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Pathomorphological Diagnosis Process Modeling for Machine Learning Algorithms' Applying

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***Abstract*— Business process management is oriented towards improving processes to best support people, who are working in them. Recent innovations in the area of artificial intelligence (AI), machine learning (ML), Internet of Things (IoT), and distributed systems have provided opportunities for new technologies applications, including process automation. This paper aims at the pathomorphological diagnosis (PD) process modeling for the ML solution implementation. The research method covers the PD laboratory case study. Authors argue that the PD process requires detailed analysis for its digitalization, automation, and combining with ML applications. Authors presented PD process models in BPMN notation, including laboratory equipment and emphasizing data and ML algorithms which are to be utilized in PD process digitalization for appropriate diagnosis for patients. Authors have found and emphasized that implementation of ML/AI algorithms is strongly based on fundamental process modeling.**

***Index Terms*— Pathomorphology Diagnosis, Digital Image Analysis, Process Modeling, BPMN, Exploratory Data Analysis, Machine Learning.**

I. Introduction

Process management has been developed for the last thirty years. In 2022, van de Aalst [27] has widely recommended the process mining concept, which has changed the process thinking way. Maas et al. [15] has done research on healthcare processes and they have developed automated medical reporting. Earlier, the process engineering focused on business or production processes' design and implementation. Authorities, i.e., Marlon et al. [16] argue that process management is a comprehensive body of tools, techniques, methods, and entire methodologies to support all stages of the business process lifecycle. They emphasize that the process approach is popular in industrial engineering, operations management, quality management, human resource management, corporate governance, computer science, and information systems engineering. However, this study aims to model the pathomorphology diagnosis (PD) process for generating valuable data for ML and AI. In this study, researchers propose to integrate process knowledge from two disciplines, i.e., science of quality and management, and science of pathomorphology. The authors claim that only through combining managerial knowledge and medical knowledge, the pathomorphological diagnosis process can be effectively and efficiently controlled and surveilled [2].

Researchers in this study have noticed that there is lack of research on the PD ecosystem architecture development to ensure the PD process surveillance and control. They are able to develop the system architecture as a setting for the process realization and management. Authors have noticed that so far, the PD processes at various laboratories were utilized for human decision-making. This study presents the PD processes, which are to provide high quality pre-processed data for ML and AI-based analysis and prediction. Various researchers of ML and AI mostly focus just on reasoning and prediction. However, in this study, authors emphasize the issue of data provenance and governance, as well as the PD process modeling. Authors know that analysis of histopathological images is a highly required standard for patient therapies, hence this study results are expected to be valuable for the PD laboratory managers, pathomorphologists, and researchers of machine learning. Authors agree with Kratsch et al. [14] that process management is data-driven as well as model-driven approach. Data-driven orientation focuses on data for process discovery, analysis, monitoring, and process mining. It is true that data-driven approaches help analyze and monitor processes and to determine how efficient and effective their performance is. However, data concerns task attributes as well as tasks' results. In this case study, authors propose the ML and AI algorithms for analysis of the digitalized PD process results. The authors conducted a survey of literature [12, 20] in the field of pathomorphology diagnosis processes, and they searched for publications on PD processes in repositories, i.e., PubMed, Web of Science (WoS), and Scopus. Research works pub-

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lished in 2000-2004 and in 2019-2023 were examined, revealing noticeable changes in popularity of the searched terms. Particularly, the researchers have noticed a decrease in the occurrence of terms such as 'results' and 'methods' and an increase of popularity of the term 'patient'. This indicates a shift in the articles' focus towards patient-oriented perspectives. Hence, in this study authors focused on modeling of patient-oriented process.

This paper is structured in the following ways. Section 2 is on the PD process modeling for ML and AI algorithms' implementation. The last section covers conclusions and recommendations.

