Advances in surgical specimen management across North Wales

In order to optimise and standardise the handling of surgical specimens, Betsi Cadwaladr University Health Board has adopted an innovative vacuum-packing solution across its three main hospital sites in North Wales, reducing formalin use, improving quality and cutting costs.

Fig 1. The SealSAFE is a system that allows automated fixative addition to a surgical specimen plus vacuum sealing in a dedicated bag.

In 2016, following laboratory centralisation across North Wales, Betsi Cadwaladr University Health Board (BCUHB) installed five Menarini Diagnostics SealSAFE systems across its three main hospital sites. As the largest health organisation in Wales, BCUHB has a budget of £1.3 billion and a workforce of over 17,000 staff. The Health Board serves a population of around 694,000 people across six principal areas (Anglesey, Conwy, Denbighshire, Flintshire, Gwynedd and Wrexham) as well as some parts of Mid Wales, Cheshire and Shropshire. The Board is responsible for the operation of three district general hospitals, at Ysbyty Gwynedd (Gwynedd Hospital) in Bangor, Ysbyty Glan Clwyd (Glan Clwyd Hospital) in Bodelwyddan and Ysbyty Wrecsam Maelor (Wrexham Maelor Hospital) in Wrexham.

The main diagnostic laboratory for the histopathology service for BCUHB is located at Glan Clwyd Hospital. Satellite laboratories at Gwynedd Hospital and Wrexham Maelor Hospital serve primarily as specimen collection points as well as offering specialist services such as frozen sections. The histopathology department typically processes 45,000 requests per annum and receives a range of different samples, from small biopsies to organ resections, of all tissue types from theatre areas across the Health Board.

Situation prior to adoption of SealSAFE

Prior to laboratory centralisation, the histopathology service for BCUHB was run from three dedicated laboratories based at the Health Board's three main hospital sites. Typically, endoscopic, colposcopic, colonoscopic and core biopsies were received into the laboratories in 60-mL containers, with larger surgical specimens in buckets. As a rule, most specimens received were in 10% buffered neutral formalin (BNF) with the exception of those for frozen section, immunofluorescence and one-step nucleic acid amplification (OSNA).

On receipt in the laboratory, specimens would be checked to ensure they were in an appropriately sized container and formalin added if levels were too low. Larger specimens were sliced or opened to allow formalin to penetrate the tissue adequately. Specimens would remain in formalin until they were examined by a pathologist. Any remaining wet tissue not

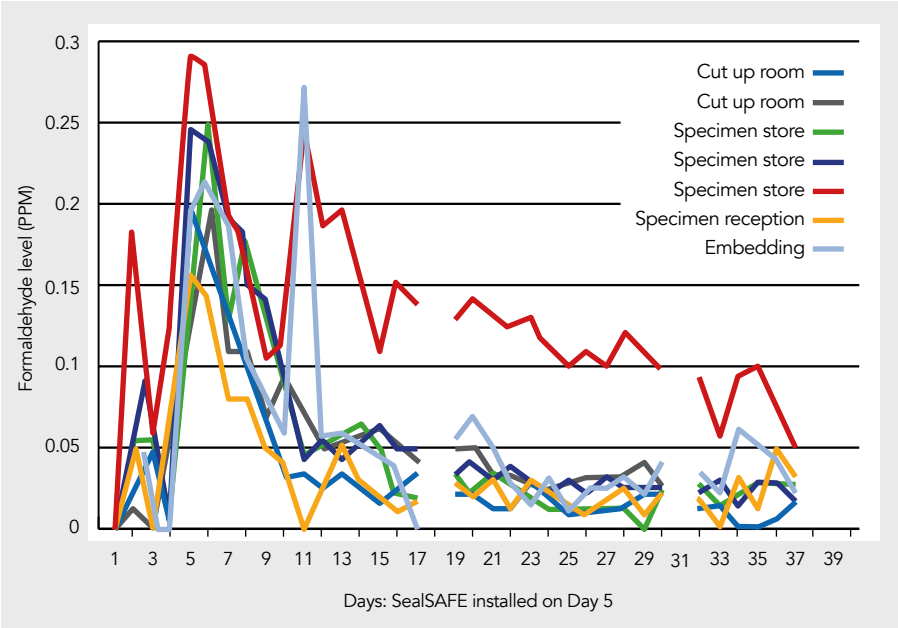

Fig 2. Reduced BNF exposure (PPM) in different areas of the cellular pathology laboratory at Glan Clwyd Hospital post installation of SealSAFE systems on Day 5.

continuing down the diagnostic pathway would then be returned to their original pot/bucket for storage.

Following dissection, all tissue was discarded six weeks post-authorisation of reporting. Laboratory staff would use a generated list to select the relevant specimens from the store and discard into heavy duty clinical waste bags for clinical waste disposal. Pots and buckets were only used once and were not washed and recycled.

