Toxic by Tradition: The Hidden Cost of Formalin Exposure and the Price of Inaction

INTRODUCTION

Formalin is a chemical that is widely used in healthcare settings to preserve biological tissue. This chemical, which is a liquid form of formaldehyde, is exceptional at killing bacteria, stopping the breakdown of live tissue, and locking cells in place, which is vital when preserving tissue for medical testing and diagnosis. Out of all the different types of fixatives, formalin has been shown to be the most effective at preserving tissue in as life-like a condition as possible.[1] While formalin is particularly useful and necessary in hospitals, it presents a significant amount of risk. Formalin exposure to hospital workers can occur via ingestion, inhalation, skin absorption, and blood exchange. Formalin has also been shown to be a human carcinogen with links to a variety of cancers.[2] However, while formalin bans have been suggested, its high level of effectiveness in tissue preservation makes it a necessary risk. For this reason, safe handling and management of formalin is of utmost importance.

HISTORY OF FORMALIN

Formaldehyde did not originate in the healthcare setting. In fact, according to Mucci et al's[3] study from 2019, formaldehyde was originally discovered by European chemists in the mid-1800s and was used commercially for leather tanning and dye production. It was later developed for use with embalming because of its disinfectant properties. Because of formaldehyde's ease of production and low cost, it was adapted for other uses, such as fabric coatings, to make clothing resistant to creases. Table 1 provides a historical timeline of the key milestones in the discovery, medical adoption, and safety regulation of Formaldehyde.

Musial et al[4] in their 2016 paper discussed how medical applications for formaldehyde began to develop around 1880, beginning with utilizing the compound as an antiseptic. Then, in 1892, Jean Auguste Trillat observed formaldehyde hardening soft tissues and triggering coagulation. Not long after that, German physician and biologist Ferdinand Blum compared the effectiveness of formaldehyde to that of traditionally used preserving agents such as alcohol and found that formaldehyde was more effective at maintaining the color and shape of tissues without affecting the microscopic structure.[4]

Later studies confirmed Blum's results by exploring the use of different percentage solutions of formaldehyde, which would eventually be given the name formalin, on animal and plant tissues. These studies supported formalin's effectiveness in tissue preservation and gave practical guidelines for its use in fixing histological sections.[4]

As the evidence of formalin's effectiveness increased, it also began to grow in frequency of use. Near the end of the 19th century, the cost of formaldehyde production dropped below the cost of other fixatives, and, thus, formaldehyde replaced alcohol as the main ingredient in anatomical and histological preparation techniques.[4]

Polish surgeon Victo Wehr began using formalin in 1893 to preserve pathologically altered organs and tissues removed during surgeries and focused especially on tumors. He noted the effectiveness in preventing decay and bacteria growth on these tissues. He also confirmed formalin's ability to ensure resected organs retained their color and shape, noting that only the tissues saturated with blood lost some of their color but that they could be treated with alcohol to restore the original color.[4]

Solutions of formaldehyde continued to be used in tissue preparation throughout the 1900s, and they were continually assessed for long-term effectiveness. Study after study continued to observe similar results in comparing different concentrations of formaldehyde with other preservative agents.[4]

As the use of formalin became more common, the health risks became more apparent. Reports of toxicity were noted as early as 1905 when an American physician published a report citing formaldehyde inhalation causing bronchitis and pneumonia.[4] Over time, the allergenic effects of formaldehyde became well-documented as well as the risks for developing chronic diseases like cancer with prolonged exposure. Some countries even banned its use in certain products like cosmetics.[4]

Currently, formaldehyde solutions are widely used for histopathological preservation and are not likely to be replaced with alternative fixatives, at least for the foreseeable future,[3] even though they can be harmful to health.

Table 1 – Formaldehyde Historical Timeline[3,4]

YEAR	MILESTONE	CATEGORY
~1850	Formaldehyde chemically identified by European chemists	Discovery
1880	Initial medical use as an antiseptic	Medical Use
1892	Trillat documents tissue hardening properties	Medical Use
1893	Blum demonstrates superiority over alcohol fixation	Medical Use
1905	First published report of inhalation toxicity	Safety
1950	Routine adoption in histology and pathology labs	Medical Standardization
2019	Modern occupational exposure research highlights hospital risk	Safety
2024	EPA releases hazard assessment concluding formaldehyde is carcinogenic	Regulation & Safety

NEED FOR FORMALIN

According to Compton et al. (2019),[5] most of the molecular data that physicians rely on to understand a patient's disease and guide precision medicine comes from samples collected during routine medical care. However, because these tissue samples begin to break down quickly once collected, it is imperative that they be preserved effectively. Thus, stabilization by freezing or fixation in formalin is important, and must be completed promptly.[6]

Hojat et al[6] discussed how formalin is used to preserve biological tissue for a variety of purposes, including diagnostic biopsies, lab testing for guiding targeted therapies, or even long-term storage of tissue samples. Surgical tissues have unique biological characteristics, which present a challenge for biobanks to preserve the quality of original samples for future use. To correctly diagnose disease in tissue removed during surgery, the tissue must first be preserved using formalin. This preservation step is important in clinical testing to maintain the integrity of the tissue structures as they were in the body.