II. Pathomorphological Diagnosis Process Decomposition

The aim of this paper is to provide a guide on how to select the best strategy for modeling the pathomorphological diagnosis process. Authors considered theoretical and practical perspectives. They began from the literature survey. Authors have reviewed the following repositories: Scopus, Association for Information Systems electronic Library (AISeLib), PubMed, IEEEXplore, and Sage Journals. The search query used to search titles and abstracts was: "process modeling" AND "machine learning". The search included articles written in English and conference proceedings between January 2013 and January 2024. The inclusion criteria were used to select the publication first based on their title and then on their keywords and abstracts. Extra sources were added from the references of the selected publications. Although, in general, 1227 publications have been found, just 21 publications were finally selected. However, next, 14 publications have been excluded, and finally only 8 articles (i.e., [5, 7, 9, 14, 18, 24, 25, 28]) were considered as valuable contributions on the process modeling for ML/AI application.

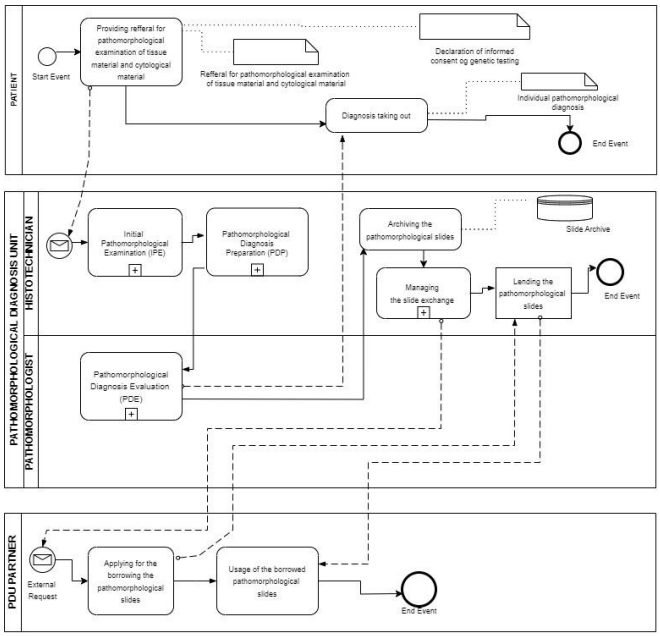

Fig 1. Pathomorphological Diagnosis Unit (PDU) main process

The others are mostly focused on ML and AI applications, but process modeling is not precisely presented. The other source of knowledge was regulations and guidelines of the Ministry of Health [17, 19, 22]. However, the individual in-depth interviews in the pathomorphological diagnosis unit (PDU) were the most valuable research method suitable for the identification of the PDU processes. According to the authors the pathomorphological diagnosis unit (PDU) process can be defined as a set of sequential and parallel activities, executed by medical and technical team members with different competencies and capabilities (see Fig. 1).