Drivers for implementing change

During the laboratory centralisation project and to coincide with future-proofing the service, the following key issues were identified by the Health Board and required to be addressed during transformation of the surgical specimen management workflow:

- Control over fixation times, particularly when the laboratory considered that the specimens were going to be generated from outlying sites. They may not have a gauge on when the fixation process had begun or any guarantee that the correct ratio of formalin was added to the specimen, which could compromise specimen quality.
- Control over fixation times to improve the quality of results, particularly for downstream molecular testing of breast specimens for ERP/HER2 testing
- Formaldehyde reclassification in 2016, where it was recognised as being carcinogenic to humans (Class 1), means that the Health Board had a responsibility to ensure that the risk of formalin exposure to employees and staff was minimised wherever possible and adequate health and safety measures were taken.
- Improving the transport process of specimens with particular emphasis on improving handling and minimising formalin exposure while having greater traceability overall of the process
- Reducing the risk of formalin spills during the collection and transport process, thus protecting employees and patients.

SealSAFE – an innovative solution

Based on all of the above, it was agreed that the best option to address the key issues identified would be to install five Menarini Diagnostics SealSAFE systems into the Health Board's theatre areas for specimen collection and in the laboratory (Table 1). The SealSAFE is a system that allows automated fixative addition to a surgical specimen plus vacuum sealing in a dedicated bag (Fig 1).

Hospital	Department	Instrument	Quantity
Wrexham Maelor Hospital	Main theatres	SealSAFE	2
Gwynedd Hospital	Main theatres	SealSAFE	1
Glan Clwyd Hospital	Main theatres	SealSAFE	1
Glan Clwyd Hospital	Cellular pathology laboratory	SealSAFE	1

Table 1. Number of SealSAFE instruments installed across Betsi Cadwaladr University Health Board.

Owing to the transport times between sites (60+ minutes) it was agreed that specimens should be receipted into the laboratory in formalin, as investment in dedicated refrigerated transport would be costly. It was acknowledged during the decision-making process that if there was ever a requirement to receipt fresh material that specimens could be vacuum-sealed onboard the SealSAFE without the controlled addition of formalin.

SealSAFE instruments were installed in sluice rooms in the named theatre location at each site. Final locations were decided based on those sluice rooms that were adjoining theatres generating the highest number of surgical specimens.

Using the SealSAFE all surgical specimens that require collection into containers larger than 60-mL prefilled pots are sealed (with formalin) in a dedicated vacuum bag. The SealSAFE is a closed system that automatically dispenses a fixed volume of formalin into the bag dependent upon weight of specimen, and then vacuum seals. Typically, formalin is added in a 1:2 or 1:3 ratio. All vacuum bags are labelled with the patient's addressograph and a label generated by the SealSAFE instrument documenting the date and time of formalin addition, sealing and which member of theatre staff performed the action. The cellular pathology request form is placed in a sealable document pouch on the front of the bag and specimens are transported to the laboratory in an appropriately marked transport box.

On receipt in the laboratory, bagged specimens are placed into a dedicated area to fix until the next working day. At the time of examination/dissection, gloves are worn and the wet specimen is removed from the bag. Appropriate blocks are selected and the remaining specimen is returned to the same bag used earlier in the process. If the remaining specimen does not require further fixation post-dissection, the used formalin is discarded and the bag is resealed on the SealSAFE instrument and stored in the specimen archiving room (stored by specimen type).

If further fixation is required, then formalin used previously for fixation (as left remaining in the bag) is used again. The bag is resealed on the SealSAFE instrument and then stored in a dedicated area for 1–2 days. After this time the bag is cut along the appropriate marked line and formalin is poured away, the bag is re-sealed and sent to storage. This practice has been adopted by the Health

Board to minimise the amount of formalin used in the laboratory and to recycle the solution wherever possible.

Key benefits of SealSAFE to the theatre and transport departments:
- reduced exposure to formalin
- reduced manual handling of heavy containers.

Key benefits of SealSAFE to the cellular pathology laboratory:
- full audit trail of tissue storage and transport conditions
- full control over the fixation process
- improved fixation for fibromuscular tissues such as uterus and prostate
- standardised fixation according to weight of specimen
- reduction of manual handling of heavy containers
- improved working conditions and capacity in cut-up areas
- reduced exposure to toxic fumes (Fig 2)
- cost saving on use of excess formalin
- cost savings on single-use buckets
- approximately 60% reduction in disposal costs
- improved storage condition and increased capacity
- better preservation of specimens for potential molecular testing.

Key benefits of SealSAFE to Betsi Cadwaladr University Health Board:
- compliance with H&S and UKAS guidelines
- reduction of formalin-related incidents and associated costs/downtime
- reduction of environmental concerns
- reduction in formalin use and lower disposal costs
- reduction in transport costs and carbon footprint due to reduction in weight of formalin used for collection.

