Practical and Ethical Considerations for Generative AI in Medical Imaging

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Abstract. Generative Artificial Intelligence (AI) has the potential to reshape medicine. It is helpful to clinicians and radiologists for diagnosis, screening, treatment planning, interventions, and drug development. It benefits the clinical flow with real-time decision-support systems. While generative AI can potentially improve healthcare, it also introduces new ethical issues that require careful analysis and mitigation strategies. This work emphasizes the ethical aspects of generative AI in medical imaging, aiming to ensure that advancements in this field align with established ethical principles and societal values. We delve into the ethical implications surrounding bias, fairness, patient privacy, consent, transparency, explainability, intellectual property, and data ownership. We explore the challenges posed by generating and using synthetic data, adversarial perturbations, and privacy risks associated with diffusion model based generated synthetic images. We also discuss regulations governing the use of synthetic medical data and offer issues to mitigate these challenges. To promote equitable application of these powerful tools, we propose clear guidelines for promoting fairness, mitigating bias, and ensuring diversity within generative AI models.

Keywords: Medical imaging · Generative AI · Diffusion model · Adversarial perturbation · Synthetic data · Fairness · Privacy · Transparency

1 Introduction

Generative Artificial Intelligence (AI) is rapidly transforming different sectors in healthcare, in particular medical imaging. The popular types of generative AI models particularly useful for image generation are diffusion models [15], Transformer-based models (GPT-4 [26]), DALL-E 3[1], Generative Adversarial

[1] https://openai.com/index/dall-e-3/

Networks (GANs) [10], and Variational Autoencoders (VAEs) [18]. These models can generate diverse, realistic-looking, high-quality synthetic images or videos, including rare medical scenarios that might be important in the medical domain for an automatic disease detection system. The synthetic data can be utilized for training and evaluating other AI algorithms. This advancement can significantly improve disease diagnosis. It sidesteps the need for manual medical annotation efforts, accelerating model deployment. It can help identify complex disease mechanisms, predict clinical outcomes, and prescribe tailored patient treatments.

The examples of recent generative AI models for image generation include stable diffusion [33], Apple Intelligence[1] and Midjourney [24]. For natural language processing tasks, GPT-4o[2], Claude 3 family (Anthropic)[3], Gemini[4], LaMDA [6], PaLM [7], Bloom [19], LLaMA [34] are some of the most popular approaches. For programming tasks, OpenAI codex [5] and Alphacode [20] are frequetly used. Related to medical imaging, the famous Medical Open Network for Artificial Intelligence (MONAI) framework [3] helps in the creation of large synthetic datasets for training AI models prioritizing patient privacy. By preserving patient anonymity and maintaining confidentiality, MONAI enables the ethical use of sensitive medical data, thus promoting ethical data usage practices [3].

Limited real patient data due to privacy concerns remains a significant hurdle in developing robust medical AI models. Fig. 1 shows the some of the ethical and practical challenges in integrating generative AI in medicine. The MONAI framework facilitates the creation of large synthetic datasets while preserving patient anonymity [3]. This promotes ethical data usage and allows researchers to train models on a broader range of data without compromising privacy. Additionally, pre-trained generative models like *RadImageGAN* [23] empower researchers to synthesize realistic medical images that closely resemble real data. These models offer flexibility to generate customized datasets tailored to specific applications. Advancements in generative models have a two-fold benefit: they significantly increase the availability of training data for medical AI models, and they democratize AI in biomedical imaging by providing access to data and expertise previously limited to specialized domains. This fosters wider adoption and innovation in the field [23].

Beyond data generation, generative models can enhance the quality of existing medical images by denoising and enhancing them using techniques like VAEs [35]. This leads to more precise visualization of subtle anatomical details for radiologists, potentially aiding in faster and more precise diagnoses [35]. Additionally, it can be useful in automating lesion segmentation tasks. Training AI models can achieve this to differentiate healthy and diseased tissues, significantly assisting radiologists in faster and more precise diagnoses [22]. Furthermore, the potential for personalized medicine is another opportunity for generative AI in

[1] https://www.apple.com/apple-intelligence/
[2] https://openai.com/index/hello-gpt-4o/
[3] https://claude.ai/new
[4] https://gemini.google.com/app

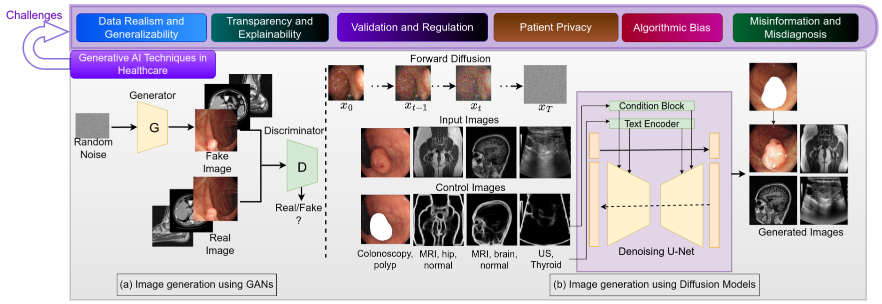

Fig. 1: Ethical and practical challenges in integrating generative AI (synthetic image generation technique) with medical imaging. Part (a) shows the GANs [10], and part (b) shows diffusion models [29] producing high-fidelity synthetic medical images.

medical imaging. The generative AI models create synthetic data tailored to particular diseases or responses to treatment. This data can then be leveraged to develop individualized treatment plans and predict patient outcomes with greater accuracy [21].