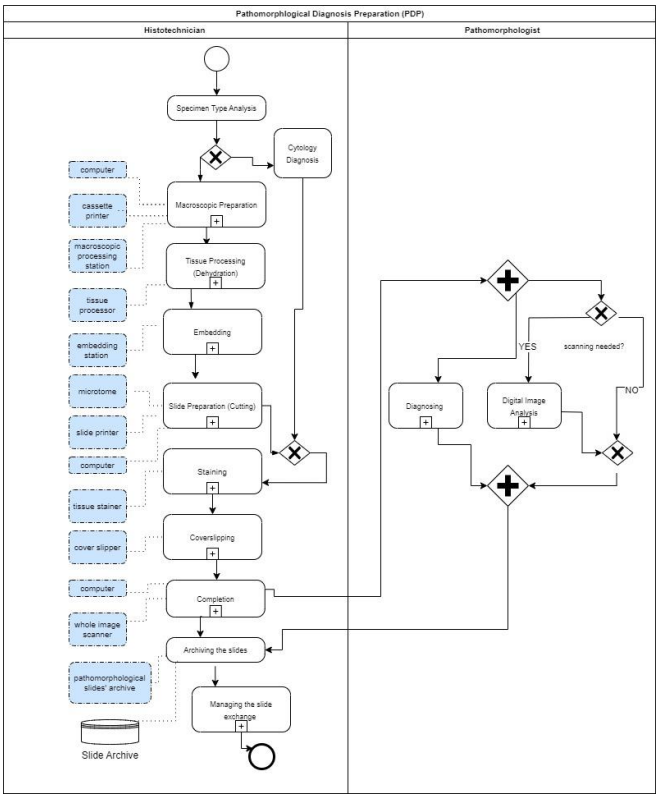

Fig 2. Pathomorphological Diagnosis Preparation (PDP) subprocess

The PDU process requires usage of special equipment and tools with the goal of high-quality treatment of materials provided to diagnose. Taking into account the literature survey, other authors focus on the material specification and its analysis. Generally, various modeling strategies are applied and characterized by their own granularity levels, data acquisition methods, modeling techniques and notations. In this paper, authors present modeling the main PDU process (Fig. 1.) and its decomposition into three subprocesses, i.e., Initial Pathomorphological Examination (IPE), Pathomorphological Diagnosis Preparation (PDP), and Pathomorphological Diagnosis Evaluation (PDE).

Generally, the pathomorphological diagnosis is a complex set of tasks, hence the process network and hierarchy of processes are necessary to order the PDU activities. The PDU has two main actors, i.e., histotechnician and pathomorphologist. The ordering of their tasks permits segregation of duties, and

finally, the pathomorphologist should focus on image recognition and evaluation, while the histotechnician should be responsible for the slides' preparation. In Fig. 1 and in Fig. 3 tasks are combined with data objects, which are generated in those tasks and which are further processed through the ML algorithms.

In Fig. 2, the PDP process tasks are combined with the equipment, which is installed in the PDU laboratory. Although the BPMN notation does not include specification of equipment in a process model [4], authors want to emphasize that equipment is essential in the PDU process. At first, after receiving the specimen, the histotechnician answers the question if it is a cytology tissue or other histology material or cytoblocks. The cytology material is analyzed in a separate way in the Cytology Diagnosis task. The Macroscopic Preparation task is performed by a histotechnician, who is using the macroscopic processing station, the cassette printer, and computer for recording the histopathology material data in the database. Next, the histotechnician performs the Tissue Processing task and uses the tissue processor. The Embedding task is also performed by the histotechnician at the embedding station. Next, the histotechnician performs the following tasks: the Slide Preparation with the microtome, slide printer, and computer for data recording, the Staining task with the tissue stainer, the Coverslipping task with the cover slipper, and the Completion task with the whole image scanner and computer for recording the scan description.

The results of histotechnician work are transferred to the pathomorphologist for diagnosis and digital image analysis. Finally, the pathomorphological slides are archived for further studying. The business process model and notation (BPMN) process modeling allows to clearly visualize workflows, making easy-to-interpret tasks and present relations between extensive sets of actions and decisions. Actually, the PDP process tasks are realized manually, but soon, the AI solutions and the robots' implementation will enable the PDP process digitalization and full automation. The PDP sub-process model is to be further used in cost effectiveness analysis of PDU laboratories.

Authors of this study assume that process modeling starts with the process discovery phase. Through the in-depth interviews, authors decide to focus on producing a detailed description of the business process as it currently exists (i.e., "as-is" process). Further, during the process analysis, application of analytical tools and techniques is to allow determining of process current weaknesses and ambiguities. The process redesign addresses the most important weaknesses and provides the "to-be" process model. That model can be used as the basis for process digitalization and automation. The PDP subprocess is also complex and as such requires further decomposition, which is presented in Fig. 2. Taking into account the literature survey presented in the section 2 of this paper, authors have focused on the Digital Image Analysis subprocess, which is the most important in the whole work of a PDU. The Digital Image Analysis (DIA) process model is included in Fig. 3. That process requires a strong involvement of histotechnician and pathomorphologist in tasks for digital images' preparation. Defectively performed tasks require repetitions, which are costly and time consuming.

