CHALLENGES OF INTRODUCING ARTIFICIAL INTELLIGENCE INTO RADIOLOGICAL CLINICAL PRACTICE

Vladimir Bahun, MSc, BSc.

Sidra Medical and Research Center, Doha, Qatar
Corresponding author at Radiology Department, Sidra Medical and Research Center, Al Gharrafa Street, Ar-Rayyan, Doha, Qatar.

E-mail address: vladimir@bahun.com

Introduction

We hope you have received a fair amount of all the positives when implementing Artificial Intelligence (AI) into the radiological service reading this Special Edition of our Journal. Now, in this paper, we will focus on the possible challenges and ethical concerns when implementing AI into radiology services.

Since this is not a strictly scientific Journal, and for practical reasons, I will list findings and discuss them at the same time.

Discussion about challenges

Technical challenges

We need to mention technical challenges when implementing AI into radiology practice for a start, but we will not spend much time on the discussion here, since we can overcome most of the challenges by increasing the funding to the project. Like discussed by Shaikh *et al.* (2020), one needs to focus on workflow integration, data transfer, management and deployment, user experience, and methodological issues. Of course, we do need to address the safety concerns and physical safety to the subjects. Since every radiology department is already heavily loaded with data, I will practically assume that most of the security and safety features are already implemented.

Data collection

For any AI system, data is a crucial ingredient. The problem with data is that they can be harvested illicitly or collected from unknown sources (Castelvecchi, 2016), especially if we do not have clear regulations.

A study from 2018 (Fenech, Strukelj and Buston), has shown that people will not so voluntarily give their data to improve healthcare services. The question was simple: „How comfortable would you be with your personal medical information being used to improve healthcare?“ and 49% of the people said that they would not be comfortable, and 11% did not know. From this, it is evident that this mission (consent to giving personal data) will not be so simple, and probably the only way to overcome this is to show the real benefits to the data owners – our patients.

Patient Agreement

If AI is used as part of the research, each patient must agree to participate in the research (SFR-IA Group and CERF, 2018). In the EU, the GDPR is mandating the opt-in approach to data collection (opt-out approach is not acceptable).

Access to non-primary data

If AI systems are implemented, the bigger the data is behind it, the better will the system become. If patients

do not disclose their data fully – they will not benefit fully from AI technologies. This may seem like a minor issue, but we need to understand that not all data is stored with one healthcare provider – communications protocol will need to be updated to enable accessing the data remotely. We should not rely on current technologies and protocols to be fully competent in the AI area. Although here the logical question arises – Will patients that disclose more data get better results? The answer is positive, and the situation is the same if you will visit a physician today – the more information you will provide – the better are the chances to have a quick and correct diagnosis. The only difference is that AI is almost limitless with resources.

Data Quality

Sample source

Any diagnostic test should be evaluated performance-wise (SFR-IA Group and CERF, 2018). So, firstly **we need to define the population that the test is intended for, and later, we must ensure that we have enough data for that specific population**. We are still missing regulations in this field, and it is entirely possible that data that was used for training the AI does not match our population. Even if the data is from the same age group, and from the same geographic region, the differences can be vast.

Comparable examination techniques

We need to ensure that we are using the data from the comparable test. For example, CT of the lungs can be performed with various techniques and with multiple machines – we need to standardise them. This is not just the question of different centres; we need to have in mind that imaging techniques are continually evolving – what was the standard just a few years ago does not have to be today.

The AI training needs to be constant

The diseases are always progressing and changing, and when we are training the AI systems – we cannot know how the disease will progress. If there will be a sharp change in the disease, how can we ensure that our algorithms will be up to date? The answer is simple – we need to train our AI algorithms with new data continually. Currently, there is no regulation regarding this challenge.

Standardised radiological findings

The standardised report should be used for AI training. Since we are matching images with findings, description of the results also needs to be standardised, but, the implementation of structured reporting in clinical routine is still scarce (Pinto dos Santos and Baeßler, 2018). Further implementation will help not only to benefit from it in the first step but to prepare our data for possible AI systems. The standardised data is not only necessary for the radiology finding, but in all aspects of Electronic Medical Record (EMR), so we can correlate not only radiological findings but also the other essential patient data like vital signs, clinical representation, or others.