In hospitals, formalin is used to collect, store, and transport tissue samples taken during surgeries and biopsies in operating rooms and clinics such as endoscopy and radiology. Formalin is also used in pathology labs because it preserves the shape and structure of cells and tissues. National and international guidelines recommend using neutral buffered formalin for tissue testing, including microscopic exams, protein testing, and genetic (gene mutation) analysis.[7] In fact, most approved laboratory testing methods are designed to work with tissues that have been preserved in formalin.[7]

RISKS AND CONSEQUENCES OF FORMALIN EXPOSURE

Because formalin is used so routinely across the healthcare industry, the occupational risks associated with formaldehyde exposure must be continuously assessed and mitigated to protect both patients and staff. Dugheri et al[1] report that healthcare environments represent some of the highest-risk settings for formaldehyde exposure, largely due to the frequency of handling and the variability of real-world work practices.

In the healthcare environment, OR nurses and surgical technicians routinely handle formalin whenever tissue is collected for diagnostic evaluation. This includes multiple touchpoints across the specimen workflow: placing biopsy specimens into pre-filled formalin containers at the sterile field, filling larger specimen containers with formalin often at eye level when needed, labeling and registering specimens in adjacent work areas, and transporting containers to the laboratory for downstream diagnostic processing.

Each of these steps introduces potential exposure through splashing, vapor release, container leakage, hazardous spills, and repeated handling, particularly in fast-paced OR environments where specimen handling must be performed quickly and consistently. For this reason, Dugheri et al[1] reported that the healthcare field has some of the highest risks of formaldehyde exposure.

Immediate Hazards

With formalin spills, initial concerns are related to direct chemical exposure via inhalation, ingestion, or contact with skin or mucus membranes. According to the Occupational Safety and Health Administration,[2] in the event of ingestion of higher concentrations of formaldehyde solutions, the individual may experience severe irritation and inflammation of the mouth, throat, and stomach followed by severe stomach pain, loss of consciousness, and even death if left untreated.

Formalin is a major skin irritant and sensitizer. If this chemical is splashed on the skin, it can cause white discoloration, discomfort, drying, cracking, and scaling. Frequent or prolonged exposure to the skin can lead to numbness and a hardening or tanning of the skin. Also, individuals with previous exposure may react to future exposure with eczematous dermatitis or hives. Akbarialiabad et al[8] discussed how a previous study demonstrated that formaldehyde could permeate through single-layer natural rubber gloves, creating an unexpected and significant risk to the skin.

If formaldehyde solutions splash into a person's eyes, it can cause a variety of symptoms ranging from short-lived discomfort to severe, permanent corneal clouding and blindness.[7] The severity of symptoms depends on the concentration of formaldehyde in the solution and whether the eyes are flushed with water immediately after exposure.[7]

Formalin exposure through inhalation can present an array of symptoms, depending on the concentration of the solution. Formaldehyde is a major irritant to the respiratory tract and the eyes. Lower concentrations may cause irritation of the eyes, nose, and throat, and slightly higher concentrations may lead to tearing of the eyes. High concentrations may cause breathing difficulty, burning of the nose and throat, coughing, heavy tearing of the eyes, and possibly severe respiratory tract injury leading to pulmonary edema and pneumonitis.[9] The highest concentrations are immediately life threatening.[9] For individuals with asthma, inhalation of formaldehyde can cause acute exacerbations of the condition.[9]

It is important to understand that the perception of formaldehyde by odor and eye irritation becomes less sensitive over time because the body naturally adapts to formaldehyde. This creates an elevated risk of overexposure if an individual is relying on formaldehyde's warning properties related to smell and eye responses to alert him or her to exposure.[2]

Environmental contamination and repeated exposure introduce an additional level of concern, as formaldehyde is classified as a human carcinogen. In its 2024 assessment, the United States Environmental Protection Agency (EPA) concluded that inhalation exposure to formaldehyde can cause cancer in humans, citing strong scientific evidence.[10] The EPA identified associations between inhaled formaldehyde and cancers of the upper respiratory tract, including the nose and paranasal sinuses.[10] The assessment also evaluated evidence related to myeloid leukemia; while some scientific advisors questioned the biological plausibility of a leukemia mechanism due to formaldehyde's reactivity and distribution, other experts agreed that the overall body of evidence supports a potential association.[10] Importantly, the EPA's decision to focus quantitative cancer risk estimates on upper respiratory cancer, rather than leukemia, reflects a conservative approach to risk modeling, not an absence of concern. From an occupational safety perspective, these findings reinforce a practical conclusion for healthcare environments: reducing inhalation exposure to formaldehyde vapors should remain a priority wherever formalin is routinely handled, including perioperative specimen workflows.

