Editorial

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The (mis)use of artificial intelligence in laboratory medicine; the good, the bad and the ugly

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Artificial intelligence (AI), in all its forms from machine learning to deep learning, is increasingly accepted as an unavoidable part of humanity's pursuit of progress – combining effectiveness (achieving more) with efficiency (using less effort). As with any other form of progress, AI brings not only opportunities but also risks. The aim of this editorial is to raise awareness among professionals in laboratory medicine of their responsibility to identify and mitigate these risks.

The good

As in industrial sectors, where repetitive processes are applied identically to high volumes of individual products according to criteria that define the differences between them, AI is increasingly used in laboratory medicine to judge individual samples against predefined criteria. Beyond this, AI can even aid in defining these criteria themselves, since its application requires implicit, human-based judgement criteria to be made explicit. By asking AI tools to analyze the results of numerous results of human judgements which were partly based on subconscious implicit criteria, AI tools are able to extract explicit criteria from such data and conclusions.

Fields where AI is used in laboratory medicine range from the pre- to the post-analytical phase.

- Pre-analysis where AI models monitor pre-analytical, analytical, and post-analytical stages to improve test requests, catch specimen collection/labeling anomalies, sample hemolysis, or instrument calibration drift before results reach patients [1].
- Analysis where FDA- and IVDR-approved AI analyzers perform automated visual recognition, cell classification, and precise enumeration of erythrocytes, leukocytes, and platelets in peripheral blood smears and fluid samples [2].
- Postanalysis where machine learning algorithms evaluate patient historical data and test order patterns to streamline test utilization, flagging redundant testing or auto-verifying routine panels [3].

The bad and its prevention

As all tools that create output, the quality of the output relies on both the quality of the input and the quality of the processing of the input to create output. Çubukçu [3] details how the synergistic enforcement of the European *In Vitro* Diagnostic Regulation (IVDR) [4], ISO 15189:2022 [5], standards for medical laboratory competence, and the EU Artificial Intelligence Act [6] establishes formal limits on AI autonomy. Under these frameworks, AI software is categorized as Medical Device Software (MDSW), requiring predefined intended-use boundaries, human override protocols, and documented post-market risk management before AI recommendations can enter patient medical records. Without proper identification and management of sources of variability application of AI tools could also harm Interoperability as Integrating AI models seamlessly with diverse Laboratory Information Management Systems (LIMS) and Electronic Health Records (EHR) remains a technical bottleneck. Governance & Validation is required to ensure safety, reducing model bias, and satisfying strict regulatory requirements.

The ugly

Even worse than AI tools that bare the risk to mistake in the generation of output, would be AI tools that are fundamentally wrong in their origin as they were designed to take over human responsibility rather than aiding the execution of human responsibility. As Editor and Reviewer of *this*

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Journal, both authors of this paper, we have recently encountered a submission that aimed to use AI to specify and document laboratory procedures in line with ISO15189 requirements. The authors of that manuscript compared the output of several AI tools with different complexity in prompts and ranked the output to judge the optimal investment in terms of prompt input and costs. What these authors failed to do was to comply with the most important of all ISO15189 requirements and that is to take leadership in creating a laboratory process that aims to do right in the best interest of the patient. To achieve that, processes not only need to comply with textual requirements in the standard, but more importantly with practical requirements communicated to the laboratory staff by the local physicians who request laboratory output. Useful translation of such process requirements also asks for application of knowledge of available local resources such as staff competences, equipment and environmental conditions. That particular paper was rejected due to a design flaw: it failed to recognize that AI cannot replace human responsibility in shaping laboratory process design according to local needs and circumstances. Quality is not merely a matter of compliance, but of leadership – and we hold that human responsibility constitutes a non-substitutable ethical dimension of quality management. However, we do realize that rejection of that paper will not end the (possibly unintended) attempt for ugly application of AI in laboratory medicine. That means that the international community of laboratory medicine must be aware of the possible emergence of such attempts and should learn to recognize and neutralize such efforts by not allowing their application.

Preventing the ugly

Rather than passive human presence, Davidović [7] has introduced an operational concept of so called Meaningful Human Control (MHC). By organizing that human oversight mechanisms must be explicitly aligned with their underlying purpose (e.g., moral accountability, error prevention, or dignity) to prevent human oversight from devolving into a rubber-stamping process. According to Davidović true MHC requires that humans retain the contextual understanding, technical capacity, and formal authority needed to override or decline algorithmic recommendations. Control, however, can be understood as 'check', and then is reactive by nature. To prevent the unnecessary use of resources in generating erroneous results – and, more importantly, the risk that such errors may not be recognized in a timely manner, thereby allowing potentially harmful results to be reported and acted upon – we propose that "human control" in MHC should not be interpreted merely as a "human check of the output", but rather as "human command".

Only by taking command laboratory professionals can assure that they take their responsibility in leadership as required by ISO15189. We therefore propose to replace Meaningful Human Control with Meaningful Human Command, maintaining the abbreviation MHC. Only then, the human in the loop is triggered to be the proactive leader, rather than reactive damage mitigator.

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