

Reducing formalin exposure risks in the management of surgical specimens

To combat concerns about the dangers posed by the use and transport of formalin solutions, histopathology staff in Sheffield explored an innovative biospecimen transfer system, as Karen Lester explains.

Concerns about the health effects of formalin exposure, together with the reclassification of formaldehyde as a Class 1 carcinogen (IARC) has prompted hospital authorities, surgical staff and biomedical laboratories to assess alternative solutions aimed at reducing exposure to the substance. A critical exposure point for hospital personnel is in the transfer of tissue from operating theatres to the pathology laboratory. This project aims to assess alternative systems that minimise the risk of formalin exposure in theatres.

Sheffield: the current situation

The histopathology department in Sheffield is split over two sites, the Royal Hallamshire Hospital (RHH) and Northern General Hospital (NGH). Previously, the two sites had separate, fully functioning laboratories, but in 2013 the sites merged into one large laboratory at RHH, with a small 'satellite' laboratory at NGH for specimen receipt and urgent protocols. Both sites have theatre units which send surgical specimens for histological analysis.

At RHH the theatres are situated in the same building as histopathology. The specimens taken in theatres are collected into specimen buckets, refrigerated until the next scheduled delivery and then brought to histopathology where they are fixed in

formalin on receipt. Fixation is performed within the histopathology department where staff are trained to handle formalin safely over downdraft benches and have access to spillage kits and training in case of an accidental spill.

'There has been no detrimental effects on the quality of the histological or IHC slides produced or on subsequent reporting after using the TissueSAFE and SealSAFE systems'



Bagged specimens with formalin for fixation.

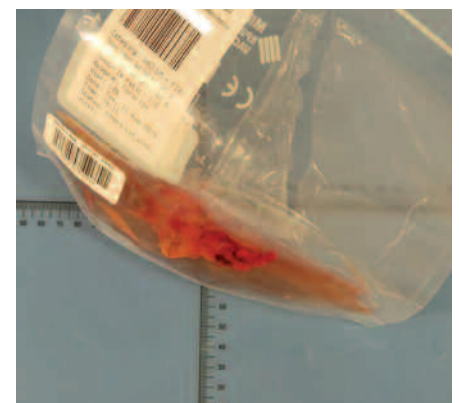
At NGH the campus is large and the histopathology department is situated across the site from the theatres. On this site, large specimen pots containing formalin are supplied to the theatre units where they are stored until required. When a specimen has been taken, the pot is transported to the satellite laboratory.

Once in the laboratory at NGH the specimens are fixed overnight, formalin is drained off and the specimens bagged up and transported to RHH for dissection and histological analysis, to bring it into line with the practice at the main site. Removing formalin from theatres at NGH is the main aim of this project.

Available options

The following two options were considered initially:

- providing theatres with empty specimen pots (as is done at the RHH site) and the introduction of large, purpose-built refrigerators in the theatres for storage of specimens prior to delivery to the histopathology department for fixation.
- direct transportation of unfixed specimens to the RHH histopathology



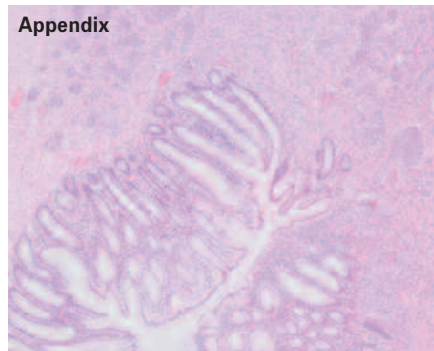
'The bags are heat-sealed under pressure to reduce the volume and thus the space taken by the specimens'

department from NGH theatres, bypassing the NGH satellite laboratory reception, using a designated transport route or taxi service.

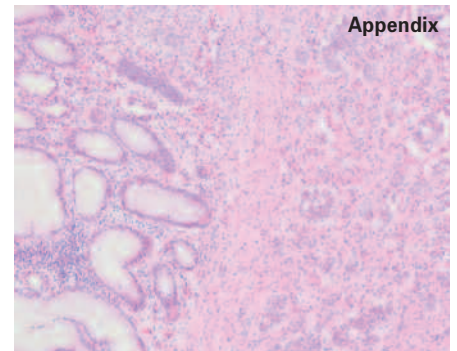
Both options would require a way of keeping the specimens fresh and the volume of specimens created by theatres daily would require large refrigerators if specimens were still placed in plastic buckets; they also take up space and are bulky for transportation, while some specimen bags are not robust enough for transportation.

Alternative solution

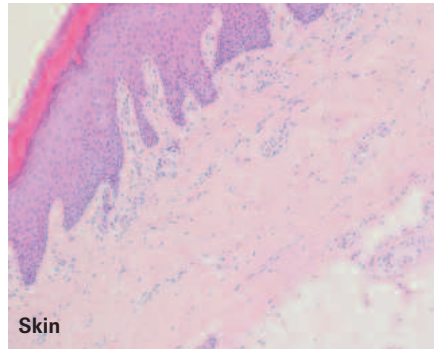
Tissue samples from theatres are currently transferred to the laboratory in pots of formalin. The TissueSAFE and SealSAFE high-vacuum biospecimen transfer system (Menarini Diagnostics) were trialled as an alternative solution to the above. The trial started in November 2014 with one TissueSAFE placed in theatres at NGH and one SealSAFE placed in the dissection room in histopathology at RHH. Following some pilot runs using non-diagnostic material, the trial began using gall bladder and appendix specimens, as these were deemed to be low-risk for a