Mucci et al[2] reported in 2019 that the most significant concerns with repeated exposure to formaldehyde are sensitization and cancer. According to Tupper et al[9] formaldehyde can cause cancer in several ways, mainly by directly damaging DNA. Studies have shown DNA damage, changes in chromosomes, and other genetic problems in blood cells and nasal tissue of people who are exposed to formaldehyde routinely at work.[9] The cancers most often linked to formaldehyde exposure affect the upper part of the throat behind the nose.[9] This supports the idea that breathing in formaldehyde is the main risk, because formaldehyde dissolves easily in water and reacts quickly, causing it to stay in the nasal tissues after inhalation.[9]

Tupper et al[9] also reported that cardiovascular disease has been linked to formaldehyde exposure. This study suggested that formaldehyde can interact with certain immune system enzymes during a heart attack, affect the heart's natural pacemaker and cause irregular heart rhythms, and damage blood vessel cells. In people with diabetes, formaldehyde produced in the body may increase injury to blood vessels, raising the risk of hardening of the arteries, stroke, heart failure, and death. Other diseases that have been linked to prolonged and repeated exposure to formaldehyde include Alzheimer's disease, Parkinson's disease, and amyotrophic lateral sclerosis or ALS.

Operational Disruptions

In addition to chronic exposure concerns, formalin spills in the OR can disrupt workflows and create immediate safety hazards. Formalin solutions are both toxic and volatile; even modest spills can release formaldehyde vapors that irritate respiratory mucosa and necessitate evacuation or containment measures while the area is cleaned and ventilated. In some hospital settings, formalin spills have led to emergency responses, evacuation of personnel, and reevaluation of departmental policies to prevent recurrence. While data specific to OR spill incidences are limited, guidance from occupational health sources underscores that spill response procedures and decontamination can interrupt clinical workflows, require staff time and resources to manage, and raise the likelihood of unplanned exposures if not controlled. Formalin spill management protocols commonly recommend area isolation, specialized absorbents/neutralizers, and trained responders, all of which extend turnover times and divert attention from patient care in high-acuity environments.

Zach Swartz[11] in his training on specimen handling cites the following procedure in the event of a formalin spill or accident:

- If a surgical team member experiences a formalin splash on the skin, he or she must:
    1. Immediately remove any clothing that has come in contact with the chemical
    2. Wash the area with soap and large amounts of water
    3. Report the exposure incident to the supervisor or facility employee health department according to the policies and procedures of that facility
    4. Seek medical attention if there is contact with the eyes or respiratory irritation
- If formaldehyde comes in contact with the eyes, the surgical team member should immediately flush the eyes with large amounts of water, lifting the upper and lower eyelids to allow water to flush the entire eye area and then seek medical attention.
- After occupational exposure to formaldehyde at or above the exposure limit levels, the health care facility must provide medical surveillance that includes a medical disease questionnaire and a physical examination, if necessary.

The Association of Surgical Technologies in their Standard of Practice[12] states the following procedures for cleaning up formalin spills:

- For small spills, the healthcare worker should don the appropriate PPE, immediately remove sources of ignition from the area of the spill, neutralize the spill with use of sodium hydroxide and use absorbent material to clean the spill. The absorbent material should be placed into a container marked with a hazardous label and disposed of properly.
- In the event of a large formalin spill that the facility is properly trained to handle internally, the healthcare worker should immediately leave the area and report it to the proper healthcare facility personnel. Designated healthcare workers that are responsible for the cleanup should isolate the area and not allow personnel who are not wearing the proper personal protective equipment (PPE) to enter. Sources of ignition should be immediately removed from the area of spill. Only properly trained staff members who are comfortable with cleaning up the spill should proceed to clean it up.
- In the event of a large formalin spill that the facility is not properly trained to handle internally, an external cleanup company must be called in. A spill requires an external cleanup company when its size, hazards, PPE needs, operational impact, or regulatory requirements exceed what trained healthcare staff can safely manage—such as emergencies under OSHA HAZWOPER, high-toxicity or vapor-producing chemicals (eg,

formaldehyde), situations requiring advanced PPE or environmental testing, or any spill staff are not trained or comfortable handling.[13-16.]

COST OF SPILLS

The consequences of formalin spills are not limited simply to health hazards and cleanup times. Costs are another significant consideration regarding accidents associated with formalin.