Key benefits of SealSAFE to the patient:
- guaranteed specimen collection facilities at both sites to ensure optimal tissue viability for histological processing and diagnosis.

Impact of the SealSAFE system on the surgical specimen workflow

Prior to installation, meetings were held between theatres, the laboratory and Menarini Diagnostics to address concerns about the system and ensure everyone involved was fully onboard and aware of the change in process in line with local policies and procedures. Implementation was phased between the sites, with Glan Clwyd Hospital going live first. After the first installation, a frequently asked questions (FAQs) resource for theatres was generated by the laboratory to address common questions asked by staff during the training process.

By installing the systems at the Health Board, formalin usage and waste disposal costs have been dramatically reduced. The SealSAFE system has allowed for the formalin batch used onboard the system to be tracked, allowing the laboratory to have full transparency over which batch of formalin has been used with which individual specimen, should any issues arise.

Turnaround times have been unaffected by the introduction of SealSAFE. Data collected for smaller laparoscopic resections suggest that fixation is more rapid and complete under vacuum as opposed to in a bucket. Since installation there have been no issues raised with respect to diagnostic reporting, degradation of tissue and fixation quality. During the initial verification phase, pathologists were asked to review cases and comment on the fixation compared to the traditional bucket method (Fig 3).

As vacuum bags are labelled with identifiers from the SealSAFE, specimen disposal is improved as staff do not have to separate the specimen from the bucket to dispose of separately. Time taken to dispose of vacuum bags compared to buckets is improved, and there have been no reported leakages. Specimens are also able to be stored in bays by specimen type due to the increased space capacity of storing a bag compared to a bucket. By taking full control of the fixation process, staff in the laboratory are able to manage work and pathologist time more effectively, as they are better placed to denote when a specimen will be ready for examination/dissection.

The Health and Safety Executive (HSE) for Wales is also aware of the installation of the SealSAFE systems and is happy with the associated benefits and reduction to staff and patient with regards to formalin exposure.

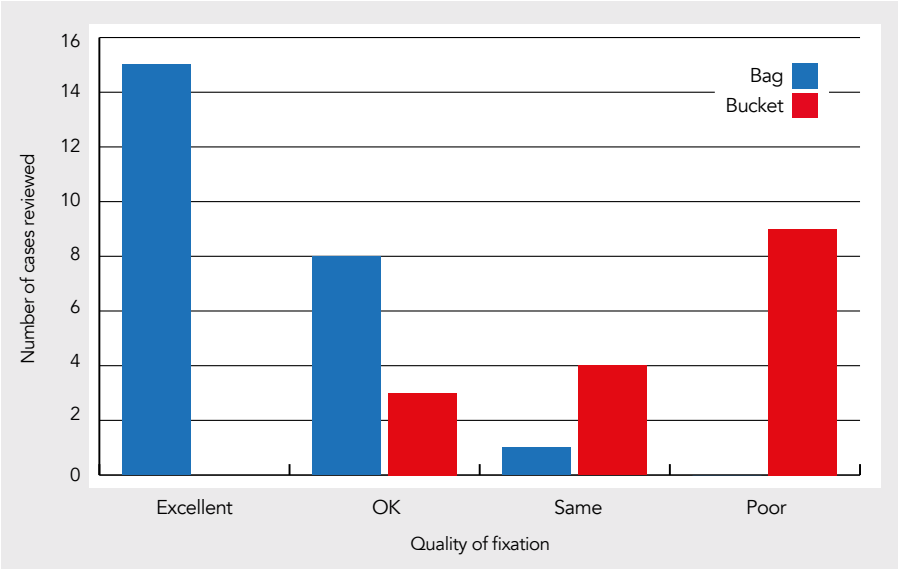

Fig 3. During the initial verification phase of the SealSAFE systems, pathologists were asked to review cases and comment on the fixation compared to the traditional bucket method.

Conclusions and lessons learned

The installation of SealSAFE by Menarini Diagnostics in theatre and laboratory areas at the Betsi Cadwaladr University Health Board has provided process and safety benefits as described in this report, effectively limiting the distribution and management of formalin. A thorough implementation plan was key to the project's success, considering the many 'human factors' required to enable a smooth transition of processes.

Robert Bonwick-Salisbury (Senior Specialist Biomedical Scientist in Dissection/Trainee Dissection Practitioner) has been key in the implementation and ongoing cascading of training for the systems and acknowledges that one of the biggest drawbacks of the system is user error. Robust training material, meetings and standard operation procedures (SOPs) are required to ensure where possible that this is avoided. This also has to be coupled with strong communication links between the laboratory and theatres so that any issues can be addressed and resolved in a timely manner.

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