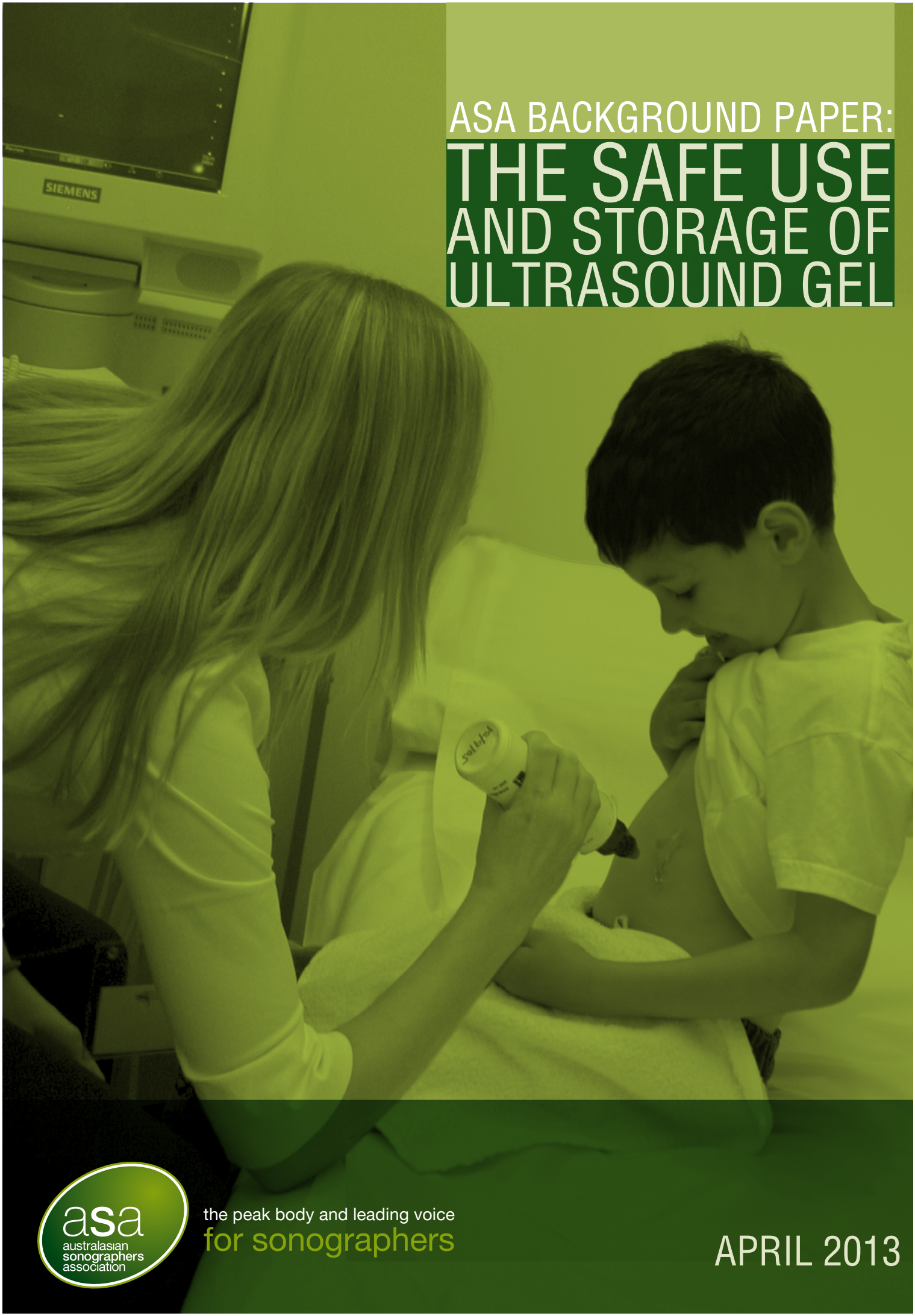

ASA BACKGROUND PAPER:
THE SAFE USE AND STORAGE OF ULTRASOUND GEL

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for sonographers

APRIL 2013

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April 2013

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Introduction

The Australasian Sonographers Association (ASA) is dedicated to guiding the advancement of the sonography profession to ensure the community has access to quality sonographic services. A key strategic objective of the ASA is to promote and advocate for best practice in medical sonography through the development of evidence-based standards and guidelines. The ASA guideline on *The safe use and storage of ultrasound gel* provides sonographers with recommendations on how to minimise the risk of transmitting infection that may occur due to the use of contaminated ultrasound gel.