How much data do we need?

And for the end of this section– how can we determine what amount of data is enough? Can we just run a parallel test with comparing AI with radiologists on the X number of analysis? What about if we are talking about the rare disease? Will the rule stay the same? What about if we are discussing a minor difference in the image that could change the whole treatment? Now add progressing of the disease into the equation – do we need regulation about the constant training also? Will it be the same for all conditions? How can we achieve a consensus between stakeholders? These are all questions that should have a detailed discussion with all stakeholders, and of course, we should never forget the public.

Anonymisation

Radiology uses the DICOM standard for all imaging files. It is not a problem to remove all personal and healthcare institution data, but the issues can arise from the images itself. If we are talking about rare diseases with rare clinical presentations, it is not hard to identify the patient just with that in mind. If we combine this with just the age of the patient in time of imaging, the identification is almost inevitable.

Furthermore, 3D volume reconstructions can be paired with facial recognition applications to reidentify the patient (Mazura *et al.*, 2012; Chen *et al.*, 2014). That is the reason why we should remove, or de-face any facial 3D reconstructed images, even if they are partly present. Moreover, this is not only applicable to the head and face imaging – when there is a large amount of data involved

„entities facile with manipulating massive data can likely re-identify just about any radiology exam“ (Na *et al.*, 2018).

Thus, all stakeholders in AI development must be aware of these potential risks and take all steps to protect patient privacy.

Big Data challenges

One interesting issue in the AI area arises from different sets of data that would not previously have been considered as having privacy implications. Now they can be combined in ways that threaten privacy (Nunan and Di Domenico, 2013). The authors call these phenomena the unintended use paradox. For example, we could be using publicly available pictures and other information from one social media site and after that, with facial recognition and biography reidentify the users of major dating site.

Additionally, one needs to be careful when using big data in AI. Inevitably, a smooth data collection has disruptive potential for science and society. However, some authors will say that some of them may „lead to false expectations and, at their nadir, even to dangerous social, economic and political manipulation“ (Succi and Coveney, 2019). The same authors have based their conclusions on four points:

Complex systems are strongly correlated; hence they do not (generally) obey Gaussian statistics.

No data are big enough for systems with a strong sensitivity to data inaccuracies.

Correlation does not imply causation, the link between the two becoming exponentially fainter at increasing data size.

In a finite-capacity world, too much data is just as bad as no data.

Now, when we have an enormous amount of data in one place, we might sacrifice the classical research experiment (hypothesise > gather data > analyse) in favour of data collection activities (Succi and Coveney, 2019). **If the data is large enough, you are more likely to find correlations.** The problem is additionally that, with enough arbitrary parameters, it will be possible to find a curve that will fit through just about any set of data points. With that in mind, it will be amusing to end this section with the great conversation between Enrico Fermi and Freeman Dyson: „How many arbitrary parameters did you use for your calculations?“ I thought for a moment about our cut-off procedures and said, „Four.“ He said, „I remember my friend Johnny von Neumann used to say, with four parameters I can fit an elephant, and with five I can make him wiggle his trunk (Dyson, 2004).

Who owns the data?

At first, this is a simple question that is regulated already, but, if we dig a little bit deeper, we will found out that the answer is not so simple. It is easy to answer when we are discussing the last images based on which radiologist is making a decision, what about the steps before? Who is the owner of the raw data that is produced in the machine? Will it be the machine owner or patient in EU (GDPR)? Kindly note that some raw data can only be used on the compatible devices, and often not even between different vendors. After this step, who is the owner of the „pixel data“, the image that is created from the raw data with AI algorithms? Most likely it will be machine owner in the US, or patient in the EU. What about the annotations or other non-clinical data? Outside the EU, if the company will use the private data and if they will develop a profitable AI system, it is not clear who should benefit from it. From everything here, we need better regulations, not just in terms of the ownership, but more in terms of the responsibilities.

