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Cost analysis of archives in the pathology laboratories: from safety to management

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ABSTRACT

Context Despite the reluctance to invest and the challenging estimation of necessary supporting costs, optimising the archives seems to be one of the hottest topics in the future management of the pathology laboratories. Historically, archives were only partially designed to securely store and organise tissue specimens, and tracking systems were often flawed, posing significant risks to patients' health and legal ramifications for pathologists.

Objective The current review explores the available data from the literature on archives' management in pathology, including comprehensive business plans, structure setup, outfit, inventories, ongoing conservation and functional charges.

Data sources Electronic searches in PubMed-MEDLINE and Embase were made to extract pertinent articles from the literature. Works about the archiving process and storage were included and analysed to extract information. Prepublication servers were ignored. Italian Institutional Regional databases for public competitive bidding processes were queried too.

Conclusions A new emergent feeling in the pathology laboratory is growing for archives management; the digital pathology era is a great opportunity to apply innovation to tracking systems and samples preservation. The main aim is a critical evaluation of the return of investment in developing automatic and tracked archiving processes for improving not only quality, efficacy and efficiency of the labs but also patients' healthcare.

ARCHIVES IN PATHOLOGY: A HISTORICAL REBUS

The archives in pathology are crucial, but at the same time, they are the least-observed places of our departments, basically consisting of formalin-fixed paraffin-embedded (FFPE) blocks and glass slides, filed in a consecutive order, with the purpose of retrieval based on patient requests or for scientific studies.^{1,2} Essentially, archives can be placed underground, in a basement, or in a secluded area around the hospital, although in the last years they dramatically gained importance largely due to the advent of molecular pathology and the need to preserve biological samples for DNA/RNA profiling.^{3–6} Despite the reluctance to invest and the challenging estimation of necessary supporting costs, optimising the archives seems to be one of the hottest topics in the future management of the pathology laboratories.⁷ Historically, archives were only partially

designed to securely store and organise tissue specimens, and tracking systems were often flawed, posing significant risks to patients' health and legal ramifications for pathologists.⁸ The archive should include a specially designed place that meets all the standards to prevent conditions that accelerate tissue ageing and degradation processes. For FFPE blocks, according to the National Cancer Institutes Best Practices for Biospecimen Resources, controlled temperature (a maximum of 26°C) and humidity (30%–70%) are recommended, including control systems for parasite infestation and flooding risk.⁹ Blocks stored in areas that do not respect these environmental conditions showed significant variability in terms of antigen detection through immunohistochemistry, as well as potentially compromising the integrity of nucleic acid for molecular analysis, whose optimal preservation is set in the –20°C/–80°C temperature range.^{10–12} To make practical examples, previous studies already investigated the stability of specific antigens (eg, predictive markers in breast cancer) on FFPE specimens with different ages, as in the case of oestrogen receptor (ER), human epidermal growth factor receptor 2 (HER2) and Ki67 that showed an average of 10% signal loss after 9.9, 8.5 and 4.5 years, respectively.¹³ Similar impact has been demonstrated for the humidity variations, with markedly decreased scores for ER and progesterone receptor (PR) in humid conditions compared with fresh-cut tissue, slower degradation of HER2 antigenicity and RNA integrity of breast sections stored in dry environment, and differences in Ki67 labelling index (9% vs 31.9% decrease) for tissue sections stored for 3 months in dry versus wet archives as compared with fresh sections.¹⁴ For glass slides, systems suitable for guaranteeing their safety, traceability and conservation are recommended. Respecting these storage recommendations is pivotal when considering the current retention policy recommendations of the major national and international pathology associations/societies, as well as the local/national indications of the governance. In this setting, variability exists regarding the minimum time of retention set by the different authorities for FFPE blocks, histological glass slides and whole slide images, as reported in [table 1](#).

A general agreement exists on the minimum retention of these types of material for at least 10 years, which further stresses the need for optimal preservation in our archives for the potential

Table 1 Summary of the recommended retention policies for different material within the pathology laboratories proposed by national and international pathology colleges/societies and national/local governance authority

Authority	FFPE blocks	Histological slides	Gynaecological cytology slides	Non-gynaecological cytology slides	WSI
CAP (USA) ³¹	10y	10y	5y	10y	10y
RCPATH (UK) ³²	30y*	15y†	10y	10y	8y
SIAPEC/MoH (IT) ⁹	10y	10y	10y	10y	10y
Lombardy Region governance (IT) ³³	50y	50y	10y	50y‡	30y§

*If no facilities, 10 years, retaining most relevant blocks permanently.

