

Formalin-free surgical specimen management: transforming the workflow

An innovative vacuum packing solution has been adopted in order to reduce formalin use and exposure throughout the Cwm Taf Morgannwg University Health Board in Wales, as the following overview of progress illustrates.



Fig 1. Surgical specimens sealed in a dedicated vacuum bag are placed in a refrigerator at 4°C until transport to the laboratory takes place.

Cwm Taf Morgannwg UHB, South Wales, provides healthcare services for the population of Merthyr Tydfil County Borough, Rhondda Cynon Taf and Bridgend County Borough. The United Kingdom Accreditation Service (UKAS)-accredited cellular pathology department is split over two sites, one large laboratory at the Royal Glamorgan Hospital (RGH), and a smaller 'satellite' laboratory for specimen receipt at Prince Charles Hospital (PCH). Both sites have theatres that send surgical specimens for histological analysis. Concerns about the health effects of formalin (formaldehyde) exposure, reclassified as a Class 1 carcinogen to humans (IARC) prompted the Health Board to assess ways to reduce staff exposure. Critical exposure points for hospital personnel were identified as the theatre area and during transfer of specimens to the pathology laboratory.

Situation before adoption of vacuum packing solutions

Prior to adoption of vacuum packing, 10% neutral buffered formalin (NBF) was made up in 50-L batches from concentrate as and when required in the cellular pathology specimen reception areas of RGH and PCH. Theatre staff would replenish NBF by bringing empty carboys to the laboratory area and refilling. The filled carboys would be carried back to the theatre area and kept in sluice rooms near to the operating

theatres where formalin was manually decanted into specimen buckets.

The amount of NBF placed onto specimens by theatre staff varied widely according to the bucket size and the person performing the decanting. As PCH is situated approximately 20 miles from the RGH main processing laboratory, NBF was decanted to a minimum level to permit safe transportation (by hospital van/porters) and then topped up once received in the laboratory at RGH. Typically, the recommended volume-to-weight ratio (10:1) was not adhered to, with samples being received into the RGH laboratory with too little NBF for the specimen size. Often specimens were also placed into containers that were too small, and they had to be transferred to a larger container.

Upon receipt in the RGH laboratory, specimens would be checked to ensure they were in an appropriately sized container and NBF added if levels were too low. Larger specimens were sliced or opened to allow NBF to penetrate the tissue adequately. Specimens would remain in formalin until they were examined by a biomedical scientist/pathologist. Any remaining wet tissue not continuing down the diagnostic pathway would then be transferred to a 'BiTran' bag for storage. The bag would be labelled manually with the laboratory accession number and minimum identifiers before being stored numerically in a designated store area by laboratory staff. Tissues were not stored in their originating pots/bucket due to space constraints and the requirement to retrieve archived tissue rapidly on a regular basis.

Dirty buckets were either washed and recycled or discarded and replaced depending on condition. It was not uncommon for staff to be offered

SURGICAL PATHOLOGY

overtime to perform bucket washing, as often there was no time to perform this duty during the normal working day. At RGH clean buckets were stored in a cupboard for collection by theatre staff when required. Cleaned buckets for PCH were transported back to theatres via van for storage and use. There were repeated issues with buckets and lids not matching, which led to formalin spillages and leaks. At times, PCH experienced supply issues as the stock levels were not monitored effectively.

All wet tissue was disposed of six weeks post-authorisation of reporting. Laboratory staff would use a generated list to select the relevant specimens from the store and transfer them to heavy-duty clinical waste bags for clinical waste disposal.

Drivers for implementing change

The following were the key issues that Cwm Taf Morgannwg University Health Board identified and required to be addressed during the transformation of the surgical specimen management workflow:

- staff formalin exposure in theatres, during transport and in the laboratory
- staff manual handling risks – carrying heavy containers, formalin carboys and twisting caps on bulk formalin containers
- staff time in preparation, collection and tracking of formalin
- non-standardised formalin addition to specimens
- risk of formalin spillage during preparation, decanting, collection and transportation
- delays to fixation of specimens when being transported
- no audit trail of the fixation process before the specimen enters the laboratory
- use of formalin inhibiting markers for downstream molecular genetic testing
- use of buckets – risk of inadequate supply to PCH theatres, risk of leaking, no room to archive dirty or clean pots, time-consuming to wash/dry/stack, lids do not fit, cost of replacing buckets
- use of 'BiTran' bags – very good storage solution but extremely time-consuming to transfer/label specimens and carried a risk of transcription error.



Fig 2. Specimens are transported in a cool box and are tracked using a temperature monitoring system supplied with the TissueSAFE.

