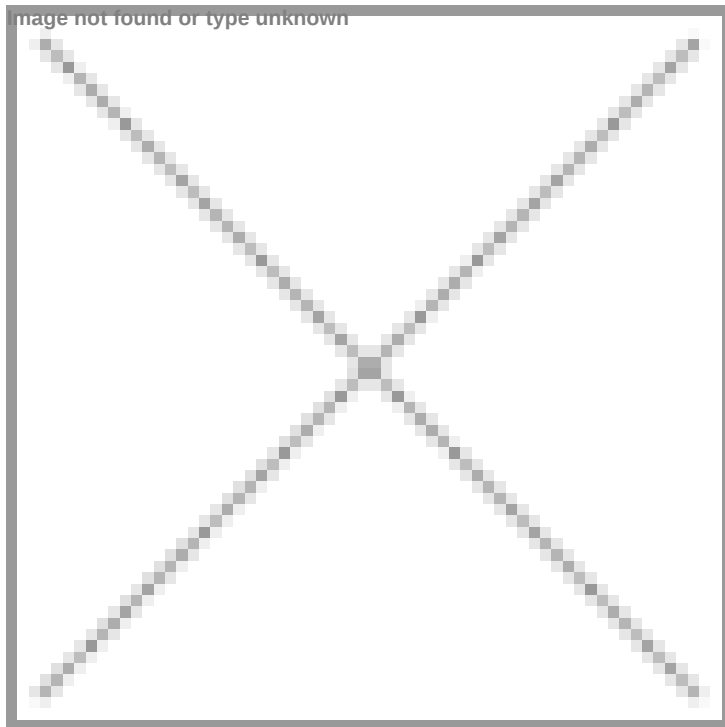


Technology Advancements: Digital Pathology

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Healthcare is perhaps the only sector which remains impervious to technology advancements, though things are changing at a pretty fast speed.

Digital pathology involves the scanning of whole histopathology or cytopathology glass slides into digital images interpretable on a computer screen, along with data management, translates to additional functionalities such as web accessibility, annotations, automated image analysis, and a host of breakthrough applications in the practice of pathology, and health care systems as a whole.

Digital Pathology vs conventional pathology

Traditional pathology workflows have innate delays built into the processes. Transferring unique glass slides runs the risk of loss, and when collaborating with others requires time, which delays diagnostics.

"Digitizing images that are normally viewed through a microscope can help improve the operational efficiency of a lab. Direct access to files can make diagnosis - in particular consults - simpler, more efficient and safer. It lowers barriers for internal and external consults, and can be done more quickly since colleagues can view the same case at the same time. This all can help increase the quality and speed of the lab. Furthermore, a digital workflow is the prerequisite and first important step to unlock the huge potential of future digital analysis in pathology," said Mr Hans Driessen, Marketing & Communications Manager, Philips Digital Pathology Solutions.

Virtual slides can be transmitted from remote locations for review by pathologists and for second opinions. This is even more beneficial in cancer diagnosis. The conventional method involves transportation of the slides to avail the opinion of the experts and this has a direct impact on the time taken for diagnosis.

"Digital pathology has made it easy to obtain second opinions from the experts, across geographies, without transporting slides. This facilitates faster reporting. The only prerequisites are the scanned digital images and a good internet speed! This innovation brings several advantages to all the different stakeholders associated with an anatomic pathology lab. Pathologists can provide faster consultation and diagnosis, while clinicians see a faster turnaround time for referrals. The histotechnologists benefit due to the improvement in efficiency on account of reduced glass slide movement," said Dr Sandeep Sewlikar, Head - Medical & Scientific Affairs, Roche Diagnostics India.

Digital pathology also plays a key role in education, by providing an interactive learning environment. Virtual slides are single (although complex) giant images, they can be placed on a server with a URL and thus can be used in Web-based education.

"Imagine changing the teaching methods from the conventional methods of reading each slide under a microscope, one student at a time, Vs the use of a digital image with zoom, pan, annotate, crop feature in a classroom on a projector wall. The same concept can be easily extended to tele-pathology, and hence increase the reach of a pathology lab and closer to areas which lack full fledged Pathology labs and qualified Pathologists," said Mr Prasanth Perugupalli co-founder and CEO at Spectral Insights.

Adoption in the developing vs developed world

The adoption of this technology is at a rather slow pace. The reason for the delayed adoption is primarily linked to the need for investment, as the high-end, whole slide imaging (WSI) scanners are expensive. Since the image sizes are also huge (ranging from a few MB to several GB) the image storage servers also contribute to further increasing the overall investment cost.

"Western world had adopted digital pathology for several years now, driven initially by insurance mandates as well as lack of skilled manpower. As the advantages of digital pathology started to become more and more evident, there has been a tremendous push towards digitization becoming a de-facto standard," said Dr Sewlikar.

He added, "However, there are still no standards for digital pathology in lines of digital radiology. Also, the systems made to address the primary drivers as stated above have been very expensive due to heavy reliance on robotics and automation."