In the Digital Image Analysis process, the pathomorphologist performed tasks, which provide data needed for diagnoses based on Machine Learning (ML) as well as Artificial Intelligence (AI) reasoning. The process in Fig. 3 includes specifications of data objects that are necessary for ML/AI analyses. The tasks identified in the DIA process are further characterized in Table 1.

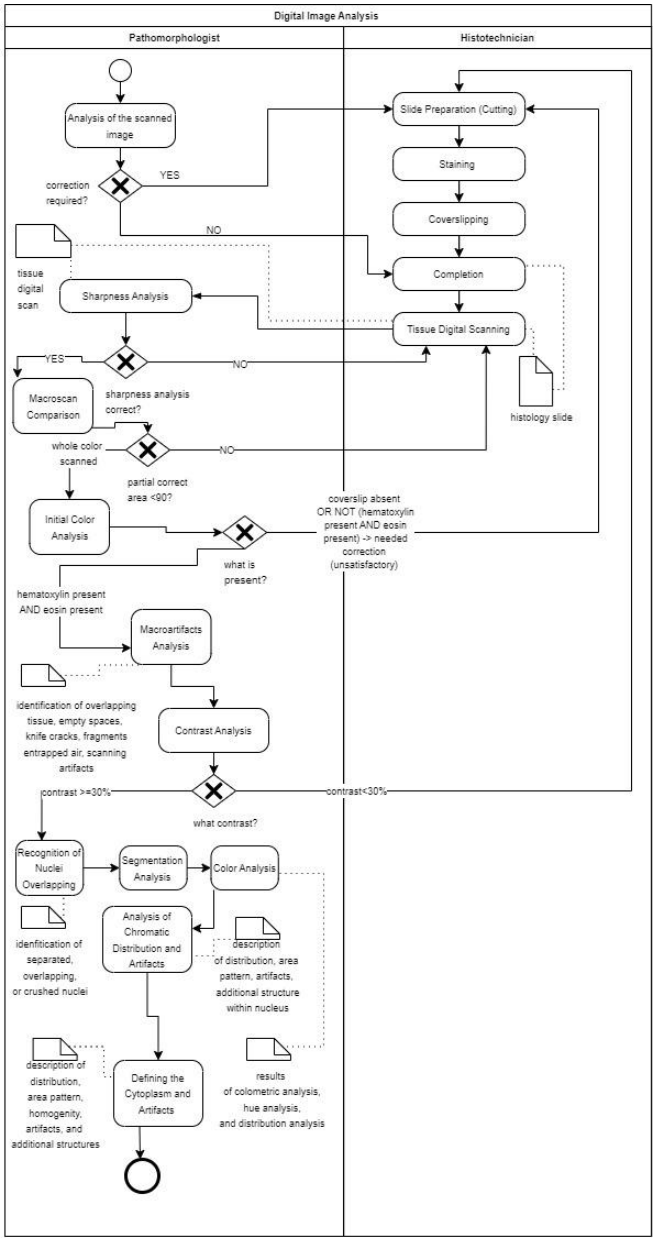

Fig 3. Digital Image Analysis (DIA) subprocess

The tasks indicated in the Tables I-II and in the Fig. 1 are performed manually by the pathomorphologist for the processing of the digital image of the specimen. By specifying and characterizing them in a process model, it is possible to

design an image processing workflow that will automate the Digital Image Analysis process. This workflow will consist of three stages:

1. Each task identifies an existing computer vision algorithm that can be used to automatically process the original image into a feature map that is appropriate for evaluating the image in the job.
2. The resulting feature map, in point 1, and the possible error classes in a given task are used to train artificial intelligence models, e.g., a deep convolutional network for each task, which classifies the image as correct or finds an error class [13, 26]. In the case of transforming the image to a different form (e.g., histogram), an expert system based on detailed expert decision-making rules will be applied [1].
3. On the basis of the classification assigned to the image in a given task, in point 2, a decision is made to further process the image of the original specimen in accordance with the process diagram.