Hospitals

The cost of formalin spills to hospitals can be broken down into cleanup and decontamination expenses, regulatory fines, legal costs, and the loss of income if an operating room must be shut down due to a large spill. Based on an example of a formalin spill at Providence St. Peter Hospital in Olympia, Washington,[17] the state fine can be upwards of $100,000, but in this case a settlement reduced the fine to $45,000. OSHA fines can be as high as $112,000, and additionally, there may be legal expenses to consider.[17]

The cleanup and decontamination expenses depend on the size of the hospital, the type of formalin used, the extent of the chemical spill, and many other variables. The national average for a biohazard spill cleanup is around $5000 but can go as high as approximately $25,000 for a major accident, according to one company who specializes in these types of incidents.[17] Other companies have cited up to $600 per hour for biohazard cleanup, depending on the safety level as determined by the Center for Disease Control.[18] Depending on how large the chemical spill is, the cleanup and decontamination can take from just a few hours to months to complete.[18]

In the event of a large spill that will take days to weeks to even months to clean up, the financial impact of the lost operating room time can be severe. According to Childers et al[19] in their 2018 study, a formalin spill occurring in or near an operating room can force hospitals to immediately halt surgical operations to allow for hazardous materials containment, ventilation clearance, and regulatory compliance. Even a short interruption in operating room activity can result in substantial financial loss, driven primarily by lost revenue and case disruption. A 2025 perioperative efficiency report found that operating-room time costs $15–$100 per minute, with a U.S. hospital survey showing an average of $62 per minute and high-complexity surgeries reaching $133 per minute.[20] Childers et al[19] reported that the mean cost of OR time in California in 2014 was approximately $37 per minute according to financial data from California's short-term general and specialty hospitals. A single, standardized figure for current healthcare spill-related costs has not been published recently; however, there is substantial citable evidence identifying modern cost drivers that indicate 2026 healthcare spill expenses exceed older benchmark ranges. The most relevant available data comes from industrial-facility studies, which—while not healthcare-specific—reflect the same operational, regulatory, and financial mechanisms that drive spill-cost escalation in hospitals. These findings include EPA penalties that can exceed $70,000 per day, a 2025 chemical-violation fine totaling $850,000, and documented evidence that prolonged operational downtime often surpasses the value of the chemicals lost within just a few days.[21] Together, these data points provide the strongest available proxy demonstrating that contemporary healthcare spill-related costs are significantly higher than previously reported estimates. In a 2024 report from Sacramento Medical Center looking at the frequency and severity of formalin spills, 13% of all reported hospital incidents over a ten-month period were related to chemical exposure, including formalin.[22] Depending on the size of these chemical exposure incidents, the cost impact over time can be substantial. (Table 2)

Table 2 - Formalin Spill Cost Summary [17-22]

Cost Category	Key Figures / Ranges	Notes
State Fines	Up to $100,000 (settled for $45,000)	Example: Providence St. Peter Hospital
OSHA Fines	Up to $112,000	Maximum penalty
EPA Penalties	$70,000+/day; one case $850,000	Industrial data used as proxy
Legal Costs	Variable	Additional to fines
Cleanup & Decontamination	$5,000 avg; up to $25,000; $600/hr	Depends on spill size & hazard level
Cleanup Duration	Hours → Months	Larger spills drive higher cost
OR Downtime Cost	$15–$100/min; avg $62/min; high $133/min	One of the biggest financial impacts
Operational Downtime	Often exceeds value of chemicals	Prolonged closures = major cost driver
Chemical Exposure Rates	13% of all hospital incidents	2024 Sacramento Medical Center review

Loss of revenue and high cleanup costs are not the only unfortunate impact of formalin spills. Spills with longer cleanup and decontamination times create major disruptions in workflow and can delay treatment for patients. As discussed previously, timing is of upmost importance when it comes to formalin fixation for tissue samples that will determine the appropriate plan of care for the patient. A significant spill can greatly impact the time it takes to get tissue samples safely preserved for medical testing, diagnosis, and treatment planning. Also, according to OSHA,[2] there must be designated hospital personnel who are trained in properly handling formalin spills. When a spill takes place, those trained personnel must be called upon, effectively removing those hospital employees from their daily tasks and severely impacting hospital workflows.

Employee Healthcare

In the event of a formalin spill, healthcare facilities must also be aware of the cost of healthcare for employees impacted by the spill. If formalin is splashed in the eyes or on the skin, as mentioned above[2] the employee affected may experience a range of symptoms from mild irritation to hives and even loss of vision. This type of incident can lead to the loss of workdays so that the individual can receive necessary care and recover. In the event of inhalation, the effects on health can cause symptoms varying from irritation headaches and minor respiratory irritation to more catastrophic outcomes depending on the concentration of formaldehyde.[2] More severe cases could result in employees taking a significant amount of leave, resulting in more costs for the employee and the facility alike.