TissueSAFE/SealSAFE: an innovative solution

To address all the key issues identified, the TissueSAFE and SealSAFE by Menarini Diagnostics were installed in the operating theatres and cellular pathology laboratories (Table 1).

TissueSAFE 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 that generated the highest number of surgical specimens.

Using the TissueSAFE, all surgical specimens which require collection into containers larger than 60-mL pre-filled pots are sealed (without formalin) in a dedicated vacuum bag and placed into a refrigerator at 4°C until transport takes place (Fig 1). Fresh vacuum packed specimens (without formalin) can be stored at 4°C for up to 24–72 hours (depending on specimen type). All vacuum bags are labelled with the patient's addressograph and a label generated by the TissueSAFE instrument documenting the date and time of sealing, and which member of theatre staff performed the action.

The cellular pathology request form is placed in the sealable document pouch on the front of the bag. Specimens are transported in a cool box (Fig 2) and are tracked using a temperature monitoring system supplied with the TissueSAFE. Upon receipt in the laboratory, temperature monitoring data are retrieved and specimens are placed into the SealSAFE instrument. The SealSAFE is a closed system that automatically

dispenses a fixed volume of formalin into the bag depending on the weight of the specimen, and reseals (Fig 3).

Specimens requiring opening/cleaning or slicing are held in a refrigerator until an appropriate member of staff is available to deal with them. Typically, a 2:1 volume-to-weight ratio is employed by the laboratory. Bagged specimens (with formalin) are then placed into a dedicated area to fix until the next working day. At the time of examination/dissection long-cuffed gloves are worn and the wet specimen is removed from the bag. Appropriate blocks are prepared 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 (Fig 4).

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 one to two days. Subsequently, the bag is opened along the appropriate marked line and the formalin is poured away, the bag is resealed and then 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.

The cellular pathology laboratory at RGH receives approximately 20,000 specimens per annum for processing, of which 7000 surgical specimens are received in vacuum bags. The remaining specimens are either too large to fit in a dedicated vacuum bag or are smaller biopsies and are received in 60-mL pre-filled containers. It is estimated that 5% of surgical cases are too large to fit into a dedicated vacuum bag and, in this scenario, a large bucket is used and the specimen is stored in the refrigerator with the TissueSAFE samples and transported fresh to the laboratory.

Key benefits of TissueSAFE to the theatre and transport departments:

- reduced exposure to formalin
- reduced manual handling of heavy containers.

Table 1. Number of TissueSAFE and SealSAFE instruments installed at the Cwm Taf Morgannwg University

Hospital	Department	Instrument	Quantity
Royal Glamorgan Hospital	Main theatres	TissueSAFE	2
Royal Glamorgan Hospital	Cellular pathology laboratory	SealSAFE	1
Prince Charles Hospital	Main theatres	TissueSAFE	1

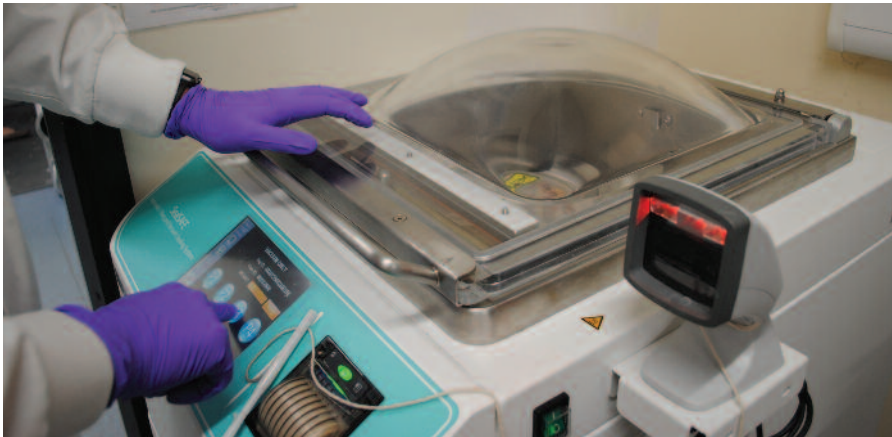


Fig 3. The SealSAFE automatically dispenses a fixed volume of formalin into the bag depending on the weight of the specimen, and reseals.

Key benefits of TissueSAFE and SealSAFE to Cwm Taf Morgannwg University Health Board:

- compliance with health and safety (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.

Key benefits of TissueSAFE and SealSAFE to the patient:

- guaranteed specimen collection facilities at both sites to ensure optimal tissue viability for histological processing and diagnosis.