According to the literature survey, there are researchers who undertake the challenge to combine process modeling and ML/AI solution implementation [7, 8, 9, 14, 18, 24, 25, 28]. They argue that machine learning (ML) models offer different and wide-ranging capabilities to improve business processes.

TABLE I.
DESCRIPTION OF THE TASKS OF THE DIGITAL IMAGE PROCESSING PROCESS OF THE SPECIMEN

No	Task name	Purpose of the task	What is the algorithm used/ what happens to the image	Evaluation criterion	Indication of the reasons of irregularities/ linking the result of the task with other elements of the process
1	Sharpness Analysis	Assessing whether the specimen is scanned sharply over the entire surface	You can apply an algorithm to detect the edges [23] in the image and evaluate their thickness. If the thickness is too thick, the user has the impression of blurring.	There must be sharpness on the surface of the preparation, e.g.,: >=80%	It results directly from the process of scanning the specimen in a histopathology scanner.
2	Macroscan comparison	Comparison of whether the surface of the scanned specimen in the micro view corresponds to the surface in the macro view	An algorithm can be applied to capture images in micro and macro view. Image registration can be based on elements of ML/Artificial Intelligence [3, 21]. If these views do not coincide, the content of the micro offense is distorted.	Images must overlap at least, e.g., 80%	Abnormal tissue detection by histopathology scanner algorithm.
3	Initial Color Analysis	Color separation; Is there hematoxlin? Is there eosin? Are there other colors?	The proportion of the number of pixels in the image is checked, and compared with colors in the shade range for hematoxylin and eosin. The image histogram processing algorithm can be applied [6,10].	1. Is there a correct number of pixels with color in the hematoxylin range? 2. Is there a correct number of pixels with color in the range? Is there eosin? 3. Are there other colors in the image histogram and what is their distribution?	Lack of hematoxylin, eosin - failures in staining task. In this case, the slide is discarded. If everything is monochrome, it means that there is no cover slip (the specimen is not sealed) - we reject the specimen from further analysis. In this case, the return to cover slipping is necessary. Recording that the process failed at this stage.
4	Macro Artifacts Analysis	Analysis of the surface of the preparation for the occurrence of specific phenomena.	A local correlation detection algorithm can be used [6, 10]. 1. Do the shapes of the "white" field form repetitive fields, e.g., the line. Do the shapes of the "white" field coincide with the lack of a pattern?	The following abnormal patterns can be detected: 1. Qualitative - slots 2. Mesh/disintegrating - poorly fixed 3. The tissue overlaps geometrically (triangle, square) with a more saturated area.	1. Damaged knife when slicing slides in a microtome job. 2. Error in tissue processing. 3. Poorly applied material to the slide.
5	Contrast Analysis	Is the scan image contrasting, e.g., between hematoxylin or eosin?	Algorithm for detecting the directional ratio of simple contrast [6,10]. 1. Edges are low contrast. 2. Too big contrast	The contrast must be within the given range.	1. Improper dyeing. 2. Improper fixation. 3. Dried material - tissue processor.

