Deployment of AI segmentation algorithms in a clinical environment

1.1 Introduction to AI in Healthcare:

Artificial Intelligence (AI) is a field of computer science that aims to automate intellectual tasks normally performed by humans. The old approach of AI was to have programmers handicraft large sets of explicit rules for manipulating knowledge, known as symbolic AI. It was thought that this was the way to go to achieve human-level artificial intelligence. And despite the suitability to solve well-defined logical problems, it had difficulties for solving more complex problems such as image classification, speech recognition or language translation. It wasn't until the fields of Machine Learning (ML) and Deep Learning (DL) arised and started to get somewhat good results in those types of more complex problems. These past few years some tools have been developed that have transmitted the power of AI to the vast majority of users with an average knowledge in computers (for instance ChatGPT).

However, ML has been studied for a very long time. With machine learning, humans input data as well as the answers expected from the data, and out come the rules. These rules can then be applied to new data to produce original answers. A ML model is trained rather than programmed and those models can be put in three different types: supervised learning, in which the algorithm is trained on a labeled dataset that has its input data paired with the correct output, unsupervised learning, in which the algorithm is trained on a unlabeled dataset and tries to identify patterns within the data on its own, and finally, reinforcement learning, which is about training agents, that by trial and error, they make sequences of decisions in an environment to achieve a specific goal.

And then there is DL which is a specific subfield of machine learning which puts emphasis on learning successive layers of increasingly meaningful representations. Modern deep learning often involves tens or even hundreds of successive layers of representations and they're all learned automatically from exposure to training data. These models are called neuronal networks, which is a reference to neurobiology. DL has been advancing and getting more impressive results these past decade because of three fundamental factors: hardware, DL has a need of massive computational power and companies like NVIDIA and AMD have been investing billions of dollars in developing GPUs (Graphical Processing Unit) that, when joined in clusters, achieve the results needed for training huge DL models. Some companies even have developed specific processing units called TPU's (Tensor Processing Unit) that are faster and more efficient to train the models. The other important factor is Data, which is fundamental to train good DL and ML algorithms, and its progress in storage hardware and feasibility to collect and distribute very large datasets. In addition to the previous two factors, important algorithmic improvements that, with the possibility of training models with more than 10 layers, made DL start to shine [4].

The integration of AI into healthcare is still in its early stages, but it has the potential to revolutionize the way medicine is practiced. AI-powered medical devices can help healthcare workers make more accurate and timely diagnosis, prescribe more effective and personalized treatments, and operationalize public health measures. Purposefully designed AI-augmented healthcare systems will help improve the productivity, access, and equity of healthcare delivery. [5]

While unlikely to replace human healthcare providers entirely, AI may perform certain tasks with greater consistency, speed, and reproducibility than humans. Examples include estimation of bone age on radiographic exams, diagnosing treatable retinal diseases on optical coherence tomography, or quantifying vessel stenosis and other metrics on cardiac imaging. By automating tasks which are not theoretically complex but can be incredibly labor and time intensive, healthcare providers may be freed to tackle more complex tasks, representing an improved use of human capital. Studies have demonstrated a synergistic effect when clinicians and AI work together, producing better results than either alone [8]

1.2 Medical Imaging and Its Importance:

Image Segmentation involves partitioning images (or video frames) into multiple segments or objects [1]. Segmentation plays a central role in a broad range of applications, including autonomous vehicles (e.g., navigable surface and pedestrian detection), video surveillance, and augmented reality to count a few. Medical image analysis is also one of the fields of image segmentation in which most research is being undertaken nowadays.

Medical imaging is a pivotal field at the intersection of medicine and computer science that leverages cutting-edge technology to visualize and interpret internal anatomical structures and physiological processes within the human body. It plays a critical role in clinical diagnosis, treatment planning, and medical research. Through the use of various imaging modalities such as X-ray, MRI (Magnetic Resonance Imaging), CT (Computed Tomography), ultrasound, and nuclear medicine, medical professionals can non-invasively capture detailed images of the body's internal structures. It encompasses segmentation of image, extraction of features, classification, image matching/registration, risk prediction, disease diagnosis and radiology assistance among some of them [7]. For example, in cancer care, medical imaging helps determine the size and location of tumors, enabling oncologists to plan surgeries, radiation therapy, and chemotherapy with precision.

