

The Role and Financial Implications of Digital Pathology for the System Health

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Abstract

Public health system is under great pressure to cope with old and new threats which can have different causes. Progresses regarding methods of diagnosis and treatment options pushed the pathology filed to move forward. The aim of the present study is to analyze the impact on finances secondary to introduce digital analyses of whole slide imaging in the pathology laboratory workflow and the effect of digital pathology on health care system from the economical point of view. Digital pathology embraces the present and future economical traits providing a faster, better, efficient and accurate method for earlier depicting of different chronic medical conditions. Based on forecasted trends, anatomical pathology laboratories must do the effort to deployment a digital pathology system and must have an overview when considering the return on investment. In time, the revenues will be enough to consider digital pathology system a successful business model.

Key words: digital pathology market, whole slide imaging, virtual microscopy, business model

J.E.L. classification: I15, M15, M21

1. Introduction

Public health system is under great pressure to cope with old and new threats which can have different causes. Numerous factors may influence the performance of the health-system which resides not only in a better and quickly diagnosis or a tailored therapy, but also in the presence of enough human and capital resources. Informatization of the healthcare have being and is an important issue for many countries and huge funds have been allocated to develop and to improve this domain, which brings great benefits for the patients, doctors and ultimately for society. Nowadays, information management is a constant presence in the daily practice of medicine and is a “must have” for many hospitals around the world. It is involved in many aspects: from individual patient to public health management.

Pathology is defined as “that branch of medicine which treats of essential nature of disease” (www.medicinenet.com). It is an important tool for medicine which provides a diagnosis for surgical specimens. Oncology is one field of medicine in which the role of a pathologist is crucial

for established a correct diagnosis and the specific treatment for patients. There had been huge progress in improving the prognosis of this patients by applying principles of personalized medicine, in which specific drugs are recommended based on different molecular features. These specific morphological and molecular features of a tumor can be unravel based on special techniques of pathology (e.g. immunohistochemistry) or molecular techniques (e.g. chromogenic in situ hybridization, fluorescence in situ hybridization). The main goal of "tailored therapy" concept in medicine is to provide the correct drug and dose to the patient at the proper time, based on cancer tests, known as companion tests which can characterize a tumor from multiple points of view: the DNA, the RNA and protein levels (Walk, E.E. 2009). All these tests provide essential information to the clinicians which will help them to predict which treatment scheme is best for the patient.

2. Theoretical background

Progresses regarding methods of diagnosis and treatment options pushed the pathology filed to move forward in order to be able to provide answers to all variables which may influence the prognosis of the patients. So, from primary tasks (diagnosis, classification and subclassification of tumors), the pathology laboratory is now responsible for providing important prognostic features of the tumor for an individual person. In the present, the pathology filed has a huge impact on personalized medicine paradigm and it is directly responsible for the quality of life of a patient undergoing cancer treatment. The shift from general therapies to personalized medicine targeted for individual patient implied also high costs in all the steps required to reach to the final diagnosis and to initiate a proper therapy. For this reason, digital pathology emerged two decades ago as a new tool in the service of pathology lab to improve the quality of medical reports and to enhance the researches studies.

In radiology department, image digitalization is already successfully implemented and proved its utility, but digitalization of usual slide of pathology laboratory proved to be a difficult task. Digital pathology means that high resolution images are captured from scanning the entire morphological, usual slides and visualized them on the monitor. The process of acquisition, processing, analyzing and storage of these images is defined as "virtual microscopy" or "whole slide imaging" (WSI) and it was possible due to innovation and developing the scanners machines (Felten C.L.1999). The first virtual microscopy was announced in 1997 by the Computer Science Department at the University of Maryland and the Pathology Department at Johns Hopkins Hospital, Baltimore, Maryland (Afework, A. 1998; Consolato, M.S. 2019). Since than many vendors came up with new, better, faster machines which are capable to scan many slides in a relatively short of time and with a high quality of the images obtained. In the same time, different software solutions have been developed to analyze de whole slide images using artificial intelligence which eventually bring a great value to scientific world and to the patient by providing tools used in the management of the oncologic or other chronic patients.