The new generation WSI scanners are fast and specifically intended to facilitate complete digitization within the lab. This has encouraged faster adoption. The advent of high computer processing power, improved storage capability at reduced costs, high data transfer speed due to improvement in internet services are all facilitators to early adoption.

In the developing world, the problems and challenges are different.

"The emphasis is on lowering the test costs while providing accurate analysis. The systems built for western world have not been successful in finding markets in the developing world because of high pricing as well as stringent environmental requirements for cleanliness, conditioned labs, etc. Also, the servicing of such equipment is a concern," stated Mr Perugupalli.

Due to these constraints, and also the historical lack of mid-high tier computing and networking capabilities at Pathology labs and hospitals, Digital Pathology has remained at a nascent state for several years now.

"The opportunity is for the developing world to take a big stride in healthcare by embracing digital pathology to bridge the gaps in coverage and quality between the few central labs in large cities and the rest of the labs elsewhere across the country," said Mr Perugupalli.

Digitization involves a mindset change, that demands moving from microscopes to monitors for diagnosis and this is also one

of the reasons for delayed adoption.

"Studies have shown that the attitude of the pathologist towards the digital workflow is important. For more than a hundred years pathologists have been working with the conventional microscope, so the most difficult part is to learn to trust the digital image," said Mr Driessen.

He continued, "The digital transition of the pathology workflow is much more than a technical experience, and change management is key to be successful. Education and user-training, together with the digital pathology vendor, can help. Though the old way was good, the new way knows no boundaries. While working with the digital workflow, it will show pathologist what this innovation means to their profession."

Digital Pathology makes tele-pathology a reality, and fills holes in the basic infrastructure prevalent in the developing world. It raises quality of services, while raising productivity of the specialists. These factors, coupled with innovative business models are expected to make digital pathology wide-spread in the developing world. However, to achieve this goal, systems need to be designed keeping the local conditions in mind, and a one-size-fits-all solution has less likelihood to be successful.

Limitations of WSI

The biggest limitation to widespread adoption of WSI has been cost. High end microscope with automated scanning stage is needed, and also large amount of storage and image processing software is required to perform WSI.

"WSI can be used to review histologic sections, cytology slides, and/or hematology slides to render diagnosis. Validation of WSI is crucial to ensure that diagnostic performance based on digitized slides is at least equivalent to that of glass slides and light microscopy. Currently, there are limited standard guidelines regarding validation of WSI for diagnostic use," said Dr Sewlikar.

Mr Driessen added, "Until now, there has been little public guidance provided to the industry with respect to the regulatory route in the United States. Through close collaboration among all the benefactor members of the Digital Pathology Association (DPA) including Leica Biosystems, Omnyx, Philips and Roche, the industry was able to work with the FDA to gain valuable clarity and guidance."

New systems are being proposed around the world to bring digital pathology and WSI to neighborhood labs, while making compromises on some aspects that are specific to demographics.

Digital Pathology for Personalized Medicine

The use of digital pathology has the potential to enhance the pathologist's contribution in the successful development of personalized targeted therapy. One of the components of personalized medicine for cancer patients includes the standardization of biomarkers for identification of a molecular target, and the application of an effective therapy against it.

"In Digital Pathology, there are inbuilt quantitative companion diagnostic algorithms that help in selection of patients for targeted therapy. For clinical laboratory applications, the confidence levels for reporting is further enhanced if these algorithms are backed by regulatory approvals like the FDA," said Dr Sewlikar.

Personalized treatment options demand a more confident diagnosis. Collaborative involvement to obtain and integrate relevant information from different disciplines is necessary to achieve this goal.

"Developing an effective treatment plan requires access to related patient information from multiple sources (EMR, LIS, PACS). The development of specific algorithms for automated interpretation of advanced stains will facilitate the objective analysis of images. By developing advanced algorithms and data management systems, we can help researchers translate the 'Big Data' promise into knowledge," said Mr Driessen.

With digital images, the ability to run many Software tests as you can on the same images provides the potential to flag any abnormalities that weren't prescribed for testing at the current time. This has the potential to discover and alert conditions that may be at nascent stages and yet to cause a noticeable physiological change to the patient.

"Based on digital images obtained from a number of specimens, new predictive insights can be drawn that have a bearing on demographics, socio-economic and environmental conditions, leading to actionable outcomes from personal as well as public health level," said Mr Perugupalli.

Although Digital Pathology was primarily intended for second opinions and consultations, the biggest benefit it provides is in terms of improved workflow management in the anatomic Pathology lab.

While embarking on a journey of digitization, it is important to identify an industry partner who can provide the requisite high speed scanners and also support entire journey from IT integration to efficient image & workflow management. Ultimately this

digital pathology workflow will help to increase service levels to physicians, reduce cost and improve care.

Some of the products available in the market:

Philips IntelliSite Pathology Solution

Aperio Digital Pathology Slide Scanners by Leica Biosystems

Omnyx IDP Solution by GE healthcare

Roche Digital Pathology Solutions