†If from children, until they reach the age of 25.

‡If representing the only pathological sample available, otherwise 5 years.

§From the elimination of the corresponding glass slide.

FFPE, formalin-fixed paraffin-embedded; WSI, whole slide images; y, years; CAP, College of American Pathologists; RCPATH, The Royal College of Pathologists; SIAPEC, Società Italiana di Anatomia Patologica e Citologia Diagnostica; Ministry of Health.

future retrieval of such specimens for diagnostic and research purposes.

To face these challenges, archives should ideally consist of several parts, including:

- ▶ FFPE samples stored in paraffin blocks, histology plates, microscope slides or other suitable carriers for long-term storage.^{15 16}
- ▶ Clinical data, such as patient information, medical history, diagnostic test results, imaging reports and other information related to disease diagnosis and treatment.
- ▶ Photo files that may be used for reference, teaching or academic purposes.
- ▶ Laboratory information system (LIS) or document management system (DMS) for efficiently organising, cataloguing and retrieving data. These systems maintain accurate records of specimens, diagnoses and associated clinical data. Depending on the country scenario, regulations require compliance with privacy laws, such as the General Data Protection Regulation in Europe or the Health Insurance Portability and Accountability Act (HIPAA) in the USA.^{9 17} This needs the implementation of security measures to protect personal data of patients and ensure informed consent for the storage and use of samples.

ARCHIVES IN PATHOLOGY: IN OR OUT?

In practice, hospitals underestimate the selection of suitable locations for archives, forgetting factors such as accessibility, space requirements and proximity to medical institutions. Furthermore, it largely lacks systematic classification of samples according to different types such as histopathology, cytopathology and molecular pathology, as well as adequate ventilation, lighting and safety measures. Qualified personnel, such as tissue technologists, cytotechnologists, medical laboratory scientists/technicians and administrative staff, should be involved in the archiving process. Archivists, however, were not always a coveted role in our labs.¹⁸ Furthermore, worldwide, a dichotomy is observed between hospitals that have their own archives areas (in-house) or institutions that have opted for external (out-sourced) solutions, with different levels of comprehensive quality control and quality assurance programmes to guarantee the accuracy, reliability and validity of storage. Basically, external solutions offer Standard Operating Procedures, maintaining appropriate documentation, conducting regular equipment maintenance, participating in external proficiency testing programmes and adhering to regulatory guidelines. Instead, internal archives should allow faster sample retrieval and have robust information technology (LIS) to manage patient records, test orders and results, and ensure privacy and security standards, such as compliance with

the HIPAA.^{19 20} Ultimately, the ideal solution should ensure safety and biohazard management to protect workers, patients and the environment. These include proper handling, storage, and disposal of biohazardous materials, adherence to infection control measures, provision of personal protective equipment (PPE) and adequate employee training.

ARCHIVES IN PATHOLOGY: FINANCIAL CONSIDERATIONS

Only a few pathology labs developed a comprehensive business plan for the archives, including estimates for structure setup, outfit, inventories, ongoing conservation and functional charges. The costs can vary depending on several factors, such as the size of the laboratory, the volume of data being archived, the chosen storehouse structure and the specific conditions of the institution. The costs associated with maintaining an archive can be quantified in several ways, including the following:

- ▶ Direct costs: physical storage (eg, shelving, containers), equipment and staff salaries and benefits. Limited staff can manage moderately growing FFPE and slide sample management collection, storage and distribution processes for years as long as these processes remain relatively stable. Otherwise, significant changes in staffing levels and numbers would be needed to handle a larger demand. Most daily requests concern the recovery of blocks from the archive, with most archives being operated by healthcare assistants or administrative staff with a gross salary of approximately €30 000 per employee. Most laboratories need more than one person to manage their archive to guarantee the timing and management of sample requests from patients or clinicians.
- ▶ Indirect costs: utilities, building maintenance and upkeep, insurance and administrative costs.
- ▶ Opportunity costs: the cost of using additional staff time for archival tasks rather than other responsibilities, as well as the compensation costs for reimbursement if the archive is not properly maintained (eg, loss of or failure to find an FFPE block).
- ▶ Future costs: the cost of future conservation efforts and storage upgrades. Indeed, the saturation of space forces most healthcare companies to identify archives outside the hospitals, with a surcharge for this service that is in addition to the budget allocated. Furthermore, the information technology (IT) cost associated with the massive digitisation of slides is increasing the problems of the archive, creating new needs regarding where to archive digital images.