3. Research methodology

In the present study we analyzed the effect of digital pathology on health care system from the economical point of view. In order to reach this goal, we used as a research methodology an indirect method by analyzing secondary data selected from specialized literature and from internet resources. Our research is a descriptive research, presenting the facts identified and mentioned in the references. Also, it is an observational and transversal type of research by synthesizing the results regarding the impact on finances secondary to introduce digital analyses of whole slide imaging in the pathology laboratory workflow.

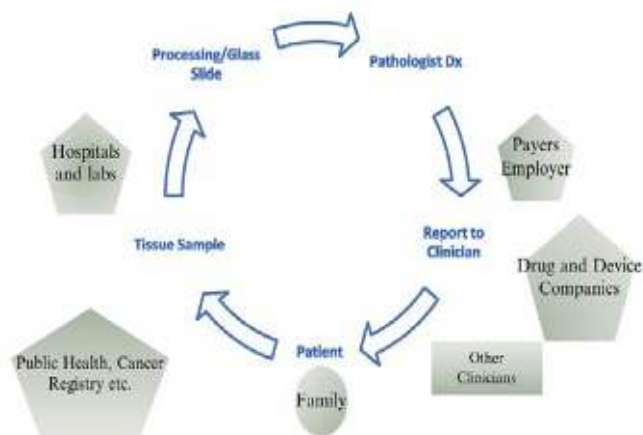
4. Findings

Precision medicine implies many financial resources in order to deployment this new way of therapy management. This is a continuing growing field and there are needed many new or ongoing technologies in order to fulfill all the tasks required by the target therapy. The goal is sometimes

difficult to reach and one of the most requesting action is to deliver a system of health information. Its complex data base can allow an access to an integrated health care system, so the physicians, having access to all clinical, para-clinical, imagistic or socioeconomic data, can make the correct decision regarding the therapy for their patients. Huge financial resources had been available in many countries through different health care programs to support this vision of health care management – an information technology (IT) systems – which ultimately represent a strong foundation for the development and providing new methods of intervention (Peter, J.E. 2019). In 2015, president Obama launched in SUA a special program – Precision Medicine Initiative - with the aim to “accelerate biomedical discoveries and provide clinicians with new tools, knowledge, and therapies to select witch treatments will work best for which patients” with a \$213millions budget (www.nih.gov, 2015). Other initiatives were successful like “the Health Care System Collaboratory” or Patient-Centered Outcomes Research Institute (PICORI) were different networks were integrated in health services organizations (Terry, S.F. 2015).

There are many stakeholders involved in the health care system and anatomical pathology laboratory are playing in important role (Figure no. 1). In beginning, digital pathology was used for education and for different presentations on pathological or clinical conferences. It was also used as useful tool for research and for external quality control. In time, it was introduced into the process of pathological diagnosis for both intraoperative consultations, known as frozen sections, and expert diagnosis for a secondary opinion (Hassell L.A. 2016). Telepathology, defined by the College of American Pathologist as “the practice of pathology, in which the pathologist views digitized or analog video or still image(s), and renders an interpretation that is included in a formal diagnostic report or documented in the patient record”, is another important feature of digital pathology which proved its effectiveness (Williams, S. 2010).

Figure no. 1. Stakeholders involved in the health care system



Source. Hassell L.A. in Digital Pathology 2016, Kaplan,K.J., Rao, L.K.F. (eds.),p 36

The present and the future changes in the medical specialty of the pathology come with a shift in the technological workflow. As Food and Drug Association (FDA) approved in 2017 the first digital pathology system and whole slide imaging in USA to be used as an instrument for primary diagnosis, pathology laboratory and doctors with this medical specialty must eventually embrace these changes. If implementation of digitalization process in the radiology medical field brought advantages not only for the medical world but also from financial point of view, in pathology lab this is not a smooth pathway. The deployment of digital pathology system in a pathological lab does not skip steps or reduces costs in the same way as it was in radiology digitalization process (Patterson ES 2011).

