| Guideline for the Safe Use of Ultrasound Gel | University Hospitals of Leicester NHS NHS Trust<br>**Trust Reference Number: B4/2022** |
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# 1. Introduction and who the guidelines apply to

This document sets out the University Hospitals of Leicester (UHL) NHS guideline for the Safe Use of Ultrasound Gel. Ultrasound gel is available in both sterile and non-sterile preparations.

Ultrasound gel has been associated with outbreaks of infection in various settings worldwide and risk of contamination of non-sterile ultrasound gel has been highlighted (1 to 9). Such outbreaks have typically included serious clinical infections (1 to 5, 8).

Standard ultrasound gel is not produced as a sterile product, although sterile versions are available. Examinations using ultrasound and ultrasound-guided invasive procedures are conducted routinely in various clinical settings and situations. Patients range from those who are 'fit and well' to vulnerable individuals, such as those with severe immunosuppression and those who are critically ill.

This document provides guidance on the safe use of ultrasound gel to reduce risk of transmission of infection arising from these products. This replaces interim guidance first published by Public Health England (PHE), now the UK Health Security Agency (UKHSA), in January 2021 and is an outcome of close collaboration between UKHSA and key stakeholders with expertise relating to the use of ultrasound in UK settings (Appendix 1). This updated guidance clarifies the aims, implications, and user groups targeted. It includes additional guidance including on scenarios when sterile gel is recommended and what types of gel containers should be used.

# *2.* Aim

To reduce risk to patients associated with the use of non-sterile ultrasound gel in healthcare settings.

## 3. Audience and target groups

This guideline applies to any clinicians and practitioners using ultrasound gel in their practice in healthcare settings, including:

- Any user such as sonographers, radiologists, intensivists, midwives, vascular access specialists, emergency department and medical clinicians, physiotherapists, nurses and health care assistants
- Healthcare providers (NHS and independent) of facilities providing ultrasound services

## 4. Scope

This guidance relates to the use of ultrasound gel (therefore principles here are applicable broadly, including in relation to non-invasive and invasive ultrasound procedures and therapeutic ultrasound).