The cost to the healthcare facility for injury to personnel is another factor that will make a financial impact after a formalin spill. The severity of the injury to the employee will affect the cost of care. The employee may require an emergency room visit as well as specialist follow-ups in the event of more severe exposure. If the employee qualifies for worker's compensation, there will be additional costs related to that, possibly including wage replacement and disability benefits.[23]

COMMON CURRENT FORMALIN HANDLING PRACTICES

Manually Pouring Formalin

One method that is commonly used to dispense formalin is to simply pour it from bulk containers into the necessary receptacles. Bellisario et al[24] discussed the dangers of this practice in their 2016 study, showing that most formaldehyde exposure comes from the practice of pouring large amounts of liquid formaldehyde, usually 3 to 5 liters at a time, into big containers. People in the study who worked with liquid formaldehyde had much higher exposure levels than those who did not.[24]

Dugheri et al[1] pointed out that one of the most widely used solutions to this exposure problem is to use benches with aspiration hoods or conventional fume hoods to protect healthcare workers when pouring formalin. However, this study also noted that these fume hoods negatively impacted worker ergonomics. This method of formalin dispensing also affects documentation in that the amounts of formalin are not standardized.

Pre-Filled Containers

Dugheri et al[1] in their 2021 study discussed how tissue samples are often placed into containers that are already filled with formalin to lower the risk of formaldehyde being released into the air during collection, handling, and storage. This method is safer than older systems where large amounts of formalin were mixed and stored in pathology labs and then poured into containers. However, even pre-filled containers can still cause exposure through fume exposure or if they leak or spill, and the employee responsible for filling the container is at risk.

FORMALDEHYDE SAFETY IN THE PERIOPERATIVE ENVIRONMENT

Formaldehyde safety in the perioperative environment begins with eliminating or reducing employee exposure. Eliminating or reducing employee exposure is important because the risks associated with exposure to formaldehyde increase as exposure to the chemical increases.[25] When possible, elimination is preferred. However, because complete elimination of formaldehyde use is unlikely and adds complexity to current workflow practices, occupational safety personnel should focus on reducing exposure.

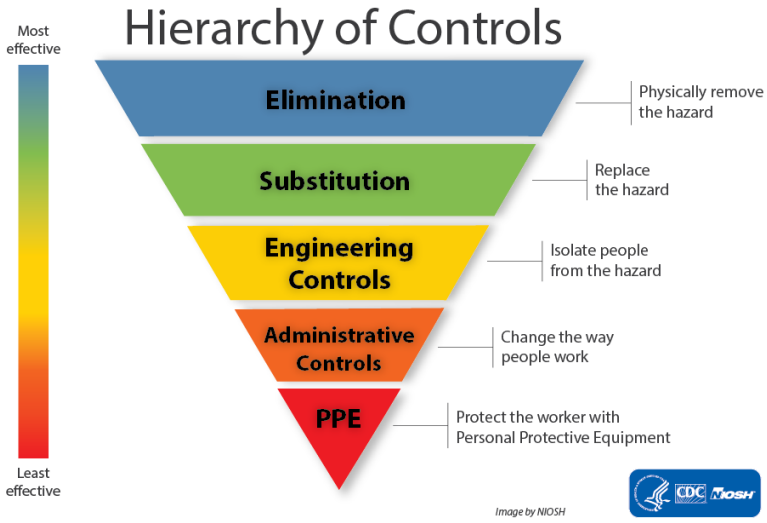
Hierarchy of Controls

The *National Institute for Occupational Safety and Health* (NIOSH) is the federal agency responsible for conducting research and making recommendations for the prevention of work-related injury and illness. NIOSH is part of the Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services.[26] Figure 1 shows the NIOSH/CDC *Hierarchy of Controls*. The Hierarchy provides a pathway for implementing feasible and effective controls to eliminate or reduce exposure to occupational hazards.[27]

The Hierarchy moves from the most effective to the least effective control measures.[26] The first step is *elimination* of the hazard by physical removal of the chemical.[26] If exposure to formaldehyde cannot be eliminated, the next step is *substitution*, which involves reducing the hazard by replacing formaldehyde with a less hazardous chemical.[26] If this is not possible, *engineering controls* should be implemented to provide a barrier from the hazard or remove the hazard by air ventilation.[26] *Administrative controls* involve changing the way people work by making changes to processes, procedures, and policies.[26] The final step of the Hierarchy involves protecting the worker from the hazard by using *personal protective equipment* (PPE; ie, clothing or other equipment that protects a person from exposure to chemicals or other potentially infectious substances, such as gloves, goggles, or impervious clothing.[27] Scrub

clothes, head coverings, and lab coats worn by healthcare workers are not impervious and are therefore not considered to be PPE.[26] Note that although using PPE is important, it is the lowest and least effective level of control.

