Reducing Formalin exposure risks in Surgical Specimen Management

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Introduction
Concerns regarding the health effects of formalin exposure, together with the reclassification of formaldehyde to 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 surgical theatres to the pathology lab. This project aims to assess the alternative systems for minimising the risk of formalin exposure in theatres.

Current Situation:
The Histology Department in Sheffield is split over two sites: Royal Hallamshire hospital and the Northern General hospital. Previously the two sites had separate fully functioning laboratories, but in 2013 the sites merged to one large site at Arn and a small ‘satellite’ laboratory at NGH for specimen receipt and argent processing. Both sites have theatre units which send surgical specimens for histological analysis. At both theatres, specimens are collected into specimen bags, refrigerated until the next scheduled delivery and then brought to Histology where they are fixed in formalin on receipt. The fixation is done within the Histology department where staff are trained to handle formalin safely over down-draft benches and have spillage kits and training in case of an accidental spill. At NGH the campus is large and the Histology Department is across the site from the theatres. On this site, large-specimen pots are filled with formalin in-Histology, and then transported to theatres by the theatre porters on trolleys, across car parks and through the hospital buildings. The theatre unit encompasses a large number of theatres and bed bays for patients pre- and post-operative. There are no facilities for down-draft in theatres; the pots are stored on shelves in a small store room which is accessible to anyone in the unit, with no lockable cabinets to store them in or ventilation in the room. There are no spill kits or training in how to deal with spills, and when specimens are taken from patients, the formalin pots are taken into the theatre and opened there. Once in the pots, specimens are then loaded onto the trolley and brought back to histology across the same route as before.

Once in histology at NGH the specimens are fixed overnight then the formalin is drained off and the specimen bagged up and transported to Aim for dissection and histological analysis.

Aims:
All of the above issues at the NGH site obviously require a large health and safety risk to both staff and patients and need to be addressed. Removing formalin from theatres at NGH is the main aim of this project.

Options available to us:
1. Providing theatres with empty specimen pots (as is done at the Hallamshire site) and the introduction of larger, purpose-bought fixatives in the theatres for storage of specimens prior to delivery to the Histology department for fixation.
2. Direct transportation of unfixed specimens to the tissue histology department from NGH theatres, bypassing the NGH satellite laboratory reception, using a designated transport route or task service.

Both these options would require a way of keeping the specimens fresh and the volume of specimens created by theatres daily will need to be addressed.

3. Alternative solution:
Tissue samples from Theatres are currently transferred to the Laboratory in pots of formalin. The TissueSAFE and SeaSAFE high vacuum specimen transport system (Memerini Diagnostics) was trialed as a solution to the issue. The trial started in November 2014 with one TissueSAFE placed in theatres at NGH and one SeaSAFE placed in the dissection room in histology-4th. The trial began using goldbladder and appendices specimens, as these were deemed to be low risk for a new system and we received at least 2 or 3 of each per day from NGH theatres.

Method
The validation included assessment of a selection of non-diagnostic tissues from theatres. All tissues were sutured sealed, formalin free using the TissueSAFE, stored and transported at 4°C in the laboratory and then immersed into formalin using SeaSAFE. All specimens from these tissues were compared to routine formalin fixed tissues sections.

The system uses robust specimen bags, which will withstand any transportation. The bags are 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 forms sealed in a designated pouch on the front of the bag.

Specimens are then sealed into the bags by theatre staff using the TissueSAFE machine, which removes all the 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 fixative bottles or, and transported easily. Specimens are transported at 4°C, together with a cold temperature bag (which maintains the temperature through out the transport process); the system also tracks the batch of samples from theatre to laboratory.

On receipt at histology, the sealed bag is cut along the line at the bag below the heat seal, and then placed in the SeaSAFE machine which adds formalin to the sealed specimen bag and then the bag is unsealed and the tissue is ready for 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
Though only used for a limited amount of tissue types, the number of specimens we have so far received have shown good fixation and have shown no physical damage from transportation this way. The results of histological and immunohistochemistry 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 reporting of the specimens from using the TissueSAFE and SeaSAFE system.

Discussion/Conclusion
We demonstrated that the TissueSAFE and SeaSAFE vacuum transfer system gives equivalent results to current procedures. There is no evidence of any effect on the subsequent processing of the tissues and no change is observed in the IHC slides in the majority of tissues.

All of the trials will be replaced by alternative specimen collection and then once deemed suitable and not detrimental to the tissue, the resultant rejections will be transported this way.

References

Karen Assenati - Department of Biomedical Sciences and Human Oncology, University of Turin, Italy

Malignant colorectal resections have been considered to be tumour downgraded following chemoradiotherapy and then once deemed suitable and not detrimental to the tissue, the resultant rejections will be transported this way.

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Seal Safe with Data Logger Reader & Touchscreen controls

Immunohistochemistry and Slides from Vacuum sealed tissues

TissueSAFE Tissue Transfer System

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