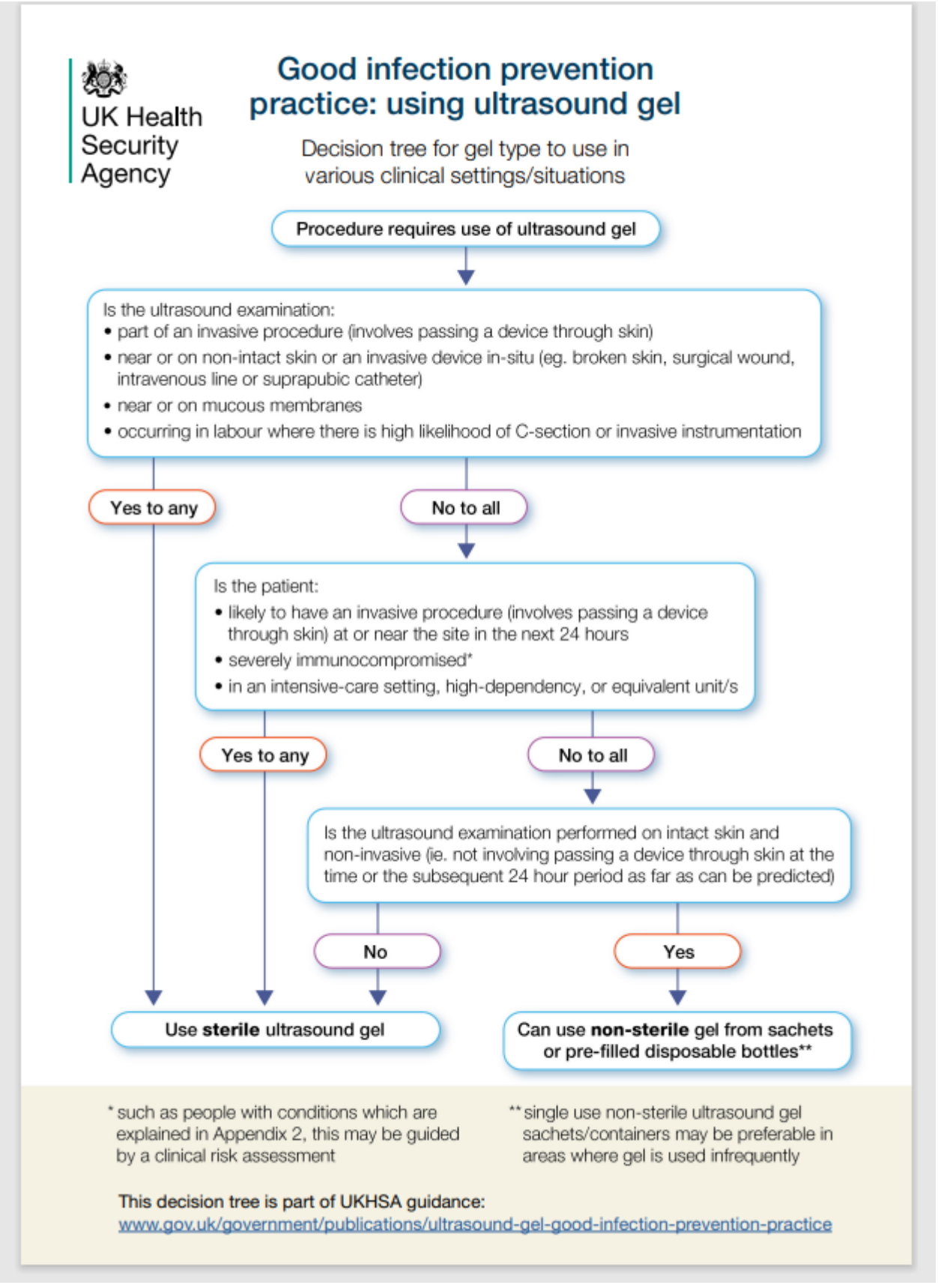
### 4.1 Implications

Consider the following:

- this guidance should be considered in the wider context of standard IPC precautions
- though patient safety is paramount, the environmental impact associated with adhering to this guidance needs to be considered
- while evidence and expert consensus have been used to inform this guidance, local risk assessments could be used to augment these recommendations

## 5. When to use sterile and non-sterile ultrasound gel

A decision tree indicating:



# 6. Type of gel to be used

Sterile ultrasound gel in single-use containers should be used in the following scenarios:

- for invasive procedures, that is any ultrasound-guided procedure that involves passing a device through skin into sterile tissue, such as intravenous line insertion or fine needle aspirate
- if an invasive procedure is likely or planned on or near the site in the following 24 hours – this includes 'viewing or initial assessment' of a site by ultrasound prior to undertaking an (aseptic) invasive procedure. If an unplanned invasive procedure is indicated and undertaken within 24 hours of non-sterile gel use, then clean and prepare the site as indicated in the general principles of non-sterile ultrasound gel use section
- in labour where there is high likelihood of C-section or invasive instrumentation during delivery
- where there is contact with or near to non-intact skin (any alteration in skin integrity such as a rash or surgical wound, including umbilicus in neonates)
- where the ultrasound examination is near to an indwelling invasive device, such as an intravenous line or suprapubic catheter
- where there is contact with a mucous membrane (for example for transrectal, transvaginal or ophthalmic procedures) – note: sterile gel to be used on the outside of probe covers and inside the probe cover if manually filled
- for examinations on severely immunocompromised individuals (such as conditions explained in (Appendix 2), this may be guided by a clinical risk assessment)
- in an intensive-care setting, high-dependency, or equivalent unit/s, including neonatal intensive care units

Non-sterile ultrasound gel in single use and multi-patient use containers may be used:

- during examinations in areas involving intact skin:
- in examinations that do not involve invasive procedures
- more than 24 hours prior to a probable invasive procedure at or near the same site

# 7. Safe use of ultrasound gel

## General principles

For both sterile and non-sterile gel:

- ensure healthcare workers carry out hand hygiene before and after use of ultrasound gel
- gel should be stored according to manufacturer's instructions in an area that is dry and away from potential sources of contamination
- dispose of container if it appears soiled, is damaged or is out of date

For sterile ultrasound gel:

- ensure that only unopened sachets and containers that are labelled as ‘sterile’ are used

- do not reuse the container or sachet once opened, either with other patients or stored and reused with the same patient, as sterile gels are single use only

For non-sterile ultrasound gel:

- gel should not be decanted from a larger container into other bottles
- use single-use sachets or pre-filled, multi-patient disposable bottles‡ – pre-filled disposable bottles must not be re-filled
- once opened, date the bottle and dispose of it when either empty, after one month or on expiry date, whichever comes first
- clean the whole bottle, including the tip, with a disinfectant wipe between uses
- tip/nozzle of bottle should not come into contact with anything – if it does, clean immediately with a disinfectant wipe
- after the procedure remove all residual gel from the patient’s skin and advise patients to wash area when feasible
- if an invasive procedure is subsequently undertaken within 24 hours of the use of non-sterile gel at or near to the site, then ensure all residual gel is removed, and the skin is thoroughly cleaned using antiseptic skin preparation in line with local policy for the procedure (note: sterile ultrasound gel should normally be used in advance of invasive procedures as detailed in the Type of gel to be used section)

‡ to avoid wastage, single use non-sterile ultrasound gel sachets may be preferable in areas where gel is used infrequently

### Warming of gel

The warming of gel is not recommended unless there is a clinical benefit that outweighs applying gel at room temperature. Where warming of gel is performed:

- use dry heat warmers instead of warm water
- gel bottles should be kept upright in warmers and not inverted
- warmers should be cleaned regularly according to the manufacturer’s instructions, where these exist, or clean according to local guidance

## 8. Education and Training

All clinical staff new to the department must undertake orientation of the department including information regarding this policy.