Figure 1 – Hierarchy of Controls



Source: Centers for Disease Control and Prevention. National Institute for Occupational Safety and Health. Hierarchy of controls. CDC. https://www.cdc.gov/niosh/hierarchy-of-controls/about/index.html. Accessed February 6, 2026

Eliminating Formalin from the OR

In order to prevent excessive formalin exposure to healthcare workers, many hospitals have removed formalin from operating rooms.[24] In some cases, this means that tissue specimens are removed, placed into a sterile container with a saline solution or wet ice, and taken to pathology by a technician.[6] The importance of timing when managing live tissue is well-documented as is the necessity of formalin use. Agrawal et al[28] in their 2018 study discussed how cold ischemic time, which is the delay before tissue is placed in formalin, is very important for deciding whether a tissue sample can be used for immunoassay testing. Many studies show that a cold ischemic time of 12 hours or less works best for immunohistochemistry.[28] However, the acceptable amount of time can vary depending on the specific protein being studied and the type of tissue sample. Factors such as the type of tumor or tissue, the size of the sample, and how it was collected can all affect results. According to Chen et al[29] delays in formalin fixation can create major degradation of tissue specimens and alter diagnostic results.

Belissario et al[24] discussed an alternative method of getting specimens from the operating room to pathology without formalin being present in the operating room. To reduce exposure to formaldehyde, the hospital in their study began using Under-Vacuum Sealing (UVS) with Milestone Medical's TissueSAFE. TissueSAFE is a patented vacuum system that allows freshly removed tissues to be preserved in their natural state without the use of fixatives like formalin. With this method, tissue removed during surgery is placed into a special plastic bag, sealed under vacuum, and kept cold at about 4 °C until being sent to the pathology laboratory. While this method is effective at reducing formalin exposure for the OR staff, it does not address the need for the specimen to be placed in formalin in a timely manner, which in turn, extends the cold ischemic time for the specimen.[24]

These delays in formalin fixation can negatively impact the accuracy of pathology results. In cases of breast cancer, for example, cold ischemic time should be limited to one hour or less according to Haight et al[30] in their 2024 study. Because of the importance of accurate results, current guidelines from the American Society of Clinical Oncology and the College of American Pathologists recommend keeping the delay before fixation to one hour or less for estrogen and progesterone receptor.[30] Thus, the removal of formalin from the OR creates more problems despite reducing exposure risk.

SAFE USAGE WITH ULTRASAFE EQUIPMENT

UltraSAFE is a cutting-edge solution designed to ensure the safety of operating room personnel and perioperative nurses by eliminating exposure to formalin fumes during biospecimen handling. Through the one-way valve lid, UltraSAFE automatically dispenses formalin into specimen buckets utilizing an automatic injection system. The buckets are filled in an enclosed and vented chamber that eliminates operator exposure to formalin fumes. Formalin is dispensed based on specimen weight and specific lab guidelines. Time to fixation, weight of specimen, and exact formalin quantity are recorded on a printed label to ensure standardized documentation. This innovative system eliminates operator exposure to formalin fumes, prioritizes operator safety, standardizes workflows, and ensures reliable biospecimen handling.[31]

AORN Recommendations

AORN provides guidance on the use of automated technology such as UltraSAFE, and supports as a recommendation, the use of this technology during specimen handling.[32] Preliminary evidence suggests that specimen errors during the preanalytical phase may be partly attributable to limited or absent process automation. Reliance on memory for complex tasks can increase the risk of error due to variability in human performance. When feasible, increased automation may reduce the likelihood of preanalytical specimen errors.[32] Table 3 outlines the benefits and Potential Harms Associated with automated dispensing systems, as stated in the AORN Guidelines, demonstrating that the benefits of utilizing UltraSAFE far outweigh the risks.

Table 3 – Benefits and Potential Harms Associated with Automated Formalin Dispensing Systems

Benefits	Potential Harms
Preserves specimen morphology	Does not eliminate formalin use
Selectable specimen-to-preservative ratio	Cross contamination if not cleaned properly
Automated calculation of preservative volume	
Automated recording of fixation time	
Traceable specimen information	
Reduced preservative volume	
Lower exposure to formaldehyde fumes/spills	
Reduced respiratory symptoms	
Improved staff satisfaction	

Association of periOperative Registered Nurses. Guideline for specimen management. In: *Guidelines for Perioperative Practice*. Denver, CO: AORN, Inc. 2026:979-1022.

