UNITED EUROPEAN GASTROENTEROLOGY

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UEG Position Paper on AI

Owing to their rapid development, artificial intelligence (AI) technologies offer great promise for gastroenterology practice and research. At present, AI-guided image interpretation has already been used with success for endoscopic detection of early malignant lesions, assistance during laparoscopic or endoscopic surgery and big-data analysis for individualized therapy. Nonetheless, there are complex challenges and possible shortcomings that must be considered before full implementation can occur.

Main messages

- We welcome the European Commission's White Paper on AI and the emphasis on the health sector. As an organisation representing the broad field of gastroenterology, we would like to stress that AI represents an opportunity in healthcare not only for big data, but also for a variety of manual tasks. The use of AI in robotic surgery and endoscopy is of particular importance in the field of gastroenterology.

  Challenges:

- To cope with the fast developments of AI and reduce the vast inequalities in the uptake of gastrointestinal robotics, the use of AI and robotics needs to be further trained, taught and certified. Likewise, to guarantee safe and accurate AI-enabled healthcare delivery, it is essential to:
  - Ensure well-defined standards of human responsibility for task supervision and control.
  - Ensure the quality of input data, adequately train the AI and categorize information to support clinical decision-making.
  - Allocate more funding into AI-related research projects. In gastroenterology, automation can significantly improve procedures such as endoscopy, surgery and surgical tasks, as well as simulation in training. It can also prevent errors in robotic surgery, polyp detection and removal.

- In order to avoid regulatory inconsistencies, harmonization is crucial in the interplay between the EU legislation regulating medical devices and the future regulatory framework for AI.

Challenges and opportunities of AI applications in gastroenterology

a. Digestive surgery

Clinical applications of AI in digestive surgery carry many benefits. Three dimensional views, access in crowded organ spaces and fine range of movements on robotic arms enable healthcare professionals to perform complex procedures with more precision, flexibility and control. Robotic assisted minimally invasive procedures are often associated with less pain, early hospital discharge and better outcomes.

The use of AI contributes significantly to the improvement of education and training through the opportunities offered by virtual reality training models. Moreover, healthcare analytics and real-life data are also contributing to the

emergence of new scientific evidence. Nevertheless, the uptake and training of digestive surgeons also represents a challenge. We should therefore make sure that AI technologies are available to wider groups of surgeons to perform operations that are otherwise limited to very experienced clinicians.

Despite the many opportunities that AI holds, the increasing levels of autonomy for surgical robots raises ethical issues which also need to be addressed. In this respect, we emphasize the importance of having well-defined standards for Meaningful Human Control according to the different autonomy levels. This includes notably: well-defined human responsibility for task supervision, informed decision-making procedures and duties' distribution among involved humans.[1] A European regulatory framework could also help to deal with liability issues.

Specific importance must be given to strengthening surgeon-patient trust, implementing feasible clinical and research actions to promote the wellbeing of patients. In order to ensure a high level of trust, it is important to review what amount of information is sufficiently rich and understandable for autonomous patient reflection and decision making. The ownership of patient data should also be addressed.

b. Endoscopy

There are several categories of AI systems applicable to endoscopy, with a large spectrum of potentially useful clinical applications, such as improved detection of lesions, differentiation of lesions based on their mucosal or vascular pattern, risk stratification before/during therapy etc. The main advantages of AI-assisted endoscopy are the reduction in workload and greater accuracy.

Nonetheless, there are also several challenges yet to be addressed, such as the lack of testing for large-scale clinical applications, standards for patient care guidelines, as well as external validation through randomised trials. Moreover, the true value of AI is based on the input data. Patients are often flooded with diverse, sometimes unqualified and false information. An AI that has been trained with such low quality data should be excluded from medical use. Hence, healthcare professionals need skills to adequately train the AI, understand the main principles underlying any given AI system, and maintain control over it.

c. Pathology and imaging

Pathology has progressed consistently through the introduction of Digital Image Analysis algorithms, followed by various deep learning models. AI brings significant opportunities for pathology and imaging (ultrasound, CT, MR) similar to those for endoscopy, including cancer diagnosis, quantitative evaluation, personalised diagnosis etc. Likewise, AI can considerably improve non-endoscopic applications, such as automated organ segmentation and identification of diffuse liver disease, digestive damage scores and metrics of inflammatory burden in Crohn's disease, cancer and polyp detection, differential diagnosis of liver and pancreatic lesions etc.

[1] Ficuciello F, Tamburrini G, Arezzo A, Villani L, Siciliano B, *Autonomy in surgical robots and its meaningful human control*, Paladyn, Journal of Behavioral Robotics | Volume 10: Issue 1, DOI: https://doi.org/10.1515/pjbr-2019-0002

The major barriers are encountered in the quality of input data sets with appropriate annotations and the lack of a robust gold standard against which to train models. Furthermore, there is also a lack of high-quality external validation of AI systems, and impact on patient care or physician decision-making is rarely shown.

d. Big data management

When treating patients, a plethora of data is generated. In parallel, treatment of almost all digestive diseases is increasingly individualized. Therefore, there is an urgent demand to analyse, harmonize and categorize data to support clinical decision-making, improve internal processes, and promote cross-sectional collaboration.

The interaction between electronic health records and patient health records, apps and wearables will be important. Data from patient symptom diaries and wearables can play a significant role in early signalling that a patient may be at risk of their condition worsening (for example, patients with IBD or those undergoing chemotherapy).

e. AI and the Medical Devices Regulation (MDR)

With increasing numbers of AI-based assistance systems developed for cancer screening and early detection, there is an urgent need for a standardized approach to classifications. We recommend that all AI-based systems for detection of polyps should be classified under the MDR as IIa-products and the AI-based systems used for differentiation of polyps as IIb-products.

For future implementations of AI, such as optimization of workflow or assistance in reporting various findings, all new products should be categorized and handled in a uniform manner.

f. AI in microbiome-based GI research

The use of AI, and in particular of machine learning (ML), brings substantial opportunities for microbiome-based research in GI diseases. Applications include the identification of microbial biomarkers to predict disease risk and to improve diagnosis, prognosis and treatment. In this context, there is a need for high-quality large-scale studies that produce high-quality training and testing datasets, in order to generate robust ML prediction models. Rigorous and standardized ML practices applied to microbiome research will be pivotal.