The first investment in spaces, physical architectures and softwares (DMS or enterprise content operation—purchasing or licensing, as well as ongoing conservation fees and support) needed for archiving may be an applicable source of counter

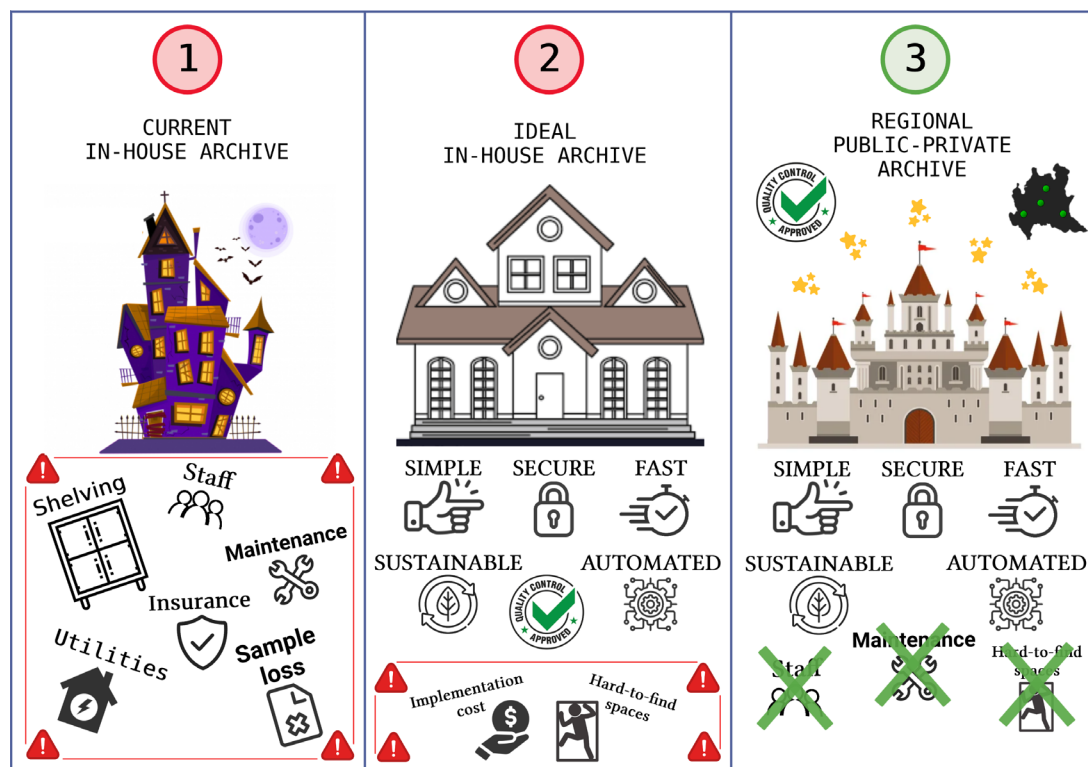


Figure 1 Comparison of the current world to the 'pro and contra' offered by in-house or outsourced solutions.

incentive for administrations. Still, a careful examination of the prospective advantages connected with a rational and trackable workflow should be considered. The return on investment (ROI) and long-term benefits of enforcing archives, such as better effectiveness, data availability and non-supervisory compliance are important factors to be considered near with well-known medical legal considerations. The need for upfront investment to tackle the current inappropriate softwares and infrastructures could represent a possible disincentive from the governance perspective. With an internal archive, we consider the costs of physical storehouse bias, similar to hard drives or tape recording drives, to store the archived data. These costs can vary based on the storehouse capacity demanded and the scalability conditions. Managing an internal archive involves ongoing conservation and support. You may need devoted IT staff to handle system administration, data migration, upgrades and troubleshooting. Enforcing robust backup and disaster recovery systems are pivotal too. External solutions, such as services or outsourced providers, generally involve subscription or operation fees. These costs can vary depending on factors such as the quantum of samples stored, timing, data transfer and fresh services required. External archives frequently give scalability and inflexibility to acclimate storehouse requirements as your conditions change. These costs can vary based on the storage capacity needed and the scalability requirements. Comparing the costs between internal and external options depends on factors similar to the scale, storehouse conditions, staffing capabilities and specific budget constraints. It is judicious to precisely estimate both options and consider the long-term costs, scalability, data security and compliance implications before making a decision.