Key benefits of TissueSAFE and SealSAFE to the cellular pathology laboratory:

- full audit trail of tissue storage and transport conditions
- full control over the fixation process
- optimal preservation of tissues: delivered to the laboratory 'fresh' with original colours preserved, elimination of drying, reduced autolysis (particularly for larger specimens that require opening) and rapid cooling of tissue due to vacuum eliminating insulating air
- 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
- cost-saving on use of excess formalin
- reduced staff time on cleaning of buckets/pots
- reduced staff time on transfer of specimens to 'BiTran' bags
- reduced risk of transcription errors for storage
- better preservation of specimens for potential molecular testing and tissue banking.

Impact on the surgical specimen workflow

By installing the system at the Health Board, formalin usage has been reduced dramatically and has made it financially viable for the cellular pathology laboratory to purchase commercially available formalin. This has allowed time to be saved on formalin preparation and removed any associated issues with H&S risks and batch-to-batch variation. The TissueSAFE and SealSAFE system has permitted the formalin batch used onboard the system to be tracked, allowing the laboratory to have full

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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 TissueSAFE and SealSAFE. In over two years since installation there has been no issues raised with respect to diagnostic reporting, degradation of tissue and fixation quality. Time savings have been realised with respect to formalin and bucket collection by theatres, as well as for the laboratory for bucket washing. As vacuum bags are labelled with identifiers from the TissueSAFE and SealSAFE, specimen disposal is improved as staff are not struggling to identify cases by deciphering differing handwriting, as well as transcription error risks being eliminated. Time taken to dispose of vacuum bags compared to 'BiTran' bags remains unchanged; however, there have been no reported leakages since the new system was employed, and space has been reduced as the bags are vacuum sealed.

The laboratory acknowledges that there is an increased amount of time required for formalin addition on the SealSAFE instrument as the specimen enters the laboratory; however, this has had no overall impact on the time taken for the specimen to be processed through the laboratory as there have been time saving gains further downstream.

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 indicate when a specimen will be ready for examination/dissection.

Another recognised cost benefit to the Health Board is that transport runs from the PCH site have been able to be reduced from three to two collections per day. This is due to specimens being preserved more optimally when vacuum packed compared to only being covered with the minimum volume of formalin before entering the laboratory at RGH.

Installation, training and verification

The vast majority of specimen types are collected by theatres at RGH and PCH, including mastectomies, bowel resections, ovarian cysts, gall bladders and prostate chippings. The key to a successful installation and training lies in clear and open communication with all interested parties, says Gerrard Fletcher (Cellular Pathology Lead Medical Laboratory Assistant). It is important to ensure dates are arranged well in advance with clear start/finish times. Prior to installation, meetings were held between theatres, the laboratory and Menarini Diagnostics to address concerns about the system



Fig 4. Bags are resealed on the SealSAFE instrument and stored in the specimen archiving room.

and to ensure everyone involved was fully onboard and aware of the change in process in line with local policies and procedures.

Go live took place one week from training at each theatre site to ensure the information given stayed fresh in everyone's mind. Gareth Llewellyn (Main Theatres Coordinator and Team Leader at RGH) commented that the system is easy to use and safer as theatre staff are no longer handling bulk formalin. Throughout the installation process and beyond there has been good support from Menarini Diagnostics and the cellular pathology team.


Verification of samples took place thereafter and data from the first 100 samples from each site were captured for auditing purposes. Based on the workload of the laboratory at RGH, data were collected for the specimens processed during the first week of go live for each site. A verification log was created which captured details such as:

- theatre site from which specimen collected
- case ID
- laboratory accession number
- vacuum bag ID
- specimen type
- date/time of vacuum sealing in theatres
- user performing operation on TissueSAFE or SealSAFE
- collection time from theatres
- temperature monitoring data
- date/time of receipt of specimen in laboratory
- date/time of formalin addition
- time elapsed before formalin addition from receipt of specimen in laboratory

- volume of formalin added
- time sample examined/dissected
- time elapsed between formalin addition and examination
- biomedical scientist/pathologist scoring for cutting
- pathologist scoring for reporting – H&E, IHC, FISH (where applicable)
- pathologist overall comments.

Conclusions and lessons learned

The recommended model for installing TissueSAFE in the theatre and SealSAFE in the laboratory has brought major process and safety benefits as described above, effectively limiting the distribution and management of formalin within the laboratory. A thorough implementation plan was key to the project's success, considering the many 'human factors' required to enable a smooth transition of processes.

According to Rhianon Webb (Cellular Pathology Healthcare Science Service Manager). The role of the change management team was vital, supported by Menarini to handle any questions from theatre staff regarding the new pathology process. Theatre and laboratory staff feel that the change in process has brought the two departments closer together, rather than working in 'silos', which has had an overall positive impact on their working environment and the patient receiving a timely and accurate diagnosis. 

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