Computer scientists have played a significant role in the development of ML and AI techniques for automated image analysis, revolutionizing the field of medical imaging by enhancing efficiency and accuracy in diagnosis. The resulting images of, for instance, CT scans or MRI have to be treated by segmenting some crucial objects and extract features from the segmented areas. That process could be more efficient and accurate diagnosis with the help of AI. Some of the popular medical image segmentation tasks include liver and liver-tumor segmentation, brain and brain-tumor segmentation, optic disc segmentation, cell segmentation , lung segmentation, pulmonary nodules, cardiac image segmentation, etc. [6]

1.4 Challenges in Clinical Settings:

Digital image processing and analysis has a critical role in clinical practice. Several studies indicated that computerized medical systems can enforce medical diagnosis by enabling automatic detection, recognition of useful information, disease evolution monitoring and accurate measurement of visible abnormalities (Iakovidis, 2015). For example, clinical diagnosis is the basic modality for identifying cancer; but visual diagnosis alone is not sufficient to define tumor depth. Imaging allows lesion mapping, which could assist surgeons to determine tumor extent that can help to reduce the next surgeries stages (Bard, 2017). [7]

Currently, the medical image data amount grew rapidly due to the development of medical image acquisition devices. Since most imaging modalities became digital, with continually increasing resolution, medical image processing has to face the challenges of big data. The exponential growth of the volume of medical images forces computational scientists to come up with innovative solutions to process this large volume of data in tractable timescales (Scholl et al., 2011).

Despite this growing interest in healthcare-related AI, substantial translation or implementation of these technologies into clinical use has not yet transpired. How we tackle issues in implementation in the next few years will likely have far-reaching impacts for the future practice of medicine.

To ensure safety and efficacy, AI-enabled medical devices must undergo the same rigorous approval process as other medical devices. This process can be time consuming and costly, because these devices have the potential to affect the health and well-being of patients, the regulatory approval process for AI-enabled medical devices requires a high level of scrutiny.
These clinical, scientific, and regulatory requirements have influenced the adoption and development of AI in the medical sector. For instance, in the U.S., the FDA (U.S. Food and Drug Administration) approved 521 AI-enabled medical devices for clinical use as of July 2022, with more expected in the future. Notably, approximately 75% of these devices are focused on a single medical specialty radiology, followed by cardiovascular disease and hematology. Certain specialties, including dermatology, have yet to see an FDA-approved AI-enabled medical device as of 2023. [5]

There are many challenges that need to be addressed to integrate AI into the healthcare workflow. These include liability, as some medical AI may communicate results or recommendations to the care team without being able to communicate the underlying reasons for those results [10]. Data quality and privacy are also significant concerns. Explainability is another issue as AI tools are often referred to as 'black boxes' because they may generate unexpected or surprising outputs that end users and even AI developers are unable to explain or understand [11].

Data standardization is also critical for implementation. Data standardization refers to the process of transforming data into a common format that can be understood across different tools and methodologies. This is a key concern because data are collected in different methods for different purposes and can be stored in a wide range of formats using variable databases and information systems. Hence, the same data (e.g., a particular biomarker such as blood glucose) can be represented in many different ways across these different systems. Healthcare data has been shown to be more heterogeneous and variable than research data produced within other fields. [8]

Interoperability will be essential given the multiple components of a typical clinical workflow. For example, for an AI-assisted radiology workflow, algorithms for protocolling, study prioritization, feature analysis and extraction, and automated report generation could each conceivably be a product of individual specialized vendors. A set of standards would be necessary to allow integration between these different algorithms and also to allow algorithms to be run on different equipment. Without early efforts to optimize interoperability, the practical effectiveness of AI technologies will be severely limited.

1.5 Motivation for the Research:

AI researchers frequently do not appreciate the complexity of clinical radiology workflows. Radiology IT systems are very complex, involving modalities, routing layers, Picture Archiving and Communication Systems (PACS), archives, clinical and mobile viewers, etc. Efficient integration in such an environment can be challenging, yet is crucial, both for algorithm validation and production. Additionally, vendors do not always provide the tool sets required for such integrations. Though, valuable, of-line evaluation fails to measure the impact that an algorithm has on patient care, because the radiologist is forced to consult a non-clinical system, breaking the flow of interpretation. In cases where researchers are able to integrate into the radiology workflow, the solutions are typically one-of systems that cannot be re-used or re-targeted to other algorithms. [9]

There are already a lot of AI models that can achieve high accuracy results in segmenting, for instance, CT images. However those models never have a real application since they are not deployed in the environment of its use. In hospitals, the doctors don’t have an integration of those models in their usual workflow, making the segmentation models not available for their real end-users. In terms of numbers, 87% of data science projects never make it into production. Several steps are involved in crossing the chasm between a model and a deployable app. These include selecting the correct DICOM datasets, preprocessing input images, performing inference, exporting the results, visualizing the results, and further applying optimizations. [3]

2. Problem:

Clearly state the problem or challenge you aim to address with your research. For example, you might discuss the limitations of current manual segmentation methods, the need for efficiency, or the potential for errors in clinical settings.