The safe use of ultrasound gel, as set out in this guideline must be followed by all staff.

## 9. Monitoring Compliance

| What will be measured to monitor compliance | How will compliance be monitored | Monitoring Lead | Frequency | Reporting arrangements |
|---|---|---|---|---|
| Room/department Cleaning checklist/book | IP Link staff | Department Lead | Monthly | IPOG meeting |
| Audit of compliance to this guideline | IP Link staff | Department Lead | Annually | IPOG meeting |

## 10. Key Words

UKHSA – UK health security agency

US Gel

*Burkholderia cepacia*

## Supporting References

Guidelines for Professional Ultrasound Practice, Society and College of Radiographers (SCoR) and British Medical Ultrasound Society (BMUS) 2020.

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# Appendices

## Appendix 1

This guidance has been produced by UKHSA through review of published literature, informed through outbreak investigations, and through consultation with key medical and subject matter experts and users of ultrasound gel within the UK.

Recommendations were discussed in workshops and agreed upon in consultation with a core working group (CWG) of stakeholders that included representatives from the following organisations:

- British Medical Ultrasound Society
- Healthcare Infection Society
- Infection Prevention Society
- Intensive Care Society
- Medicines and Healthcare products Regulatory Agency
- National Health Service (NHS) England and NHS Improvement
- National Health Service (NHS) Supply Chain
- National Infusion and Vascular Access Society
- The Society and College of Radiographers
- Royal College of Nurses
- Royal College of Midwives
- Society of Vascular Technology

The guidance was reviewed by a wider stakeholder consultation group that included public and private sector organisations or societies and user representatives. We would like to thank the following groups for their input:

- individual user representatives
- Royal College of Emergency Medicine

- British Society of Echocardiography
- representatives from Public Health Wales, Public Health Agency Northern Ireland and NHS National Services Scotland

# Appendix 2: Rationale and references

## Rationale and references for when to use sterile and non-sterile ultrasound gel

Non-sterile gel can be contaminated during manufacture or contaminated through use (5 to 8, 10, 11).

Outbreak investigations show that non-sterile gel can cause infections if used before or during an invasive procedure, on mucus membranes, or near non-intact skin (1, 3 to 6, 9, 12 to 17).

Evidence for the recommendations around probe covers suggests that in situations where probe covers are required, sterile gel should be used inside, and outside the probe covers where practical because of contamination risk (15, 16). The core working group considered that where possible, sterile gel containing probes covers should be used in preference to non-sterile gel containing products. Where prefilled probe covers are used and only non-sterile containing products are available, these can be used, though caution should be applied to avoid puncture (18). If probe covers are prepared manually these should contain sterile gel only.

Findings of a recent outbreak investigation were suggestive of risk of serious infection in some patients after having an ultrasound procedure where non-sterile gel was used on a site followed by an invasive intervention, such as for a biopsy (19).

There is a risk of transient contamination of the skin and subsequent infection if contaminated non-sterile gel is used prior to invasive procedures. Although standard disinfection procedures can be effective at removing microbes from sites where these procedures are to take place, application of contaminated ultrasound gel could allow penetration of microbes into skin ducts, glands and follicles where they are less accessible to disinfectant (20 to 22).

Notably, non-resident bacteria can survive for hours to a few days on skin, but it is anticipated that within a 24-hour period numbers of Gram-negative bacteria, potentially introduced via contaminated gel, would typically decline substantially (21).

The use of sterile gel 24 hours before a likely or planned invasive procedure was considered by the subject matter experts from the CWG as a pragmatic precaution to mitigate the risk of infection. However, it was acknowledged that there are likely to be circumstances where an invasive procedure is clinically indicated within 24 hours of non-sterile gel use on or near the site. In such circumstances, preceding use of non-sterile gel should not delay the procedure, but particular emphasis should be placed on appropriate

gel removal and thorough antiseptic skin preparation in line with local policy for the procedure.