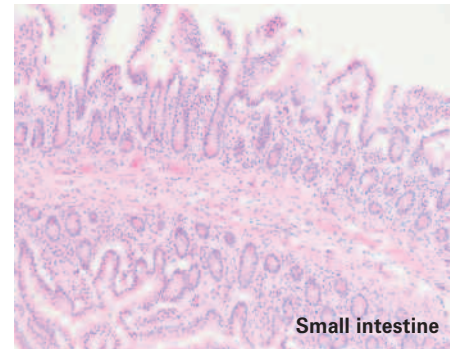
Appendix



Appendix



Skin



Small intestine

Examples of haematoxylin and eosin (H&E)-stained sections from vacuum-sealed tissues.

new system, and at least two or three of each were received each day from NGH theatres.

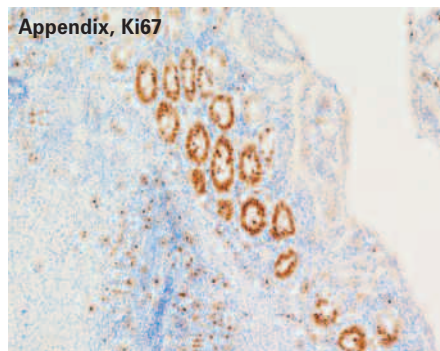
Methodology

The validation included assessment of a selection of non-diagnostic tissues from theatres. All tissues were vacuum-sealed, formalin-free using the TissueSAFE, then stored and transported at 4°C to the laboratory and then immersed in formalin using SealSAFE. Haematoxylin and eosin (H&E) slides from these tissues were

compared to routinely formalin-fixed tissue sections.

The system uses robust specimen bags that will withstand transportation. The bags were provided to theatres at NGH. The specimens were placed directly into one of these bags, the patient ID label applied directly to the bag, and the request form sealed in a designated pouch on the front of the bag. The specimens were then sealed into the bags by theatre staff using the TissueSAFE machine, which removes air from the bag using negative pressure and then heat-seals the top of the bag. The bags are heat-sealed under pressure to reduce the volume and thus the space taken by the specimens and so can be stored in smaller refrigerators if necessary, and transported easily.

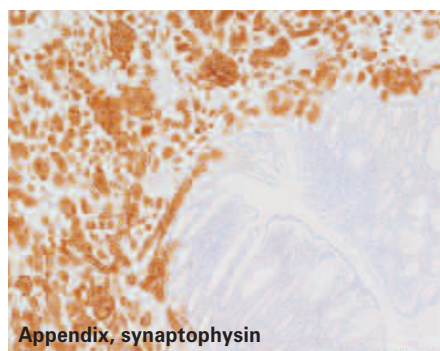
Specimens were transported at 4°C, together with a temperature log card which monitors the temperature throughout the transport process; this



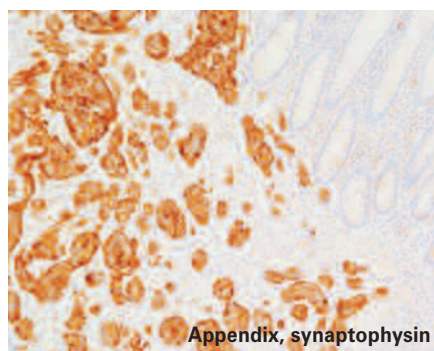
Appendix, Ki67



Appendix, Ki67



Appendix, synaptophysin



Appendix, synaptophysin

Immunohistochemistry on sections from vacuum-sealed tissues.

'Reclassification of formaldehyde as a Class 1 carcinogen has prompted hospitals, surgical staff and laboratories to assess alternative solutions aimed at reducing exposure to the substance'



SealSAFE and touchscreen controls.



system also tracks the batch of samples from theatres to laboratory. On receipt at RHH histopathology, the sealed bag is cut along the line at the top below the heat seal, and then placed in the SealSAFE machine, which adds formalin to the bag in a 1:2 weight:volume ratio, within a contained system, preventing the user being exposed to formalin. It then reseals the bag under negative pressure and the bag can then be left standing upright to allow for fixation of the specimen.

Results

Although only used with a limited number of tissue types, the specimens received

so far have shown good fixation and no evidence of physical damage sustained during transportation. The results of histological and immunohistochemical (IHC) staining has been comparable to those specimens previously and simultaneously received in formalin pots, and there has been no detrimental effects on the quality of the histological or IHC slides produced or on subsequent reporting after using the TissueSAFE and SealSAFE systems.

Conclusions

This study demonstrated that the Menarini TissueSAFE and SealSAFE

vacuum transfer system gives equivalent results to current procedures. There was no evidence of any effect on the subsequent processing of the tissues and no change was observed in the H&E-stained slides in the majority of tissues. The next phase of the trial will involve larger benign colorectal specimens, and then, once deemed suitable and not detrimental to the tissue, the malignant resections will be transported in this way.

PIP

The author wishes to thank staff in theatres at the Northern General Hospital, and the laboratory staff involved with this ongoing trial.

Further reading

- Bussolati G. Pre-analytical conditions in tissues. Report from the OECl Oncology Days 2014. *Ecancermedalscience* 2014; **8**: 496.
- Zarbo RJ. Histologic validation of vacuum sealed formalin-free tissue preservation and transport system. *Recent Results Cancer Res* 2015; **199**: 15–26.

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