Data protection

In the EU, the „Cybersecurity Directive“ (EU) 2016/1148 is prescribing the minimal measures that will prevent cyber-attacks together with the obligations to notify the supervisory bodies if the attack is happening.

Mirroring the bias

Healthcare delivery varies culturally and ethnically, so, it is not unexpected that AI can mirror the bias from human decisions into their systems. This has already been shown in the literature (Angwin, Mattu and Kirchner, 2016; Char, Shah and Magnus, 2018). Here, the case might be that developers are completely unaware of the bias – in radiology, the implication is that the available data does not precisely represent the population – only people whose benefits are more extensive than risks will undergo an examination with radiation involved. Thus, **we can assume that all radiology databases in the world are biased against more positive examination findings**, and AI might interpret that the disease is more present in the population.

Intention

Like beautifully mentioned by Pesapane et al. (2018), the intention of the AI system is essential, because some devices can be programmed to perform in unethical ways. The excellent example is the recent algorithm from Volkswagen that allowed vehicles to reduce emissions during testing. Similarly, investors to AI systems could have temptations to guide the system towards generating more profits by performing additional tests, or by recommending specific products (drugs or devices).

Conflict of Interest

There is a possible issue of conflict of interest. **Anyone involved in AI system development is potentially in a conflict of interest,** just like it is when there is a new drug development or testing. The solution here is simple – to apply the same principles.

Who is responsible?

As soon as AI will decide on something, the question of accountability will arise. Can the developer be responsible? Company? Radiologist? Regulatory agencies? The patients themselfs? The first questions often arising in these discussions is „Who will be accountable?“ Although this is an important question, I believe we are giving to much weight to it. It is not all black and white, especially not in AI systems. If the decision is simple, the AI could display the level of confidence, but we still need to remember that the match could be close to a 100%, and if the training samples were not ideal, the result would be, well, not ideal also. On the other hand, AI is based on the algorithms, i.e., on what they have learned since their creation, so, the reason why their decisions are unpredictable is twofold (Scherer, 2015). Since AI systems are making decisions based on the different approach than humans, humans will have problems to understand these decisions.

Kohli and Greis (2018) have explained it nicely: Just as the root-cause analysis is a critical tool for patient safety, **if an artificial intelligence system causes harm, we need to understand why**. Now, this is not a simple process if we are dealing with the black-box nature of some algorithms. We should have the ability to investigate and find the exact reason. This is not only because there was harm done (patient safety), this is also in the interest of the investors/owners – if we will not be able to determine reasons and mitigate them – eventually, AI system will not be used.

Threat or opportunity to radiology staff?

AI can detect and characterise abnormal findings in the radiological images, so, the role of radiologist might have a competitor. Thus, radiology is now moving from a subjective perceptual skill to a more objective science (Jha and Topol, 2016). It is not hard to imagine that AI has the potential to replace many of the routine detection, characterisation and quantification tasks currently performed by radiologists (Pesapane, Codari and Sardanelli, 2018).

On the technologists' side, AI applications may enhance the reproducibility of technical protocols, improving image quality and decreasing radiation dose, decreasing MRI scanner time (Golkov *et al.*, 2016), and optimising staffing and CT/MRI scanner utilisation, thereby reducing costs (Lakhani *et al.*, 2018). So, these applications will simplify and accelerate technicians' work, also resulting in an average higher technical quality of examinations (Pesapane, Codari and Sardanelli, 2018).

Although some authors will say that **AI is not a threat to radiology – It is, indeed a tremendous opportunity for its improvement** (Pesapane, Codari and Sardanelli, 2018). In 2019, a survey to assess undergraduate medical students' attitudes towards AI in radiology and medicine found out that 56% of them do not believe that AI would not be able to establish a definite diagnosis (Pinto dos Santos *et al.*, 2019). Other authors have shown that there is a significant mismatch between the perceived capabilities and untamed expectations of machine learning approaches compared to their actual capabilities and limitations at present (Thompson *et al.*, 2018).

AI as a medical device?