Immunocompromised individuals should be determined by clinical risk assessment, where practical, and are at increased risk of infection and/or adverse outcome from exposure to contaminated ultrasound gel (1, 16). The following list provides examples of medical issues/conditions that could cause a patient to be severely immunocompromised. This list has been adapted from previous population risk assessment in the coronavirus (COVID-19) context. It is not intended to be exhaustive and local risk assessment may be required to inform practice (23):

- solid organ transplant recipients
- people with specific cancers:
    - people with cancer who are undergoing active chemotherapy
    - people with lung cancer who are undergoing radical radiotherapy
    - people with cancers of the blood or bone marrow such as leukaemia, lymphoma or myeloma who are at any stage of treatment
    - people having immunotherapy or other continuing antibody treatments for cancer
    - people having other targeted cancer treatments that can affect the immune system, such as protein kinase inhibitors or PARP inhibitors
    - people who have had bone marrow or stem cell transplants in the last 6 months or who are still taking immunosuppression drugs
- people with severe respiratory conditions including cystic fibrosis, severe asthma and severe chronic obstructive pulmonary disease (COPD)
- people with diseases that significantly increase the risk of infections (such as severe combined immunodeficiency (SCID), homozygous sickle cell disease)
- people on immunosuppression therapies sufficient to significantly increase risk of infection
- people receiving dialysis

Patients in high dependency and intensive care settings (including neonatal intensive care units) are also specifically vulnerable to infection from contaminated ultrasound gel (1, 3 to 5, 8, 14, 24).

Because opened gel bottles should be thrown away after one month, the CWG recommends that single-use sachets would reduce waste in low-use areas.

## Rationale and references for Safe use of ultrasound gel

The CWG considered the risks arising from using gel that is decanted from larger dispensing containers into re-usable bottles. In view of prolonged use and storage of gel, exposure to air (facilitating bacterial replication), and the potential for multiple patient exposures, the group recommended that only pre-filled disposable bottles are used (9, 25).

The one-month disposal date is a pragmatic decision based on balance of risk of propagation of contamination and potential risk to patients, versus practicality and

wastage including environmental impact. In order to gauge the length of time in use, the bottle must be dated with a marker that is resistant to being wiped off when cleaning. Gel should be stored according to manufacturer's guidelines in areas free of excessive moisture and sources of potential contamination. These recommendations are consistent with guidance published elsewhere (26, 27).

The outside of the bottle and other ultrasound equipment can act as a potential source of contamination and spread microbes between patients (28, 29). The CWG agreed that cleaning the outside of bottles with a disinfectant wipe between uses would be a reasonable way to mitigate this.

The core working group recommend that if the tip of a pre-filled bottle touches another surface/person, the bottle tip should be cleaned with a disinfectant wipe immediately. This recommendation is consistent with guidance published elsewhere (26).

There is a risk of infection if contaminated gel is left on a patient's skin and minimal evidence to inform what constitutes adequate removal. The CWG recommends removing gel and advising patients to wash the area when feasible. The CWG considered this method to be practical and appropriate appreciating constraints within the clinical environment.

### Rationale for discouraging warming of gel

There is an increased risk of contamination from gel warmers and routine use should not be encouraged (25, 29, 30). The CWG recommends that gel warming should only be done in situations where the clinical benefits of using warmed gel outweigh the discomfort of applying gel stored at room temperature.

Water baths have been identified as a means of contamination for medical gel and other medical supplies/instruments, supporting the recommendation that dry heat should be used if gel is warmed (25, 31, 32).

The CWG recommendations for keeping gel bottles upright and cleaning the equipment are based on consensus and consistent with guidance published elsewhere (16, 25).

## Appendix 3: Types of gel containers mentioned in this guidance

*Single-use tube or sachet*

Used for sterile or non-sterile gel. Bottle or sachet is discarded after single examination is completed, not reusable.

*Pre-filled disposable bottle*

Contains ultrasound gel for current use on more than one patient – bottle is not refillable and is discarded when empty after one month or on expiry date, whichever comes first.

*Bulk dispensing container*

Used to store ultrasound gel to be dispensed into smaller containers which will be used for patient use (often 5L). Note: use of these containers is not recommended.

*Reusable bottle*

Contains ultrasound gel for current use on more than one patient; supplied empty and filled from a dispensing container (bottle is refillable). Note: use of these bottles is not recommended.

| CONTACT AND REVIEW DETAILS | |
|---|---|
| **Guideline Author : Catharine Berry,Consultant Radiographer**<br>**Reviewed by: Claudius Masakure, Clinical Lead Sonographer** | **Executive Lead**<br>**Medical Director** |
| **Details of Changes made during review:**<br>Sections 8 and 9: Education and Training, removed none and added requirements; Monitoring Compliance, elements and tools to monitor changed. | |