A digital pathology system includes scanners, software, storage and communication systems, and all of them must be underpinned by consistent financial resources. But, despite all these costs the evolution of the digital market is in expansion and the offer is better each year since all components are improving and new vendors are in a productive competition. Digital pathology market was evaluated between US\$ 400millions (Mn) and US\$ 450Mn for 2018 by the Industry

Analytics, Research and Consulting (IndustryARC) in business (www.industryarc.com), US\$ 767.6 million in 2019 as was stipulated in the Market Analysis Report entitled “Digital Pathology Market Size, Share & Trends Analysis Report By Product, By Application (Drug Discovery & Development, Academic Research, Diagnosis), By End Use (Hospitals, Clinics), And Segment Forecasts, 2020-2027” (www.grandview-research.com) and US\$ 613Mn in 2020 according to data provided by MarketsAndMarkets report (www.marketsandmarkets.com). These financial resources were higher than US\$ 389.7millions evaluated for 2017 by the Insight Partners market research study which was named “Digital pathology Market to 2025 – Global Analysis and Forecasts by Product, Application and End User” (www.theinsightpartners.com). These results reflect the continuous expansion of this specific market of medicine. The forecast of global digital pathology market is much higher and variable according to different studies. The prediction is US\$ 992.1Mn for 2026 according to the Insight Partners study and up to 1,139Mn for 2025 as is mentioned by MarketsAndMarkets report (www.marketsandmarkets.com). The forecast grows predicted by the compound annual growth rate (CAGR) is variable depending the group study but this growth trend is still maintained. The CAGR is 7.7%-8.5% going from 2018 through 2025 (www.industryarc.com), o11,8% from 2020 to 2027 (www.grandviewresearch.com), or 13,2% during 2020 and 2025 (www.marketsandmarkets.com).

North America is recorded with the biggest part of digital pathology market (Figure no. 2) and is the leading marketplace as in 2018 represents 38%- 40% from it (www.industryarc.com). In the future, North America will continue to be on the first place since the number of new cases of cancer is going to be increased from more than 1,7 million in 2018 to 20,3 million by 2026 according to data provided by the National Cancer Institute, almost 95% of them being diagnosed by pathology department (www.cancer.gov). Many academic-based health care or other hospitals from USA fully installed this new system and according to the National Center for Biotechnology Information almost \$18 million have been estimated to be saved in 5 years (www.industryarc.com). The second largest digital pathology market is represented by Europe with a higher weight in United Kingdom, France, Germany, Denmark and its forecast growth is 12.9% CAGE from 2017 to 2025 (www.theinsightpartners.com). But there is an increased focus also for developing countries in Asia, like China and India, which offer an open land for implementing digital pathology system sustained also by increasing number of population (www.marketsandmarkets.com). In general, this overall increasing demand is mainly due to increase number of cancer cases or other chronic disease for which there is a huge demand for accurate and faster diagnosis combined with improving the quality and efficiency of the workflow of the laboratories. In the same time, there is an astonished development of the scanners devices and image analysis through highly advance computerized system which involves artificial intelligence and deep learning algorithms.

Figure no.2 Distribution of digital pathology market in the world by regions



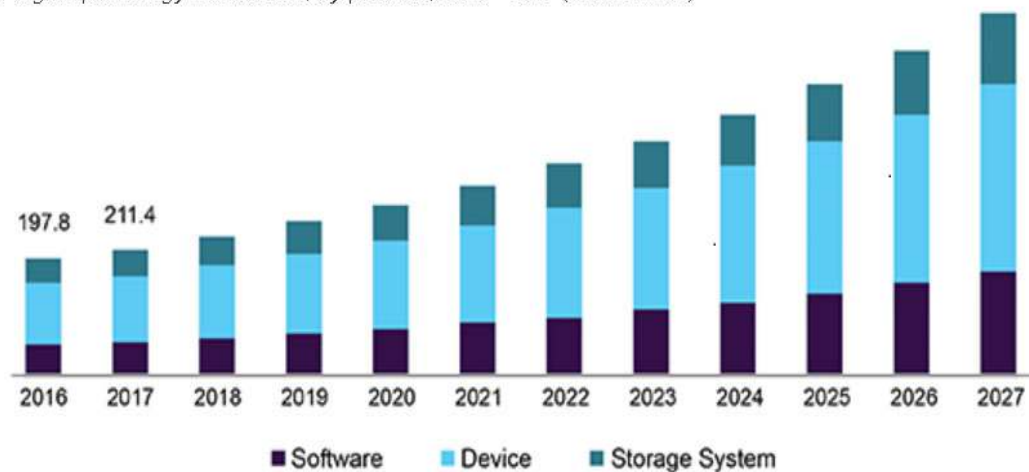
Source: <https://www.marketsandmarkets.com/Market-Reports/digital-pathology-market-844.html>