In [figure 1](#), we have synthesised the hypothetical qualitative direct and indirect costs for the implementation of a tracked

archive of a medium-size lab (around 20 000 cases per year, around 100 000–120 000 slides and 80 000–100 000 blocks).

A possible quantitative simulation of the costs for an in-house solution should consider:

- ▶ Personnel staff: €30 000/year (archivist).
- ▶ Equipment for storage: around 200 000 (closet with controlled temperature $<27^{\circ}\text{C}$ and humidity $>30\%$ and $<70\%$, carts, spares).
- ▶ Local space costs: according to a Regione Piemonte's (Italy) survey, unitary standard costs for the creation of a non-sanitary local space correspond to €1.79 507/m². Calculating a contextuality coefficient of 0.65, the realisation costs should be around €1.16 680/m². The average volume for archives is around 5% of the total hospital planimetry. The annual maintenance costs are around €100/m².²¹
- ▶ Furnishings: €30/m².
- ▶ Archiving process costs: calculating an average time of around 10 min/case (including the access to an archive in proximity of the pathology department, research and visualisation of slides/blocks, tidying up) with a staff annual costs of €30 000, 200 job days, the minimum costs is €3.5/case.²²

Alternatively, outsourced solutions are developed using rent and subscription fees including specific packages for slides handling/recovery. Contracts should include differential costs for just canned versus scattered samples, identified versus randomly piled boxes, dusting, washing, disinfestation. Urgent recovery provides additional fees. Finally many contracts do not specify the management of the entire archive at the end of the agreement and do not plan any digitisation project of the slides.

The final examination of the process should consider unpublished reports signalling the possibility of around thousands of euros spent for the reparation of a block-loss by administrations

in cases of legal controversy with medical repercussions for patients.

NEXT GENERATION ARCHIVES ERA

Automatic archiving in pathology refers to the process of digitally storing and managing pathology-related data, including patients' samples and not only laboratory test results, images and reports.^{23 24} This approach should provide a more efficient and secure way to access and retrieve samples. The implementation of automatic archiving in pathology may change the general preanalytical and postanalytical workflow of the lab, especially for technicians.²⁵ A digital conversion of the existing methods is based on a robust and secure, modern physical infrastructure. A dedicated DMS should be implemented to approach features such as indexing, search functionality, version control and access controls ensuring proper organisation and efficient retrieval of the samples. The automatic archiving system should have high interoperability parameters, being integrated with the existing LIS, allowing seamless transfer of data between systems. This integration ensures that every phase of the archiving process is automatically associated and linked to the corresponding patient records. Authorised personnel, such as pathologists, laboratory technicians and clinicians, can access the digitised records through secure authentication methods. Proper training for staff members on archive usage, data retrieval and management should be important too. So, the final costs can include training programmes, documentation development and user support.^{26 27} Borrowing from the previous experience of other imaging specialists (eg, radiologists), this type of progressive digital transition should allow our departments to progressively abandon the glass slides (and with them the relative physical storage), relying on the surrogate presence of digital files that represent the matrix on which the diagnosis is rendered. In this direction, the potential increased costs for maintaining both physical and digital archives should be envisioned as starting investment that should be progressively amortised in the longer period. This topic has already been covered by the Digital Pathology Association (DPA) in their proposal of business case for the digital pathology transition, dissecting the components of direct and indirect costs that should be taken into account when estimating the ROI of such transformation (eg, shipping costs, overhead costs and workforce efficiency).²⁸ This is further stressed by the recently proposed recommendations of the European Society of Digital and Integrative Pathology, that released a vademecum of all the steps that should be followed by single laboratories that want to go digital.²⁹ Once the digital facility is set up, the benefits of this transition (from the primary diagnosis, the telepathology capabilities without costs of slide shipping, education and multidisciplinary team discussions, as well as implementation of computer aided diagnostic tools) can be fully exploited in our laboratories.