The possible risk of transmitting infection to patients due to the use of contaminated ultrasound gel was originally brought to the attention of the ASA in 2012, when two ultrasound gel products were recalled by the Therapeutic Goods Administration (TGA) due to contamination. This prompted the ASA to conduct a background search on the current literature and guidelines available on the use of ultrasound gel, whereby we found contaminated ultrasound gel has been associated in the past with outbreaks of infection in various settings and with various organisms.

Implementing a range of infection prevention and hygiene practices in the safe use and storage of ultrasound gel can minimise the risk of microbial growth of microorganisms in gel, and as such, the potential subsequent infection of patients. This background paper provides a summary of the current available evidence on the links between contaminated ultrasound gel and patient infections, and the international recommendations that currently exist on the safe use and storage of ultrasound gel products.

Whilst the current evidence available in Australia and internationally requires further development, there is a general consensus amongst the international healthcare community that standard precautions should be followed in the use and storage of ultrasound gel. The ASA guideline on *The safe use and storage of ultrasound gel* is based on the current evidence available and international recommendations already in place, and is intended to assist sonographers in applying standard precautions as is appropriate for the circumstances of each individual workplace.

ASA Guideline: The safe use and storage of ultrasound gel can be found on the ASA website here

Views of the international healthcare community

In Australia, the only recommendations released by a healthcare authority on the handling of ultrasound gel are those developed by the TGA. In June 2012, batches of Other-Sonic Ultrasound Gel were recalled by the TGA due to the confirmed presence of the bacteria *Klebsiella oxytoca* and *Pseudomonas aeruginosa* in samples taken from the contaminated lots found [1]. In August 2012, batches of L-Gel Ultrasound Gel were recalled by the TGA due to the confirmed presence of the bacteria *Burkholderia cepacia*, *Stenotrophomonas maltophilia* and *Raoutella planticola* in samples taken from the contaminated lots. A variety of clinical conditions could result from exposure to these organisms, especially to patients with weakened immune systems, such as the occurrence of skin, soft tissue, and wound infections [2].

The second recall of ultrasound gel in 2012 prompted the TGA to include recommendations for implementing infection prevention and hygiene practices in the L-Gel Ultrasound Transmission Gel recall alert [2]. These recommendations have been included in the ASA guideline and are the suggested minimum practice standards for sonographers in their use and storage of ultrasound gel. The TGA recommendations are basic, outlining the need to maintain cleanliness of gel products and to use single-use sterile gel as intended. Though these are the only recommendations on the use and storage of ultrasound gel to come from an Australian healthcare authority, more in-depth work has been done internationally.

In North America, recommendations developed by Health Canada in 2004 have been widely endorsed by many professional associations, including the Canadian Society of Diagnostic Medical Sonographers (CSDMS), the Society of Diagnostic Medical Sonography (SDMS) and the American Institute of Ultrasound in Medicine (AIUM) [3]. Prior to the release of these recommendations, Health Canada investigated the practices of hospital staff regarding the use of ultrasound gel in clinical settings. Several instances of inadequate hygiene habits were discovered, including reusable bottles not being regularly cleaned, and non-sterile gel labelled for external use only being used for procedures involving contact with mucous membranes or during invasive procedures such as biopsies. Due to these discoveries, Health Canada developed recommendations as a directive for all healthcare professionals using ultrasound gel to abide by. The ASA guideline is strongly based on these recommendations developed by Health Canada.

In the US, the Food and Drug Administration (FDA) recalled lots of Other-Sonic Gel (also recalled by the TGA in Australia) manufactured between June–December 2011 after a hospital reported that 16 patients had either been colonised or infected by the bacteria *P. aeruginosa* [4]. The FDA investigation found the ultrasound gel used on these patients was contaminated with both the bacteria *P. aeruginosa* and *K. oxytoca*. While not every patient would develop colonisation (the presence of bacteria at a site without any signs of infection) or infection due to exposure to the bacteria found in the gel, the risk still remains present. Patients undergoing invasive procedures or those with a weakened immune system are more susceptible to developing an infection due to exposure to these organisms, although this is not exclusively so. For example, patients exposed to *P. aeruginosa* on the surface of their skin could develop inflammatory dermatitis, even on intact skin.