Milestone Medical Technologies, Inc. UltraSAFE Automated Formalin Dispensing System for Biospecimens. https://www.milestonemedsrl.com/us/wp-content/uploads/sites/3/2019/12/UltraSAFE-US-with-tech-specs-030521.pdf. Accessed February 6, 2026.

How Does UltraSAFE Mitigate Spill Risks and Prevent Formalin Exposure?

As discussed previously, the major concerns with formalin safety present themselves in situations where nurses must manually pour the solution into containers or work with pre-filled containers in the OR. UltraSAFE mitigates these safety hazards by utilizing an automated dispensing system and buckets with a one-way safety valve that allows flow of formalin into the buckets while preventing fixative backflow and without releasing fumes, thus eliminating exposure to fumes and greatly reducing risk of spills. The device also has an auto-locking door for safety while dispensing formalin, ensuring the vented cabinet cannot be opened during formalin dispensing. This method significantly enhances healthcare worker safety by eliminating the need for nurses to manually fill specimen containers or handle pre-filled containers, which are known risks for formalin spills. As discussed in this paper, one of the most common causes of formaldehyde exposure is the practice of having nurses pour large amounts of formalin into containers.[24]

The UltraSAFE system reduces this risk of spills significantly. When installed following Milestone Medical instructions, UltraSAFE reduces formalin exposure to levels compliant with World Health Organization (WHO) guidelines, providing a secure environment for operating room personnel and perioperative nurses handling biospecimens.[32]

BENEFITS OF ULTRASAFE

Regulatory Compliance

With regulatory agencies assessing and citing medical facilities for flawed formalin management practices and high exposure numbers, UltraSAFE offers a cost-conscious solution that addresses the hazardous formalin fumes without costly facility improvements to ventilation systems, while also addressing the safety of the staff. UltraSAFE ensures formalin exposure levels remain within acceptable levels according to WHO, as mentioned previously, and it provides a safer working environment for healthcare staff, including nurses and technicians, interacting with biospecimens.[32]

Improved Documentation

UltraSAFE ensures comprehensive sample traceability through its integrated barcode reader, which scans buckets and hospital requisition forms to link each bucket to a patient case ID. This guarantees accurate case matching and full traceability throughout the process.

At the end of the run, a printed label reports all the case information, including case ID, bucket ID, specimen weight, fixative weight, specimen to fixative weight ratio, institute, user, and time. This allows for improved communication between the operating room and pathology and removes the need to have a nurse or other healthcare worker going back and forth to retrieve necessary data when it is incomplete.[32]

Workflow Standardization

UltraSAFE streamlines biospecimen collection through automated, precise fixative dispensing. Equipped with a built-in scale, the system measures specimen weight and dispenses a pre-set amount of formalin based on lab-specific protocols. This ensures consistent fixation and minimizes variability in the process. Upon completion, the printed label ensures that all pertinent information is readily accessible to enhance laboratory workflow and ensure results are standardized and reliable.[32]

Error Reduction

Chen et al[30] discussed in their 2025 study the common mistakes that happen before lab testing, including incorrect paperwork or specimen labels, patient identification errors, using the wrong containers or fixatives, and delays in transporting specimens. It is estimated that problems occur in about 6% of surgical cases, causing up to 160,000 harmful events each year in the United States.[12] As mentioned above, the integrated barcode reader makes certain that samples are fully traceable and matched correctly to their intended patients, reducing the risk of labeling errors. At the end of each run, UltraSAFE generates a customizable label with all relevant case details, including fixation time and specimen data, which can be easily printed and affixed to the bucket. This automated, standardized documentation eliminates errors and enhances laboratory efficiency.

In addition to that, the UltraSAFE system uses an automated process to dispense formalin into the buckets. This process ensures that the appropriate amount of formalin is dispensed into the buckets, thus removing the guesswork for healthcare workers and preventing overfilling or underfilling.[32]

Engel et al's study[33] explained how formalin fixation time and other preanalytical variables can have a significant impact on lab results. If pathology is spending excessive time tracking down missing or incomplete data or correcting documentation errors, this time lag can have a negative impact on the tissue specimens and, thus, the end results. Poor tissue specimens can give medical professionals inaccurate information leading to ineffective plans of care.

Pathology Benefits

UltraSAFE technology allows better proficiency in workflow because formalin fixation begins in the operating room instead of relying on a nurse or pathology worker to run specimens from the operating room to the pathology laboratory. With formalin fixation starting directly in the OR, time-to-fixation is significantly reduced, which leads to better tissue preservation for diagnostic accuracy.[6] UltraSAFE also benefits pathology by ensuring the weight of the specimen is documented almost immediately after collection, and the system accurately dispenses the proper formalin ratio in correlation to the recorded weight. All this information will be found on the label affixed to the bucket, which also included all pertinent specimen details. This process further enhances accuracy in pathology.[32]

CASE STUDY: HELIOS UNIVERSITY HOSPITAL

Background

Helios University Hospital in Wuppertal, Germany is a large hospital caring with approximately 2500 employees serving around 50,000 patients per year. The pathology department of around twenty-one employees handles approximately 80,000 specimens per year. They receive specimens from not only their own operating rooms but from many other hospitals and medical facilities in their region.