Digital pathology market can be divided by product, by application or by end user. The market based on products includes scanners devices (hardware component), software, storage and communication systems and the forecast for this segment is 1.6 billion of dollars by 2026 invested in SUA (Figure no.3) (www.grandviewresearch.com). From this point of view, the largest part of the market is occupied by the scanners and this branch was leader on the market in 2019. However, the software solutions are those who will dominate the market in the next decade due to more professional informatic programs design to overcome all the problems encountered in digital images analyses and to fulfill the needs required by tailored therapy and drug discoveries.

The market of digital pathology based on its application is in continues expansion as it is involved in disease diagnosis, teleconsultation, training and education. Nevertheless, drug discoveries are consider to be the next most important application which will be also an important source of revenue (www.marketsandmarkets.com). Actually, the forecast growth for drugs discovery and development is the greatest with a CAGR of 4.2%-4.8% through 2025 (www.industryarc.com). Because of this, from the point of view of end user classification, pharmaceutical and biotechnological companies will most benefit from digital pathology. There is huge interest for established new connections between pharmaceutical researches and digital pathology as precision medicine is the current trend for oncology. Other end-user which can benefit are educational institutes, academic institutes, hospital and diagnostic centers all them representing a growing market.

Figure no. 3 The distribution of digital pathology market based on product in USA

U.S. digital pathology market size, by product, 2016 - 2027 (USD Million)



Source: www.grandviewresearch.com

Source: <https://www.grandviewresearch.com/industry-analysis/digital-pathology-systems-market>

There are many opportunities to increase the return on investment mainly because there are direct and indirect cost reductions. The direct cost reduction can be those for shipping cost or overhead cost when a second opinion is required. Another important direct cost reduction is the improvement of workflow efficiency in a pathology laboratory as digital pathology can be easily integrated in a laboratory information system and a lot of preanalytical, postanalytical and analytical problems can be minimized by this system. Indirect cost reduction can be due to improved communication with health care team and being part of the precision medicine concept. On the other hand, there are also revenue opportunities like increasing the number of cases or cases in consultation by receiving them from other, far distance, national or international laboratories. Image analyze by artificial intelligence and computational pathology can also be a source for income by itself since the huge data base obtained by digitalization of slides can be used in partnership with pharmaceutical and biotechnology industries to be more involved in personalized therapy. The importance of digital pathology will increase in the next several years also because there is a global tendency of reducing the overall number of specialists in pathology, especial in low income countries.

Nowadays, there are several laboratories which have a digital pathology system fully integrated in an informational system. A recent report of Hanna M.G. et al (2019) described the experience and the results of the implementation of such a system in the pathology department at Memorial Sloan Kettering Cancer Center (MSKCC) from New York (USA) during 5 years (2014 – 2018). The savings were more than US\$267 000/year and the prediction for cost savings through 2019 – 2023 were UD\$1.3 million (Hanna, M.G. et al. 2019). Their experience led to the conclusion that a digital pathology system increases the efficiency and reduced the errors in the laboratory, improving the daily work flow.

5. Conclusions

Digital pathology embraces the present and future economical traits providing a faster, better, efficient and accurate method for earlier depicting of different chronic medical conditions and to initiate a tailored therapy for patient. One of the most important cause which slow down the digitalization process in a pathology laboratory refers to the costs. But this issue must be overcome in order to meet the new demands and requirements from the medical society. Based on forecasted trends, anatomical pathology laboratories must do the effort to deployment a digital pathology system and must have an overview when considering the return on investment. In time, the revenues will be enough to consider digital pathology system a successful business model. The huge progresses made in digital pathology system, digital imaging and computerize pathology contributes to growth of this segment of the market. A failure in implementing this "high-tech" service for pathology workflow will be responsible for not providing the newest facilities for both patients and academic world, like image analysis, virtual tumor boards, telepathology and drug discoveries.