3. Objectives:

The main objective of this study is to integrate an image segmentation algorithm into a clinical setting, with a specific emphasis on the utilization of TotalSegmentator, an advanced medical image segmentation algorithm designed to delineate over 117 distinct categories in CT images. This project's core goal is to establish a universal standard that is not constrained by hospital components or vendor-specific limitations. This research holds significant importance as it has the capacity to bring about substantial enhancements in the field of healthcare and medical imaging. This research is crucial because it can lead to significant improvements in healthcare and medical imaging.

One of the central objectives of this research is to enhance the efficiency and effectiveness of clinical image analysis by reducing the manual labor and time required for medical image segmentation. At Hospital de la Santa Creu i Sant Pau, where this algorithm will be deployed, clinicians currently spend a significant amount of time manually segmenting and processing CT images. The introduction of TotalSegmentator aims to reduce this weight by automating these labor-intensive tasks.

Speed is a critical requirement for this algorithm. It is crucial to minimize the time clinicians spend on image segmentation, as time is often a limiting factor in healthcare settings. By significantly accelerating the segmentation process, TotalSegmentator will enable clinicians to allocate more time to the interpretation of results, diagnosis, and treatment planning, ultimately leading to improved patient outcomes.

Additionally, the user-friendliness and intuitiveness of the algorithm are vital to its success. Clinicians may not necessarily possess the same level of expertise in setting up complex segmentation tools. Therefore, it is key that TotalSegmentator is designed with this idea in mind. Clinicians should be able to use the algorithm with ease, requiring only a few steps to obtain segmented images. This user-centric approach will make the algorithm accessible to a broader range of healthcare professionals and ensure that it integrates easily into the clinical workflow.

The potential benefits of deploying TotalSegmentator in the clinical environment are many. It can significantly enhance the accuracy and consistency of medical image segmentation, reducing the risk of human error. With over 117 classes to segment, the algorithm can provide detailed and precise results that may be challenging to achieve manually. These accurate segmentations, achieved in a short amount of time, can lead to more informed diagnoses, better treatment planning, and ultimately improved patient outcomes.

Furthermore, by automating repetitive and time-consuming tasks, TotalSegmentator will free up clinicians to focus on higher-level tasks that require their expertise, such as interpreting results and making critical medical decisions. This not only saves time but also ensures that healthcare professionals can allocate their skills and knowledge where they are most needed, ultimately leading to more efficient patient care and potentially reducing healthcare costs.

4. Methodology and approach:

Briefly describe the research methods and techniques you plan to use in your study, including the AI model you intend to deploy, the clinical setting, and data sources. Explain why your chosen approach is suitable for addressing the problem and meeting your objectives.

Total segmentator
[2208.05868] TotalSegmentator: robust segmentation of 104 anatomical structures in CT images (arxiv.org)

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This article could go in a paragraph that explained the problems of implementing AI in healthcare in general. In my TFG we have already an AI model that it is implementable but that's not an easy task.

Key challenges for delivering clinical impact with artificial intelligence | BMC Medicine (springer.com) It explains other problems to implement AI in healthcare but not the lack of implementation. For instance: While AI approaches in medicine have yielded some impressive practical successes to date, their effectiveness is limited by their inability to 'explain' their decision-making in an understandable way [87]. Even if we understand the underlying mathematical principles of such models, it is difficult and often impossible to interrogate the inner workings of models to understand how and why it made a certain decision. This is potentially problematic for medical applications, where there is particular demand for approaches that are not only well-performing, but also trustworthy, transparent, interpretable and explainable. Finally, recent European Union General Data Protection Regulation legislation mandates a 'right to explanation' for algorithmically generated user-level predictions that have the potential to 'significantly affect' users; this suggests that there must be a possibility to make results re-traceable on demand

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