhalers from children and found bacterial growth on all mouthpieces and portals. Taylor et al (1990), however, failed to identify any pathogens on the inhalers of children with cystic fibrosis, despite isolating *Haemophilus influenza*, *Staphylococcus aureus* and *Pseudomonas aeruginosa* from their upper and lower respiratory tracts.

Harkins (1999) examined inhalers of people with COPD, and found that most patients had never cleaned their device. Despite this, 18 inhalers had no growth, while seven showed growth of upper respiratory tract flora - six with coagulase-negative staphylococci and one with
*Staphylococcus aureus*. All but one had scanty growth, implying that hand-held inhalers do not act as a reservoir for common respiratory tract pathogens. Patients following a good cleaning and drying regimen are also shown to have minimal or no contamination of their respiratory equipment (Blau et al, 2006; Hutchinson et al, 1996).

Within our risk assessment, we examined the likelihood and consequence of a number of infections of concern. These were:

- Tuberculosis;
- *Burkholderia cepacia*;
- MRSA;
- Rhinoviruses;
- HIV/AIDS and opportunistic organisms - such as *Pneumocystis jiroveci*;

While respiratory devices can potentially become colonised with pathogens, particularly if a strict cleaning regimen is not followed, the committee concluded that the risk and consequence of acquisition of common respiratory tract pathogens in immunocompetent individuals is not significant. A risk assessment and action plan were then formulated to reduce or eliminate risk.

The committee met clinicians to establish practical ways to reduce risk without compromising patient care. Patients at a high risk of carrying or acquiring respiratory pathogens automatically received single patient-use items (Fig 1). Low-risk patients had devices that were cleaned to a standardised regimen using manual cleaning and low-level chemical disinfection. Summaries of cleaning procedures were displayed in prominent places to disseminate information to staff.

Clinic letters were modified to emphasise the need to bring in respiratory devices, so that inhaler technique could be assessed without the need for placebo devices.

**Discussion**

Clearly, the most effective infection prevention strategy would be to designate all respiratory devices single patient-use only. However, at present, we did not feel that this was feasible. Risk assessment must be a balanced process. The committee considered the risk of poor device use in patients in the absence of placebo equipment, including (British Thoracic Society Standards of Care Committee, 2005):

- Potential poor control of respiratory diseases;
- Potential increase in morbidity and mortality;
- Inefficient resource allocation and usage (device wastage, additional healthcare use).
Our risk assessment sought to quantify the risks associated with the reuse of respiratory devices. The major issues were:

- Differentiation between high and low-risk patients;
- Reuse of single-patient-use devices;
- The lack of legislation and guidance covering placebo devices;
- The likelihood and consequence of contamination of respiratory devices and resultant transmission of infection;
- Effective decontamination of reused devices and rationalisation of practice.

There was considerable difficulty in quantifying the risk of cross-infection to patients, because of a lack of available research. Clearly, all respiratory devices have the potential to become colonised, although not always with common pathogens. The absence of research or case reports on pathogen transmission and resultant clinical infection should not necessarily lead to the assumption that no risk exists, although evidence of this, even in immunocompromised patients, is scarce. Certainly, patients accessing this kind of health care may be considered a vulnerable group.

Thorough, regular cleaning does appear to eliminate or even significantly reduce the risk of colonisation. An effective infection prevention strategy, therefore, is a systematic, scheduled decontamination regimen conducted to agreed standards. All reprocessing of items should be subject to an audit trail for quality control. Many questions were difficult to resolve. For example:

- Does potential cross-infection pose a greater risk to patients than not assessing inhaler technique and drug delivery?
- Should patients who forget to bring their own respiratory devices to clinic not have their technique assessed because of the risk?
- Should clinics withdraw particular types of inhaler if companies cannot provide adequate stocks of placebos, even if this reduces patient choice and possibly compliance?

Asking patients to bring in active drug inhalers to test technique raises concerns of overdosing. If repeated practice is necessary, clinicians should probably switch to placebo devices, rather than exceed the recommended drug dosage. However, using personal inhalers is a reasonable first-line measure to prevent cross-infection.

**Conclusion**

Clinicians are clearly engaged with the infection prevention agenda, and collaborative working produced positive results. However, the potential removal of a key resource from clinical practice and the diversion of finances into single-patient items, due to an at present unquantified, theoretical risk could have hindered clinicians’ willingness to promote infection prevention strategies. This was overcome with good communication and compromise. The variation in countrywide practice highlights the need for national guidance on the issue. If
demonstration of technique remains a central tenet of training and assessing patients (British Thoracic Society Standards of Care Committee, 2005; NICE, 2002), national interest groups and pharmaceutical companies should promote safe placebo technology or alternatives.

Until national guidelines provide a consensus on best practice, healthcare providers should conduct risk assessments to ensure that their own practice is evidence based and as robust as possible.

Disclaimer

The statements and recommendations made in this risk assessment are based on current evidence and the best judgement of the authors. This risk assessment is intended only for use within our specific healthcare trust and the authors accept no responsibility for subsequent adoption by others of any recommendations made.


References:


