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Research

The effects of digital workflow control for the performance of routine pathology

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Abstract

Introduction/ Background: Although the scanning technology for microscopic slides has been known for more than 15 years, its practical use in daily routine is still on the very beginning. Fast and reliable scanners enabled their increasing use in teaching, but not yet in consultation and primary diagnostics. So far the scanning is not handled as a process in the pathology laboratory by most of the pathology systems, leading to an interrupted workflow with delays and additional expenses. The requirement pro les for slide scanners can only be formulated with respect to their workflow integration.

Aims: The effects of different degrees of workflow digitalization have been studied as to analyze the sources of possible benefits of digital pathology as well as to identify the bottlenecks and inconsistencies in the workflow control in a routine pathology laboratory. The adherence to existing IHE Technical Frameworks has been evaluated, too.

Methods: Performance statistics of routine pathology were evaluated in different phases of digital workflow control over more than 10 years in a medium-sized institute of pathology. Three phases were defined:
1. Uncontrolled, but digitally supported workflow with digital dictation, digital macrophotography, digital microphotography at few pathology workstations, and a "classic" pathology software system;
2. Digital workflow control including digital dictation and digital photography;
3. In a pilot study at the end of the evaluation period the additional benefits of slide scanning were estimated.

Results: In the period between 2005 and 2015 a decrease of turnaround-time of roughly 20% was seen. Alone the effects of a (sub)total digital workflow control contributed about half of that effect. The implementation of slide-scanning did not add further acceleration so far, but enabled some additional functionality for improving quantitative reporting. This was achieved without an explicit commitment of the pathology software to standards in workflow control and with still leaving a few laboratory processes out of the control. Milestones and key elements of workflow management are reported in detail.

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Conclusion : All processes both in the laboratory and in the diagnostics have to be checked (and changed, if necessary) for being fit in a streamlined pathology workflow. The implementation of scanners into the routine diagnostics will enforce those essential developments leading to increased productivity and quality.

Keywords: Digital pathology, pathology workflow, LIS, IHE profiles, HL7, DICOM, WSI, effectivity.

Introduction

With the growing use of virtual slides in different fields of anatomic pathology the needs for modelling and controlling the entire workflow of the pathology laboratory and of the diagnostic process are also increasing. The pathology report will change from a plain textual document to a digital document with embedded images and embedded procedural information, and will be part of the electronic health record of a patient. Therefore there is a considerable demand both for a fast and reliable reporting to the clinicians and other health care partners and for a straightforward information transfer to electronic information systems outside the pathology departments. The key word for a bundle of solutions for such demands is „Digital Pathology“. Usually, the term is constrained to making virtual slides from traditional histological slides or cytological preparations by means of slide scanners. Recently, however, it is a growing understanding that Digital Pathology is more: the integrative use of information technology in the entire process of a department of pathology. It starts with the organization of the specimens sent by a clinician in the pathology lab and ends with an electronic, machine-readable pathology report which might be based on diagnostics performed on virtual slides supported by technologies for image improvement and pattern recognition. This paper is aimed to study only one facet of Digital Pathology, the Digital Workflow Control.

Material and Methods

Until 2002 the pathology department had not any Laboratory Information System (AP-LIS) at all. It started with a PAS.classic AP-LIS with digital dictation system and integrated macro-camera. This AP-LIS was linked with the Hospital Information System (HIS) by an HL7-Interface for exchange of administrative and performance data as well as for delivering the reports directly into the HIS. The AP-LIS was completed during the following years by 2 microscopic cameras Leica EC3 and Nikon DS-F1, both not directly linked with the workflow. At the end of the year 2014 an upgrade to a NEXUS/Pathologie AP-LIS was done, which added a complete barcode tracking (cassette printer, label printers, barcode readers at each workplace) of specimens, containers, and documents, a sophisticated workflow control, an integration of microscopic cameras as well as of the BenchMark GX platform for automated IHC/ISH slide

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staining into the AP-LIS, a secure e-mail-distribution of the signed-out reports, and the facilities for structured reporting. Between November 2015 and March 2016 a 3D-Histech Slide Scanner Panoramic Midi (Sysmex) was integrated into the AP-LIS by means of VM Scope Cognition Master.

The „real world“ of a routine pathology institute concerning its workflow regulations in terms of digital workflow control was compared with the IHE profiles APW and PaLM.

Three periods were differentiated concerning to what extent information technology has been integrated in the entire workflow. Between 2005 and 2015 the turnaround time for pathology reports from the time the order reached the institute until the report was signed out and sent to the clinicians was recorded for each case. The workload of cases, the amount of pathological billing entities, and the sales volume was also registered. Data are based on the routine workload of a medium-sized pathology department in a Municipal General Hospital in Germany.

The differences of the mean turnaround time per year were checked by Student´s t-test for statistical differences between consecutive years.

Results

The workflow models of the IHE Technical frameworks of Anatomic Pathology as well as of Pathology and Laboratory Medicine [1,2] are close to cover all aspects of a very recent workflow in a pathology department. In <Figure 1> a raw diagram of the workflow is given, taking into account that the entire diagnostic process is based on images.

In the IHE profiles the real world processes are abstracted to transactions between actors for specified use cases. Both Laboratory and Anatomic Pathology Profiles have specified identical actors and transactions for the most basic workflow components: Order management and Result management. In <Figure 2> the actor-transaction diagrams of the APW profile, in <Figure 3> of the LTW and LDA profile are given. In this combined diagram also the connection between the order management und the work order step management is shown, which lacks in the APW profile. There is no place for the sequel of laboratory processes leading from a piece of tissue taken from a patient to the stained histological slide (<Figure 4>), which itself or its image is under investigation by the pathologist as to come out with a morphological description and a final diagnosis. On the other hand, the profiles in PaLM Technical framework have not yet clearly specified actors and transactions for the management of images.

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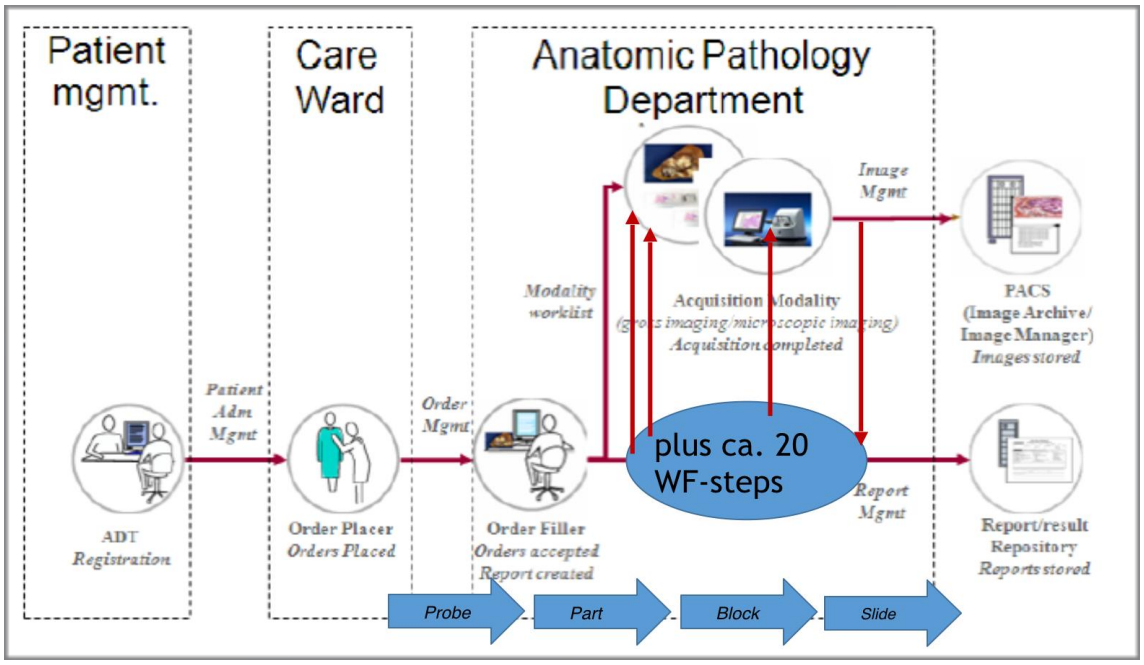

Figure 1: Process diagram of pathology workflow in the „real world“, modified acc. [1].

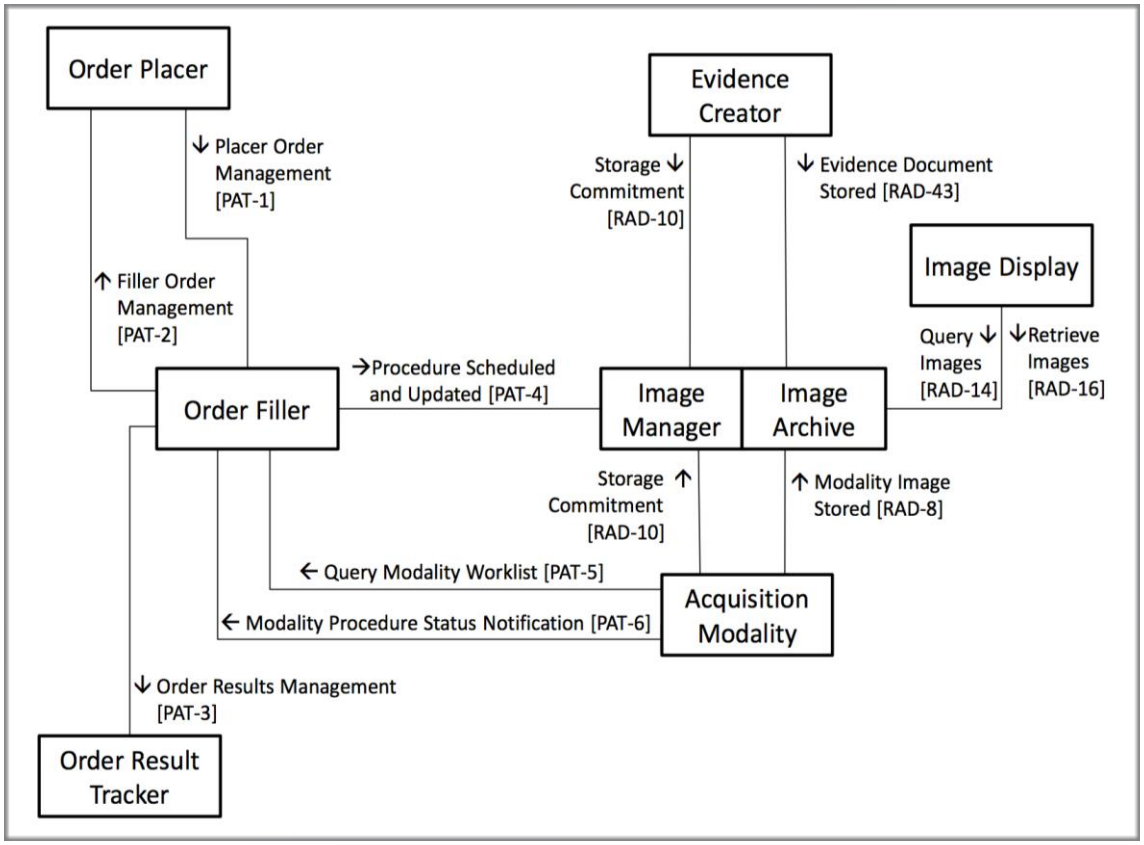

Figure 2: Anatomic Pathology Workflow - Actors & Transactions Diagram [1].

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The NEXUS / Pathologie AP-LIS, although not expressively based on IHE profiles, provides a highly sophisticated workflow control. The key for that is the consequent tracking of things and processes by means of 1D-and 2D barcodes. The management of IDs, from which the barcodes are being derived, is based on a specimen-container-model close to the HL7 DAM [3] and DICOM Suppl. 122 [4], and on a model of work units, which is similar to that of the IHE-LTW profile.

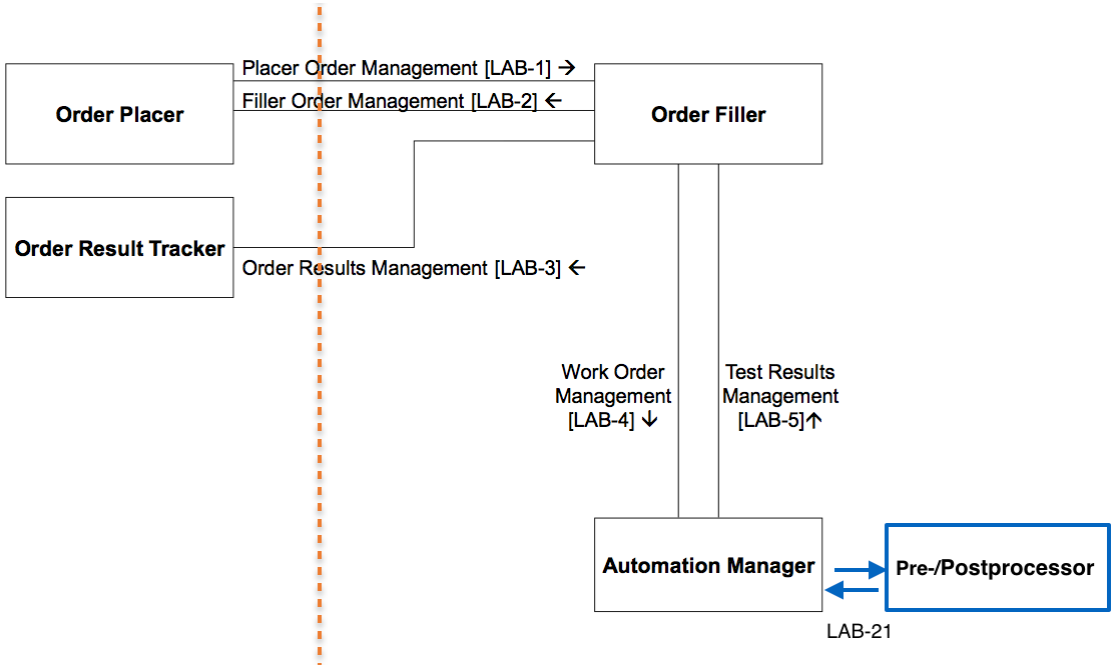

Figure 3: Laboratory Workflow - Actors & Transactions Diagram according to [2]. The dotted line marks the border between HIS and LIS. The blue rectangle marks e.g. the immunostainer.

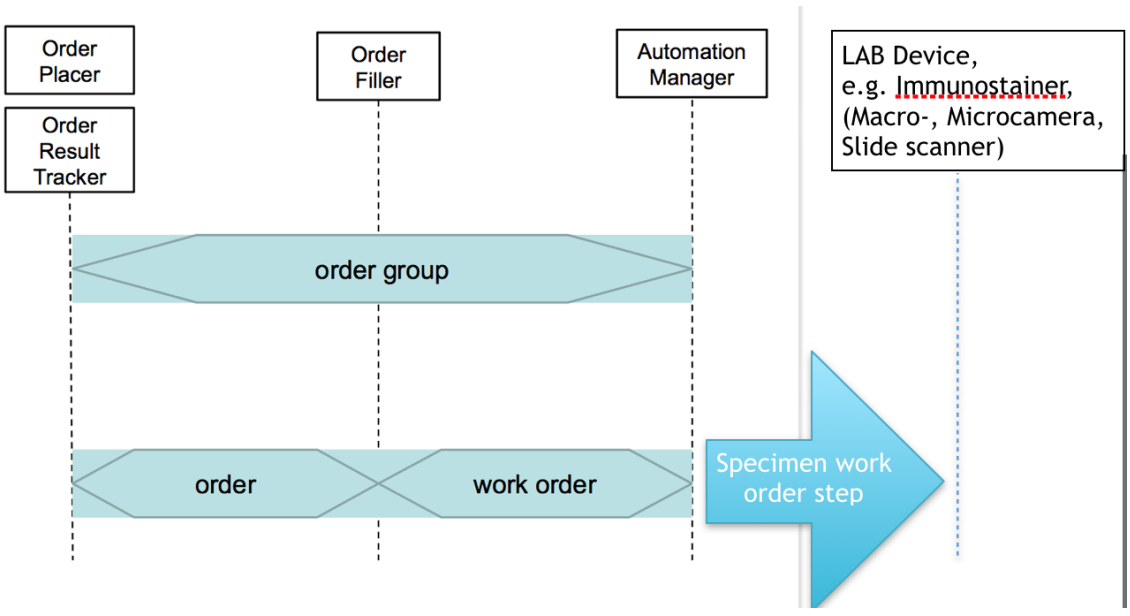

Figure 4: Work units in LAB / PAT workflow, according to [2].

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In <Figure 5> examples of 2D barcodes on cassettes/blocks and slides are shown. The barcodes for specimens/containers consist of a quadruplet of alphanumeric IDs for case-part-block-slide, e.g. „E1314/16“(case)-„2(„part)-„haut1“(block)-„1HE“(slide). By those codes an unequivocal tracking of each specimen is possible both for the computer and for the human actor, too. In <Figure 6> one front-end of the LIS is illustrated, showing the realization of the order filler / automation manager actor function in case of the ordering of additional slides for immunohistochemistry and the acknowledgement as well as the status changes of those work order steps by the immunostainer.

Figure 5: 2D-Barcodes on slides and cassettes in the laboratory routine. For human readability reasons there is also plain text printed on the labels and cassettes, demonstrating the quadruplets of IDs.

One of the most impressive effects of introducing the digital workflow control is demonstrated in <Figure 7> and <Table 1>. Whereas between 2005 and 2014 the mean turnaround time could be slightly reduced by several improvements in the machinery of the lab as well as by minor organizational improvements, the new digitalization of workflow control resulted in a significant shortening of the turnaround time. The five-month pilot study with the slide scanner, integrated in the workflow control, too, did not result in further shortening in turnaround time. If we consider the actual workload of the lab, expressed as case numbers, in comparison to the turnaround time, we may have an expression of the rationalization effects <Figure 8>. The yearly integrated workday index shows the increase or decrease of the hypothetical workload by the time, demonstrating the demand for human resources.

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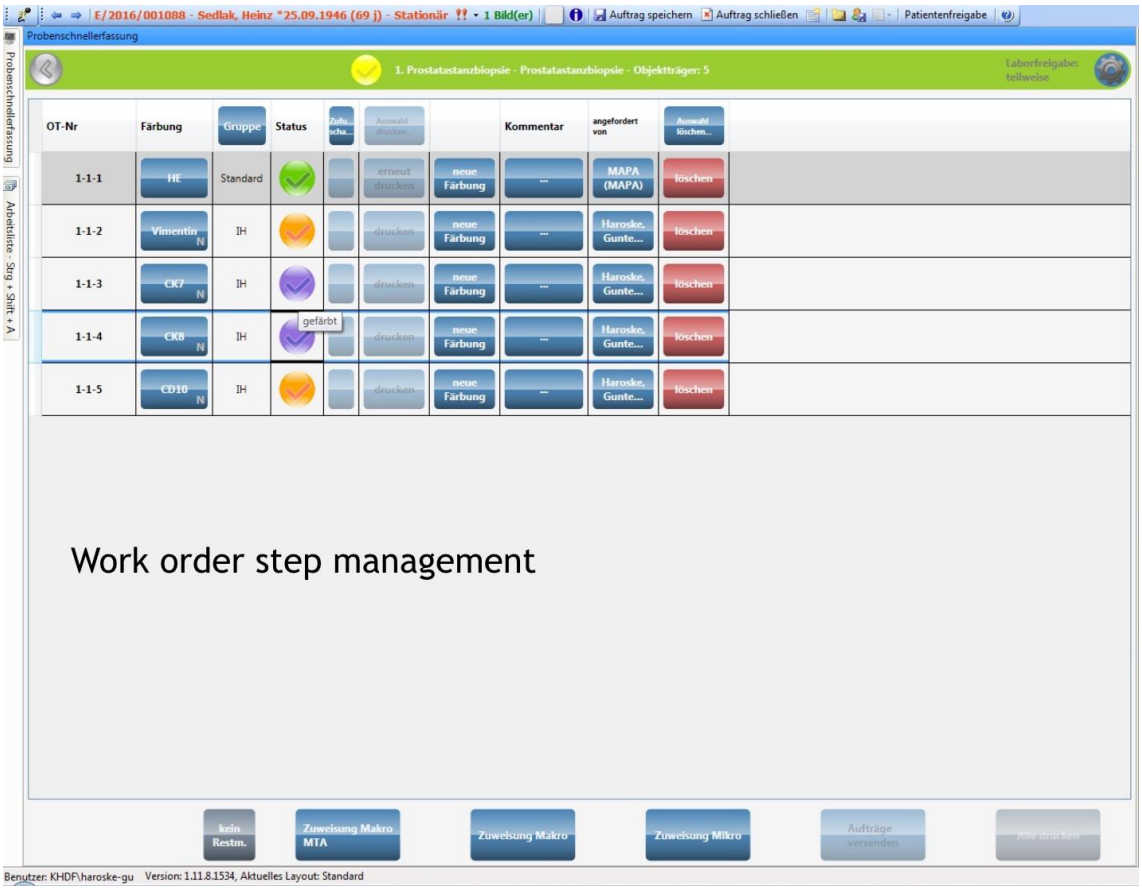

Figure 6: LIS front-end for ordering additional slides (specimen work order steps) for BenchMark. The colour of the buttons in the fourth column indicates the acceptance of the orders by BenchMark as well as the status of the appropriate SWOS. Green: work order done; Yellow: tissue section done, staining pendin; Violet: immunostaining done, checkout pending. First column: section IDs; second column: staining ordered; third column: laboratory section performing the order.

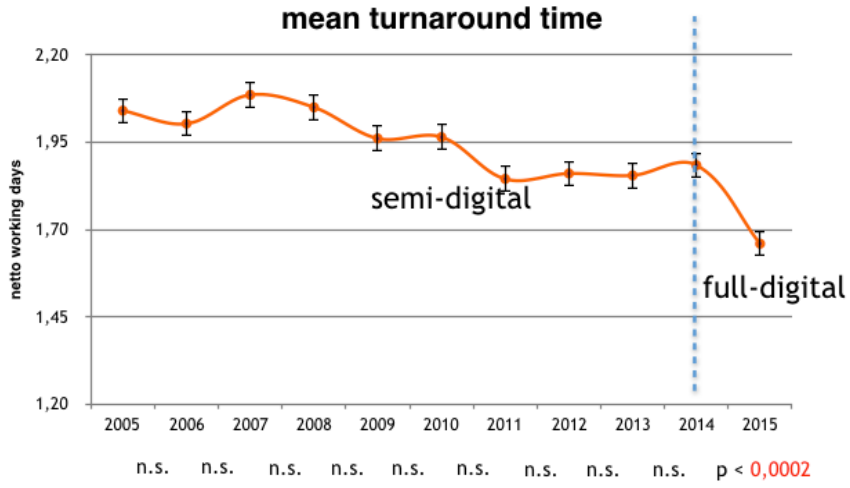

Figure 7: Mean turnaround times per year between 2005 and 2015. Weekend days and holidays are excluded.

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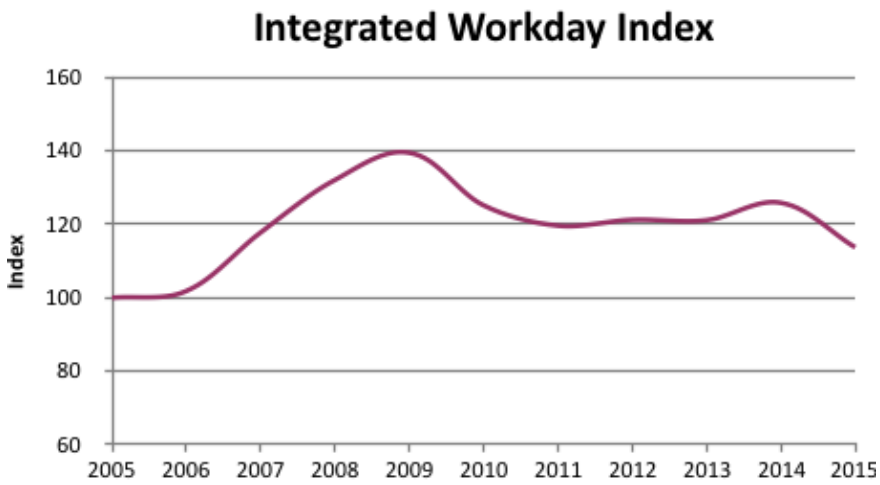

Figure 8: Yearly Integrated Workday Index (product of turnaround time and case numbers).

year	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
mean	1,94	2,00	2,09	2,05	1,96	1,96	1,84	1,86	1,85	1,88	1,65
SD	0,157	0,190	0,263	0,110	0,177	0,277	0,163	0,182	0,122	0,160	0,118
t-test	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	p < 0,0002

Table 1: Mean turnaround times (netto work days) per year between 2005 and 2015. Student´s t-test between consecutive years.

Discussion

The workflow control in pathology has been an issue for more than two decades, see as examples [5- 10]. Besides the turnaround time, the quality assessment, the reduction of errors, the upcoming diagnostic use of WSI, and the „lean“ management of a pathology lab were in the focus of discussions.

Due to the available date we concentrated our investigation on turnaround time effects exclusively.

These effects can be explained mainly by three aspects:

- Based on 8 predefined “laboratory profiles” and “58 profile groups” about 200 “laboratory protocols” have been defined, depending on specimen types and clinical information, i.e. a consequent work order and work order step management leads to a much more

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streamlined workflow in order entry completion, during the grossing of larger specimens, and through the entire following steps in cutting and staining procedures.

- The integration of electronic work-lists and the integration of an immunostainer in the workflow control.

- The integration of a variety of imaging modalities and image analysis tools.

It seems important to emphasize that no single process step in the laboratory has been accelerated; it was their more efficient sequential arrangement which led to a flattening of work peaks and a gradual reduction of lead times between the processes.

So far a few processes have not yet been included: hospital-wide electronic order entry, natural speech recognition, and sign-out by health professional cards have all the potential to a further reducing the turnaround time.

The key issue for a digital workflow control is the consequent tracking enabled by barcodes [11]. It were big players at the immunohistochemical market, who developed first systems for specimen and process tracking [12, 13]. Only a few years later the vendors of Patho-LIS invested in this development, too [14]. Most of these products are not based on international standard solutions, although a series of papers have dealt with that specific aspect for years [15-19].

Conclusion

The conclusions of our study are:

- Digital pathology is more than virtual slides.

- Digital workflow control yields to considerable improvement of performance in routine pathology.

- Digital workflow control is precondition for the integration of slide scanners in diagnostic pathology.

- Digital workflow control requires investments in computers, software, and laboratory equipment (in the order of magnitude of slide scanners!).

- Digital workflow control should be based on IHE profiles.

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