ARCHIVES IN PATHOLOGY: THE LEGAL PERSPECTIVE

The most recent data show that in Italy there are 300 000 lawsuits pending against doctors and health facilities, while claims for compensation for biological damage are 35 000 every year.³⁰ The Italian regions, in the first half of 2023, have incurred payments of €159.5 million, following executive sentences in administrative or civil cases who have seen them directly involved.³⁰ Tuscany leads the ranking of the public health systems most 'accustomed' to disputes and unfavourable sentences with a per capita expenditure of €7.54, resulting in an outlay, in absolute terms, of €28.1 million, immediately followed by Sicily with an

expenditure of €6.57 per inhabitant (€32.6 million) and Calabria with €5.97 of legal expenses per capita (€11.5 million). Lastly, to complete the grouping of health systems, two other territorial realities: Puglia and Abruzzo with an outlay for disputes, litigation and unfavourable sentences, respectively equal to €4.54 (€18.2 million) and €4.05 (€5.3 million) per inhabitant, respectively.³⁰ In this setting, legal departments have estimated that on average around 15% of these sentences are related to archiving and handling issues of pathology samples. Thus, enforcing archives in pathology comes with legal considerations and implicit pitfalls that need to be addressed to ensure compliance with applicable laws and regulations. It is important to apply reliable security measures to cover the confidentiality and integrity of the archived data, including encryption, access controls and data breach response protocols. Case concurrence and authorisation are pivotal for the storehouse and use of samples both for routine purposes or biobanks in research protocols. In some cases, patient data may be deidentified or anonymised. In case of legal disputes or litigation, archived pathology data may be subject to e-discovery, which is the process of identifying, preserving and producing electronically stored information as evidence. It is essential to have applicable mechanisms in place to ensure the integrity, authenticity and admissibility of archived data in legal proceedings. Legal costs and the implicit loss of samples are significant enterprises in pathology practice. Pathology labs may face the threat of malpractice suits if there are allegations of individual crimes, delayed judgments or indecorous running of samples. Legal costs can include attorney freights, expert substantiation fees, court freights and implicit agreement or judgement costs. If the pathology lab is involved in research or development of new testing methods or technologies, protecting intellectual property rights through patents or trademarks can involve legal costs, including attorney fees and filing fees. Loss of pathology samples can have serious consequences for patient care, including potential delays in diagnosis, treatment decisions or the need for repeat procedures. The impact on patient outcomes and potential legal liability can be significant. In cases of sample loss, there may be a need to repeat tests or procedures to obtain new samples, which can lead to additional costs for the patients, healthcare providers or insurance companies. Sample loss incidents can damage the reputation of the pathology lab, potentially resulting in a loss of trust for the entire institution from referring physicians, patients and the broader healthcare community. Establishing and maintaining robust quality assurance programmes minimise the risk of errors, misplacements or sample loss. Developing and following standardised procedures for sample running, shadowing and storehouse to ensure proper sample identification reduces the threat of loss too. Providing comprehensive training and education to the staff on proper sample handling protocols guarantees quality control measures, and compliance with non-supervisory conditions. Implemented risk management strategies, such as thorough documentation, incident reporting and carrying appropriate liability insurance coverages, mitigates potential legal costs. A regular review and update of the procedures, technology and structure may insure the loftiest position of sample integrity and security. In particular, FFPE samples are valuable clinical resources for examining relevant morphological features, and they are routinely preserved after pathological diagnosis. Formalin enables the long-term storage of specimens, preserving their morphological features. However, the quality and quantity of the information from FFPE samples are often suboptimal, as fixation in formalin is known to damage many antigens, in addition to the induction of molecular cross-linking of protein. Improving the preservation of our FFPE

archives would finally allow us to guarantee the best sample preservation, which can positively impact on the final patients' disease treatments (eg, discovering new biomarkers for targeted therapies), improving life expectancy and reducing the risk of early disease recurrence or side effects.

CONCLUSIONS

Currently, a new emergent feeling in the pathology laboratory is growing for archives management; the digital pathology era is a great opportunity to apply innovation to tracking systems and samples preservation. A greater involvement of scientific societies to produce specific surveys may be crucial to give to the administrations an evident proof of the necessary investment for improving not only quality, efficacy and efficiency of the labs but also patients' healthcare.

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