In response to the patient infections that occurred due to the use of contaminated ultrasound gel, the FDA made several recommendations on infection control practices regarding the use and storage of ultrasound gel. Many reflected the Health Canada recommendations made in 2004, and have been incorporated into the ASA guideline to the extent that they are applicable to Australian sonographers. Specifically, the FDA focused on the need to use sterile gel for critical procedures, emphasising that the only ultrasound gel that is sterile is unopened ultrasound gel packets or sachets that are specifically labelled as sterile. Ultrasound gel products that are labelled as non-sterile or that are not labelled at all with respect to sterility are not sterile.

Reported cases of infection linked to contaminated ultrasound gel

There have been a number of reported cases in the past of patient infection outbreaks that have been linked to the use of contaminated ultrasound gel, both at the point of manufacturing and the point of use. This background paper details a selection of case reports found to be most relevant. While the reported incidences of patient infection give an indication of the number of outbreaks that have occurred in the recent past, it is also possible that small clusters of infection could occur at a low rate, completely undetected and hence unreported [5]. In the most recent case, the FDA recalled contaminated lots of Other-Sonic Gel between December 2011–January 2012, after being alerted to the occurrence of *P. aeruginosa* respiratory tract infections in 16 patients that underwent a transesophageal echocardiography in a US surgical intensive care unit [6]. Of the 16 patients identified during the outbreak, two had pneumonia, five had tracheobronchitis and nine had respiratory tract colonisation only. In this case it was determined that the source of contamination most likely occurred during the manufacturing process, as unopened bottles were tested and found to be contaminated.

In September 2008, several days after undergoing a transrectal ultrasound guided prostate biopsy, four patients were hospitalised with fever and urinary symptoms in a urology unit at a tertiary care centre due to an outbreak of *Achromobacter xylosoxidans* [7]. The hospital's investigation linked the outbreak to contaminated ultrasound gel used. It was reported that the reusable plastic gel bottle in which the contaminated gel product was originally obtained was repeatedly refilled from a large bag of the product. The gel was not sterile and the bottle was not regularly replaced, cleaned or disinfected. The report stated that the bottle refilled from a larger supply bag became contaminated with bacteria, which apparently thrived in the gel. These bacteria were then directly inoculated into patients during the procedure. In a similar case, an investigation into outbreaks of serious nosocomial *B. cepacia* infections that had occurred on various occasions after transrectal prostate biopsies between 2000 and 2002 found that these infections were linked to the use of ultrasound gel intrinsically contaminated with paraben-degrading microorganisms [8].

Several incidents of neonatal and paediatric infection linked to the use of contaminated ultrasound gel have been reported. For example, since 1992 the Hospital for Sick Children in Toronto observed intermittent outbreaks of infection due to *B. cepacia* complex, primarily in the intensive care units [9]. *B. cepacia* complex species have minimal nutritional requirements that enable them to grow and proliferate in numerous aqueous products, and has been reported to cause disease in hospitalised and immunocompromised patients. In 2004 upon the discovery that contaminated ultrasound gel had been linked to outbreaks of infection in other instances, an investigation was conducted to examine the ultrasound gel used throughout the hospital. They examined 88 bottles of gel from four different manufacturers collected from seven different units of the hospital. They found no standardised protocol was followed for the handling of gel in any unit, at least half the bottles had been used for more than two years and that 37 (42%) of the in-use bottles from two different manufacturers were contaminated, 34 (92%) of them with *B. cepacia* complex. On the basis of their investigations, the hospital found contaminated ultrasound gel most likely contributed to the sustained endemicity of the *B. cepacia* complex in the hospital since 1992, although to what degree the investigators could not determine.

Standard precautions for infection prevention

Many questions of what constitutes appropriate and effective infection prevention practices have been raised due to the reports described. The primary issue in most of these cases has been the use of non-sterile gel in instances where sterile gel should have been used. All of the reports referred to in this background paper emphasise the need to use sterile gel for all potentially invasive procedures. After the 2011 outbreak of infection in the US hospital linked to contaminated Other-Sonic Gel, the facility began using single-use, sterile ultrasound gel for all potentially invasive procedures and to date have reported no further respiratory cultures positive for *P. aeruginosa* in the facility. In the tertiary care centre at which a number of infection outbreaks occurred after a series of transrectal biopsies, the use of reusable gel bottles was replaced with individual sterile gel packets for each patient undergoing a critical or invasive procedure.