Pesapane et al. (2018) are suggesting that one of the solutions to govern the AI will be to consider AI software used in healthcare as a medical device for legislative purposes. They are considering two different AI systems, two different classes – one that is not deciding on the treatment options and one that is. I firmly believe we need to have a further discussion on how to regulate AI systems in radiology since any diagnosis confirmed with imaging will usually require treatment or intervention.

Version control

Until now, there was not much need for tracking changes of the exact code in different software releases, but, from now on, I believe that we should have the whole history

of human-initiated changes in AI system. This will allow us to fine-tune and take responsibility for all human actions on the system. Another possible issue here is the consent for each version of the algorithm – will we need to obtain a new one if the algorithm is changed? Where is the line where do we need consent, and where we do not?

Will patients trust AI?

Patients are usually following the advice from medical professionals while it must be ensured that every patient right is available. It is in human nature to understand how things work before they put their trust in it. Here, **the challenge might be that AI systems could be designed to protect society more than the individual.**

Try to imagine the following discussion with your medical physician (Smith, 2018): „*I don't know why you are ill, but my computer says, 'Take these pills'*" or „*I don't know why you are ill, but my computer recommends surgery*". **I am not expecting that black box decisions involving treatment will be favourite of the population, at least not in the beginning, and we should not expect the trust from the physicians or the patients, at least not in the beginning, if we cannot explain the reasoning behind it.** This is in line with the European Society of Radiology (ESR) paper (2019), where from 675 ESR members contacted, for more than half of responders, AI-only reports would be not accepted by patients. We should take this data with the grain of salt because radiologists, and not actual patients represented the population in this study. Other authors have also shown that patients are moderately negative when it comes to their trust in AI in taking over diagnostic interpretation tasks of the radiologist, both concerning the accuracy, communication, and confidentiality (Ongena *et al.*, 2020). In the same study, patients also indicate to appreciate and prefer personal interaction over AI-based communication and, notably, patients reported that they would feel a lack of emotional support when computers would provide them with the results. So, I feel obligated to say that **healthcare should stay patient-centric.**

To overcome trust issues, **we should ensure transparency** so we can explain the benefits and risks transparently to the users (Side note: I am still shocked why we are explaining only risks and not the benefits of the medications to our patients). At a later stage, I will be happy to trust the black-box systems if they will be proven wrong at the lower rate than human experts, but then, we have a transparency problem in how to measure this. A possible solution is to measure it the same way as we measure the side-effects in drug trials. Another possible solution is to make systems available for public testing and evaluation.

AI in low resource regions?

With all challenges in mind, how can we eliminate them if one of the low-resource regions will willingly accept all the risks because the risks are smaller compared to the dangers of not having the service at all? This is covered in the article by Vaisman et al., (2020). They are stating that we need to evaluate the key issues: „Key issues discussed include the interrelationships between stakeholder engagement, consent, data security, accessibility of technology, adhering to current and evolving care standards and deciding how to effectively use resources". All good, but, what if we will be in the situation where placing an AI system in the short notice can benefit the whole world in preventing the outbreak, for example?

Limitations

There are several limitations to this article. First, there might be a publication bias, i.e. to profit more from the invention, the bias might be present, and mentioned authors might avoid publishing any detected obstacles. Second, only a few databases were searched and only with open free access to the papers. Third, there are limited keywords used. For all these reasons, it is possible that some relevant publications were missed. Nevertheless, this assignment has the potential to explore and reach the selected aims.

Conclusion

The problem of the paper like this – focusing only on challenges, one might say that it is too negative. Still, with so much positive outcomes with AI, it is essential to detect all possible challenges. Ideally, this should happen before the harm is done. Furthermore, and maybe even more critical, will we have a system in place to detect possible harm that is not obvious to humans? This was the main reason for writing this article – to identify the potential challenges when implementing AI into radiology

clinical practice – and we have identified a good, but still not a finite number of them.

We should remain careful because **probably the biggest problem with overcoming all challenges when implementing AI into radiology practice is time**. Investors and entrepreneurs understand the potentials of AI and are trying to use it as soon as possible – it is clear why we need timely and relevant regulations.

In the end – it is our obligation to implement any new technology ethically, to enable it to grow adequately so that humanity can benefit from the best possible outcomes from it. ■

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