

Whole Slide Imaging At CellNetix

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CellNetix has been using telepathology effectively since 2007. Our pathologists all have special digital cameras on their microscopes and can both capture images, and quickly and securely share a live microscopic stream with a colleague regardless of location. This has positive patient care benefits, for example, our single pathologist in Aberdeen, WA has the subspecialty depth of the 50 other pathologists in Washington and Alaska at his fingertips - a virtual pathology expertise pool. This technology is used for second

opinions only and the primary diagnosis is always based on examination of a glass slide under the pathologist's microscope.

Early in 2012 we invested in a related, but quite different technology - Whole Slide Imaging (WSI). As opposed to telepathology where one views a live capture of the slide on the microscope, WSI uses an ultra high resolution scanner to image the complete slides and store them digitally. These very high quality images are then available to any pathologist on our wide-area-network. The images are quite large, frequently more than a gigabyte and take about two minutes per slide to create. File transit time over the network is not a huge issue as the viewer software only transmits what is on the screen rather than the whole file. At CellNetix we create thousands of slides a day so cost of storage is an important consideration. We currently only scan a small subset of those slides.

Why do this? Unlike radiology that moved from film to PACS (Picture Archiving And Communication System) in the 1990's there is no immediate financial benefit for pathology groups to digitize their slides. Radiologists were able

to use significant cost savings from the reduced use of film to finance investment in PACS systems. In pathology the glass slide must still be created and we are adding a step rather than eliminating one. Additionally, there is no reimbursement for routine digital imaging and only marginal increased reimbursement for digital image analysis of a small number of immunohistochemical stains and therefore no financial benefit. The devices are expensive - approx \$200,000 for a mid-range system. After an internal evaluation process we still approved investment in WSI for the following reasons:

Distributed expertise

CellNetix recently began providing pathology services to a hospital in Alaska and in Spokane, WA. We have two pathologists stationed at our offices in Palmer, AK which is about 45 minutes from Anchorage and have five in Spokane (we are merging with a local group). Although certain complex and esoteric tests (IHC and special stains) will be performed in Seattle, for service reasons we will test most specimens at the local labs in each of these locations. Being

able to scan the resultant slides in Seattle for digital read by our remote pathologists allows us to keep the pathology local without delaying diagnosis. The glass slide is typically reviewed the next day. At CellNetix our stated vision is “*To rethink, redefine and reset the standard of care for pathology groups and laboratories in the country*”. We believe that effective use of digital pathology including WSI can remove logistical barriers and allow us to provide first rate, timely care in locations where this might not otherwise be 100% feasible.

Image analysis

Physicians who become pathologists are very good at pattern recognition and image analysis. In some cases where there are exceedingly complex pattern recognition tasks, an image analysis algorithm can produce results sooner and more consistently. We recently validated our WSI system for use in IHC HER2/neu (Immunohistochemistry Human Epidermal Growth Factor Receptor 2) related testing - this is generally used as part of breast cancer diagnosis. Our pathologist will select an area of interest on the digital image, the software will isolate the cell membrane and then measure consistently and accurately the signals from relevant cells without a human judgment call. As digital pathology evolves, we can expect more effective image analysis algorithms to become available. This is most likely to be the most beneficial aspect of digital pathology,

allowing faster more accurate diagnosis in conjunction with a pathologist’s interpretive expertise.

Conferences

CellNetix is a hospital focused pathology group. Every year we participate in hundreds of case review conferences with other specialties so that patients can benefit from collaborative and informed care. If the conference is held at our premises, we can provide a microscope with a projector and use the actual slides. If located at a partner hospital, we generally have to take microscopic photos and transport them as image files on secure thumb drives. Our WSI software includes conference management software which allows scanned slides to be reviewed securely over an internet connection and includes various annotation and comparison tools. The image quality is as good as that of the glass slide and allows remote panning and zooming. In addition, we can host ad-hoc conferences with client clinicians who want to review slides with a pathologist.

Learn the technology

We also felt that while WSI was not fully mature, that as one of the largest physician owned pathology groups in the country we needed to proactively engage with the technology to help it get there. Learning how and where it worked well and not so well would ultimately allow us to incorporate it into our future operational and expansion plans.

FDA

In 2011 the Federal Drug Administration announced their intention to classify WSI devices as Class 3 medical devices - their most stringent standard - and regulate them as such. WSI systems cannot currently be used for primary diagnosis. Pathologists opinions vary but many feel this regulatory standard is excessive and somewhat counter productive. This increased regulation will most likely drive some development and early adoption use to Canada or Europe.

What we have learned so far

We spent 6 months validating WSI for use in our diagnostic processes. We are now at the point where it is in daily use for digital IHC reads by pathologists at remote locations. This means that final diagnoses can be delivered up to 8 hours sooner so there is a direct patient care benefit and in some cases hospital stays may be reduced resulting in lower costs for our hospital partners. We have used it in hospital conference situations and it has been well received. We are just starting to use WSI for HER2/neu diagnosis after a lengthy validation (comparing diagnosis by glass slide vs. digital image for many cases by different pathologists. There has been little direct financial benefit. In fact, it has increased our costs. Ultimately our pathologists agree that for primary diagnosis looking at glass slides under a microscope is superior. The movement of the slide across the microscope stage and the ability to almost see cells in 3D by rapid focusing are valuable diagnostic elements that are hard to emulate digitally.

The future

Digital imaging will be an important element in the evolution of pathology. It will enable diagnostic delivery across regional and international lines. Ultimately, we believe it will allow the average pathologist to more accurately diagnose a higher volume of cases by reducing the

amount of slides that he/she needs to look at - more or less as image guided microscopy has already been used in Pap smear diagnosis etc. This is important in the face of healthcare reform and the aging US population. Like healthcare in general, pathologists will have to do more with less. As technology advances, image analysis will allow

accurate diagnosis in situations where a human would find it difficult. The technology is still emerging and our estimate is 5 years to relative maturity. Though it has already helped us provide better patient care in several ways, we are still learning how it can be most effectively used.

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