6. Funding

This work was supported by University "Ovidius" Constanta, Romania, through the grant number 5/14.11.2018

7. Acknowledgment

This research was performed in the Center for Research and Development of the Morphological and Genetic Studies of Malignant Pathology from the "Ovidius" University of Constanța, POSCCE 2.2.1. Project ID: 1844, code SMIS:48750, CEDMOG, contract 627/11.03.2014.

This work is sustained by the project ANTREPENORDOC, in the framework of Human Resources Development Operational Programme 2014-2020, financed from the European Social Fund under the contract number 36355/23.05.2019 HRD OP /380/6/13 – SMIS Code: 123847."

9. References

- Afework, A., Beynon, M. D., Bustamante, F., Cho, S., Demarzo, A., Ferreira, R., Miller, R., Silberman, M., Saltz, J., Sussman, A., Tsang, H., 1998. Digital dynamic telepathology-the Virtual Microscope. *Proceedings. AMIA Symposium*, pp.912–916.
- Consolato, M.S., 2019. Digital Pathology: The Time Is Now to Bridge the Gap between Medicine and Technological Singularity. In Cvetković, D. (ed). *"Interactive Multimedia – Multimedia Production and Digital Storytelling"* doi: 10.5772/intechopen.77566.
- Felten, C.L., Strauss, J.S., Okada, D.H., Marchevsky, A.M., 1999. Virtual microscopy: High resolution digital photomicrography as a tool for light microscopy simulation. *Human Pathology*; 30(4), pp:477-483. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/10208472>
- Hanna, M. G., Reuter, V. E., Samboy, J., England, C., Corsale, L., Fine, S. W., Agaram, N. P., Stamelos, E., Yagi, Y., Hameed, M., Klimstra, D. S., & Sirintrapun, S. J., 2019. Implementation of Digital Pathology Offers Clinical and Operational Increase in Efficiency and Cost Savings. *Archives of pathology & laboratory medicine*, 143(12), pp:1545–1555. Available from: <https://doi.org/10.5858/arpa.2018-0514-OA>.

- Hassell, L.A.,2016. Business Models in Digital Pathology Connecting Patients, Pathologists, and Others. In:K.J. Kaplan, L.K.F. Rao (eds.),2016. *Digital Pathology, Historical Perspectives,Current Concepts & Future Applications*. Springer International Publishing Switzerland.
- <https://www.alliedmarketresearch.com/digital-pathology-market>. [Accessed May 10, 2020]
- <https://www.cancer.gov/about-cancer/understanding/statistics>. [Accessed May 3, 2020]
- <https://www.darkdaily.com/even-as-digital-pathology-is-poised-to-be-disruptive-in-primary-diagnosis-most-anatomic-pathology-groups-are-unprepared-for-how-their-incomes-will-change-814/>. [Accessed May 13, 2020]
- <https://www.grandviewresearch.com/industry-analysis/digital-pathology-systems-market>. [Accessed May 9, 2020]
- <https://www.industryarc.com/Report/16354/digital-pathology-market.html>. [Accessed May 3, 2020]
- <https://www.marketsandmarkets.com/Market-Reports/digital-pathology-market-844.html>. [Accessed May 3, 2020]
- <https://www.theinsightpartners.com/pr/digital-pathology-market>. [Accessed May 9, 2020]
- N.I.H. 2017 - *All of Us Research Program*. Available online. <https://allofus.nih.gov/>. [Accessed May 2, 2020].
- Patterson, E.S., Rayo, M., Gill, C., Gurcan, M.N., 2011. Barriers and facilitators to adoption of soft copy interpretation from the user perspective: lessons learned from filmless radiology for slideless pathology. *Journal Pathology Information*.2:1.Published online, doi: 10.4103/2153-3539.74940.
- Walk, E.E., 2009. The Role of Pathologists in the Era of Personalized Medicine. *Archives of Pathology & Laboratory Medicine*. 133(4), pp: 605-610.
- Williams, S., Henricks, W.H., Becich, M.J., Toscano, M., Carter, A.B. 2010. Telepathology for patient care: what am I getting myself into? *Advance Anatomical Pathology*;17(2), pp:130–49.