TABLE II.
DESCRIPTION OF THE TASKS OF THE DIGITAL IMAGE PROCESSING PROCESS OF THE SPECIMEN- CONTINUED

No	Task name	Purpose of the task	What is the algorithm used/ what happens to the image	Evaluation criterion	Indication of the reasons of irregularities/ linking the result of the task with other elements of the process
6	Recognition of Nuclei Overlapping	Color separation to hematoxylin (violet-blue color). Determine the cell nuclei, do they have a lot of outlines?	Segmentation of cell nuclei by dynamic thresholding based on the image histogram [6, 10], corresponding to the color of the hemotoxiline (violet-blue color). - there is a separation of pixels lying in this range: analysis of envelopes, shapes.	A high degree of overlapping of the testicles indicates a coarse cut.	In the case as it is written on the left, the material is too coarsely cut.
7	Segmentation Analysis	Segmentation of nuclei and cell bodies in the image	Segmentation algorithms corresponding to tiny numerous structures in pathological images. The possibility of using AI elements: deep neural networks in two modes of processing image fragments: – dividing the image into small areas and combining them [11]; Whole Slice Image Analysis [13, 29].		
8	Color Analysis	Analysis of the shade of dyes in the context of the thickness of the section, uniformity of coloration, shade change, color zoning	Analysis of color distribution in image chromatogram [3].	The base shade should be uniform within the cutter	Staining, reagent consumption, pH disturbances, poor dewaxing
9	Analysis of Chromatin Distribution and Artifacts	Analysis of chromatin distribution (haematoxylin) within the nuclei, surface analysis	Analysis of color distribution in the image chromatogram, analysis in the range of chromatin (chemotoxylin) colors [6, 10]		Distribution, area pattern, artifacts, additional structures within nucleus
10	Defining the Cytoplasm and Artifacts	Analysis of color within cell bodies	Analysis of color distribution using segmentation results from task 7 [6, 10].		Distribution, area pattern, homogenity, artifacts, additional structures

However, Take et al. [24] have noticed that there is still a lack of possibilities to model business processes, which include the ML models. Hence, an extension of process patterns is needed. Davies et al. [7] claim that the ML use significantly increases processing speed, optimizes the processes, reduces costs, and increases purity.

III. CONCLUSION

The article presents a model of the histopathological specimen processing process, with emphasis on the part of the process concerning the processing of the digital image of the specimen. A two-stage architecture of the image processing system has been proposed, which enables automatic execution of individual tasks of the process and automation of the decision-making process regarding the image quality of the digital specimen. The proposed process model raises a number of potential possibilities. Firstly, it allows you to automate individual tasks of the process. Secondly, it reduces the burden on the pathologist by eliminating the need to deal with incorrect digital images of slides. Thirdly, it is potentially a step towards full automation of the process and the use of the Internet of Things (IoT) architecture. Authors argue that the pathomorphological diagnosis unit (PDU) procedures and processes are valuable for its control, auditing, monitoring, and digitalization and automation. The procedures for control and auditing purposes should be supported by PD process models in a standard notation, e.g., BPMN. In this study, authors present just three processes including one in another, but the hierarchy of all PDU processes would be needed for the PDU auditing. So far, research works have not described sufficiently well the quantitative relationships between the measurable features of the PD process and the tissue effect. The global recommendations for quality control in pathomorphological diagnosis laboratories emphasize "process quality control"; however, there is no recommended model of this control, recommended control methods and "points" relevant to process quality.

The in-depth interviewing allows for the conclusions that there are also no precise indications and recommendations for dealing with problems arising during the histological process, in particular indication of the precise algorithms of actions, which depend on the type of tissue, size of the section and the correlation of the nature of artifacts (or damage) with the process disturbance. The assessment of the correctness of the process is currently based only on non-parametric evaluation - literally "by eye" of the pathomorphologist, depending on staff knowledge and experience, there are no tools for synthetic assessment of the quality of the histological process that could indicate the risk of a disorder in subsequent repetitions of the process.

Arrangement of synthetic characteristics and their definition, and establishing of the relationship between changes at the earlier stages of the process and the final

effect will enable the creation of a system of continuous quality control of the histological process in pathology departments. This study is to fill that gap, by emphasizing that the first step in PDU process audit, i.e., PDU process modeling needs to be done. In the presented models authors highlight what equipment is to be used as well as what data and algorithms would be utilized.

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