As is the case with most hospitals, formalin use is a necessity for daily operations, but they wanted to find a solution to the risks that formalin poses to their employees. Originally, when they began working on reducing employee exposure, buckets for biospecimens were routinely cleaned from formalin after use to save money on buckets.

However, this method proved less cost effective as staff costs for cleaning the buckets were higher than simply purchasing more buckets. This process also put staff in a situation of constant exposure to formalin, and it heightened the risk of contamination between biospecimens, potentially impacting the results of lab testing and ultimately patient safety.

Implementation

In response to this problem, Prof. Dr. Hans Michael Kvasnicka and Ralf Lieberz decided to introduce a new closed system to significantly reduce staff exposure to formalin while also enhancing traceability of biospecimens from the operating room to pathology. They decided to implement use of two UltraSAFE devices placed in operating rooms so that biospecimens could be placed immediately into buckets after extraction, and formalin could be automatically dispensed in the enclosed and vented UltraSAFE unit. Nurses handling the specimens were no longer risking exposure to formalin because the specimen was weighed and the appropriate amount of formalin was dispensed in the UltraSAFE closed chamber.

Conclusions

Since the implementation of UltraSAFE, this hospital has seen significant improvements in the fixation of biospecimens due to the ability of this device to dispense the correct amount of formalin automatically. This process has resulted in uniformly high quality biospecimens as well as provided the ability to trace how each specimen has been fixed in formalin. The unique bar code on each bucket that contains all the necessary information for each biospecimen has allowed the specimen and its data to travel together through the pre-analytical process.

Nurses in the operating rooms also noticed quickly that the enhanced safety and ease of dosing formalin with the UltraSAFE devices. With many of the nurses being of reproductive age or even already pregnant, they were very satisfied with the reduced risk of formalin inhalation or other exposure. The nurses also reported how simple UltraSAFE is to use after a brief introduction. In fact, it took a mere 2-3 days after installation for everyone to begin using the device with confidence.

Prof. Dr. Kvasnicka and Mr. Lieberz explain that the success of UltraSAFE comes from its focus on supporting staff so they can work in a safer environment. The pathology department and operating rooms worked closely together to launch the project, ensuring strong acceptance in the operating rooms and a smooth handoff of specimens to pathology.

HOSPITAL TESTIMONIALS

“After months of formalin spills in our OR, we decided to explore other options for safe specimen handling. We came across literature from Milestone regarding the UltraSAFE closed formalin dispensing system. This system has been one of the most successful purchases for our department. No more spills, breathing dangerous fumes, and skin exposures – wouldn’t go back!”

“The Milestone UltraSAFE has elevated our ability to fix specimens accurately and safely. The zero exposure has been a triumphant win for our OR team. The representative and team made ordering, installation, and new user education accessible and easy!”

“The UltraSAFE machine is very convenient and easy to use. It is also comforting, changing from manually filling containers with formalin to using this machine. Ever since the change, I have yet to smell even a hint of the formalin.”

“Milestone provides a safer alternative to formalin handling, with user-friendly equipment enhanced by advanced technology for added convenience. The training provided by the representative was clear, step-by-step, and well-received. Additionally, whenever I reach out to our representative, I always receive a prompt and helpful response.”

SUMMARY/KEY TAKEAWAYS

- While formalin is necessary in hospitals for a variety of uses, it comes with many risks, including damage to the skin and eyes in the event of chemical splashes, respiratory distress if inhaled, and it can even be life threatening with high concentrations of formaldehyde. Formalin is also a known human carcinogen with prolonged and repeated exposure.[2,10]
- Formalin spills can cost hospitals thousands of dollars to clean up and decontaminate, and they can result in significant losses in revenue as well as harm to healthcare workers.
- Hospitals have implemented different solutions to mitigate the risk of formalin exposure. One such solution is having one nurse pour formalin into containers and then bring the chemical to the operating room. This solution has not proven safe or efficient. The other most common option is the use of pre-filled containers, but this option has not reduced exposure enough to keep healthcare workers safe in the operating room or the pathology lab.
- UltraSAFE is a critical investment for hospitals as it eliminates the risk of exposure to healthcare workers, and at the same time, it significantly enhances the accuracy and reliability of documentation and improves workflows with biospecimen samples.

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