This practice is in line with the widely accepted Spaulding classification scheme of medical devices that requires devices used for critical medical procedures (e.g. device that passes through tissue) to be sterile [10]. In accordance with the Spaulding classification scheme, intracavity procedures, such as examinations involving contact with non-intact skin or mucous membranes (e.g. transvaginal and transrectal examinations), are classified as semi-critical. For semi-critical procedures, the use of devices that are sterile is highly recommended, but not required [11]. However, a number of authors of the case reports detailed in this background paper expressed support for the use of sterile gel for semi-critical examinations [3,5–7].

As far as the ASA is aware, there is not sufficient evidence currently available to concretely determine the effective level of hygienic infection prevention practices needed to reasonably avoid patient infection due to the use of contaminated ultrasound gel, other than the need to use sterile gel for critical and ideally semi-critical examinations. However, there is a range of universal standard precautions that can be adopted to substantially minimise the potential risk. Jacobson et al. (2006) recommend the adoption of a range of standard protocols, such as for the use of non-sterile gel bottles, including that bottles be discarded at least three months after being opened, bottles should be disinfected and dried by an established process between each refill, and the refilling of bottles that are still partially filled should be prohibited [9].

Additionally, the possibility of contamination due to the inappropriate use of gel warmers has been raised as a concern in a number of articles. Tunstall (2010) argues that gel warmers provide the optimal temperature for the growth of bacteria, and as such, gel warmers should be regularly cleaned according to the manufacturer's instructions [12]. Oleszkowicz et al. (2012) recommend that the use of gel warmers that use water as a warming method for ultrasound gel should be utilised with caution, and that dry heat should be the preferred method of warming [5]. Further research needs to be conducted on the link between the use of gel warmers and contaminated ultrasound gel to be able to determine the level of risk the use of gel warmers may have on transmitting infection to patients.

ASA guideline development process

The development of ASA guidelines follows a thorough research and rigorous consultation process to ensure all published guidelines are accurate, up-to-date and achievable. The ASA seeks input from a wide range of expert sonographers and ASA members to guarantee ASA guidelines are widely supported by the sonography community. The ASA also consults with relevant external stakeholders and experts to ensure the documents produced are of the highest standard for sonographers to confidently implement in the workplace. The development of the *ASA guideline*: *The safe use and storage of ultrasound gel* followed these steps:

1. Literature review and environmental scan

This involved a complete search for available literature on the link between infection of patients and the use of contaminated ultrasound gel, as well as a survey of ASA members to scope current practices in this area. The results of the survey suggested that there is a lack of consistency in the standard level of precautions practised across the profession. The varying difference in practice can be linked to the lack of professional guidelines, as only 23% of respondents to the survey indicated that their workplace had protocols on the safe use of ultrasound gel.

2. Drafting

This involved development of the guideline recommendations and background paper based on the results of the literature review and environmental scan. The ASA Sonographer Advancement Working Party directed the drafting process and revised drafts regularly. The party reviewed and gave final approval for the distribution of the consultation drafts.

3. Consultation

Consultation drafts of the background paper and guideline were distributed to all ASA sonographer members that are in charge of their department or volunteer on an ASA committee, as well as the President of the Australasian College for Infection Prevention and Control. The consultation drafts received positive feedback from all respondents, including a range of constructive suggestions for improvement that were adopted into the final versions.

4. Final approval

The final guideline and background paper were reviewed and approved by the Board for distribution, with a review date set for April 2016.

Further information on the ASA process for developing guidelines can be sought by contacting the ASA Office at policy@sonographers.org.

Conclusion

The ASA believes more research needs to be conducted into the appropriate and effective level of safe infection prevention practices required in the use of contaminated ultrasound gel. The ASA's background search found that while the risk of an outbreak of infection among patients due to the use of contaminated ultrasound gel appears low from the current evidence available, particularly for non-critical general examinations, a degree of risk is still apparent. Therefore, the development of a guideline on the use and storage of ultrasound gel was considered an important resource for the profession to spread awareness of the issues involved and provide consistency in the infection control practices of sonographers.

The ASA guideline on *The safe use and storage of ultrasound gel* has been developed to provide a basic foundation for workplace protocols to be developed upon, as well as a guide for individual sonographers in the absence of workplace protocols. It is intended to provide useful tips and best practice recommendations, not rigid standards, on how to minimise the risk of transmitting infection due to the use of contaminated ultrasound gel. The guideline should be used in conjunction with workplace risk assessments, cost assessments, environmental considerations and other relevant industry standards. While this guideline is primarily intended to be used by sonographers, it may also be a useful resource for other medical professions which use ultrasound gel in their dealings with patients.

Acknowledgements

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