While these advancements in generative AI models open new opportunities to enhance healthcare outcomes through better data availability and improved model performance, they also raise significant ethical concerns. One critical concern is ensuring the authenticity and *representativeness* of synthetic data. If these images aren't realistic reflections of actual patients, they could mislead AI models, leading to biased diagnoses and potentially harmful treatment decisions [1]. To address this, researchers should develop methods to evaluate the authenticity and applicability of synthetic data. Additionally, mitigating biases in generative models through diverse real-world datasets and fairness-aware learning approaches is crucial to prevent biased diagnoses and treatment recommendations [1]. Another concern is data privacy and patient rights [36]. Even anonymized patient data used for synthetic image generation requires informed consent. Open and transparent communication regarding data usage policies is important [1]. Implementing robust anonymization techniques and establishing strong governance frameworks can further ensure patient privacy protection [36]. By carefully addressing these ethical considerations, we can foster responsible development and deployment of generative AI models in medical imaging, thereby enhancing patient privacy and promoting equitable healthcare systems.

The main contributions of this work are as follows:

– We highlight practical ethical concerns (patient privacy, algorithmic bias, misinformation, or misdiagnosis) related to generative AI models in medicine. Additionally, we provide potential guidelines to address these concerns, such as ethical generation and use of synthetic data, data realism,

generalization, fairness, privacy, consent, transparency, explainability, safety, and intellectual property.
- Our study highlights some of the challenges related to privacy and security risks and performance drops associated with utilizing diffusion model-generated synthetic images in medical imaging. We show examples of specific vulnerabilities in Fig. 2 and Fig. 3).
- We examine the impact of adversarial perturbations on medical image segmentation performance. When adversarial perturbations were introduced, we observed a significant performance drop on the Cirrhotic Liver MRI dataset (see Fig. 4).
- We discuss regulations on synthetic medical data and propose techniques to mitigate them. We also discuss measuring fairness, bias, and diversity, ensuring equitable outcomes for all patients. By prioritizing fairness, safety and interpretability, generative AI can have a positive societal impact.

2 Synthetic image generation

Synthetic image generation offers a promising avenue for addressing data scarcity in medical AI. These techniques produce artificial images that mimic real-world clinical data like X-rays, CT scans, and MRIs [13]. This synthetic data can be used for various purposes, including training AI models with limited real data, simulating rare or complex medical conditions, and facilitating diverse case studies for research and education [13].

However, ethical concerns surround the potential for bias in synthetic medical images. Generative AI algorithms can unintentionally reflect biases in their training data, resulting in the generation of biased or unfair or synthetic images [14]. Addressing these biases is critical to ensure fairness and equity in healthcare applications, particularly for diagnosis and treatment decisions. Additionally, concerns arise when synthetic images fail to capture the intricate details and nuances of real patient data, leading to inaccurate conclusions or decisions in clinical practice. Therefore, it is essential to address these ethical challenges to ensure the responsible and ethical use of synthetic image generation in healthcare.

Diffusion models are emerging as powerful tools for synthetic medical image generation. However, recent work by Carlini et al. [4] suggests they may pose a greater privacy risk compared to GANs due to their tendency to memorize training data more extensively (approximately 2x). This raises concerns about potential data leakage, particularly when training data includes sensitive patient information like medical histories, personal identifiers, or genetic/biometric records.

Standard training procedures involve masking private details from training images before feeding them into the model. However, instances like those depicted in Fig. 2 raise questions. Here, synthetic images generated by diffusion models contain text alongside masked textual details. Do these texts represent:

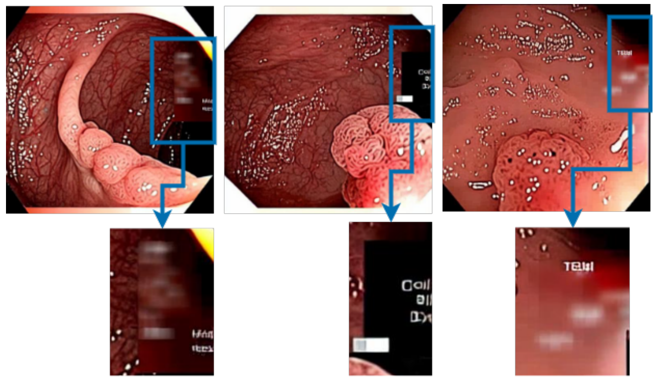

Fig. 2: Sample synthetic images generated using a diffusion model. The accompanying text within these images is not completely masked, which could be a concern if it leaks some sensitive information.

- **Unmasked Data Leakage:** Was sensitive information overlooked during the anonymization process?
- **Model Decoding Attempts:** Is the model attempting to reconstruct the masked text?

These findings and unanswered questions highlight the need for further investigation into potential privacy vulnerabilities arising from training data or the image generation process itself.

Image generative models suggest pre-trained foundation models in medical AI workflows for enterprises. The ethical use of image-generative models requires ensuring that the generated images accurately represent real medical conditions. Poorly generated images could lead to incorrect diagnoses or treatment decisions, potentially harming patients [25]. Therefore, developers must prioritize the quality and accuracy of generated images to uphold patient safety and well-being. Although AI-generated synthetic images promise to revolutionize medical imaging through improved diagnostic accuracy and patient outcomes, their development involves significant challenges. These challenges include computational demands, data availability, training data quality, and model performance [38]. Generative AI models require billions of parameters and extensive training datasets, resulting in high computational costs. However, ensuring unbiased and high-quality data remains critical but challenging due to limited data availability in the medical domain [38]. Additionally, restricting access to existing public datasets further complicates the training process. Moreover, applying synthetic images in medical imaging also introduces the following practical and ethical challenges that need to be addressed [9].

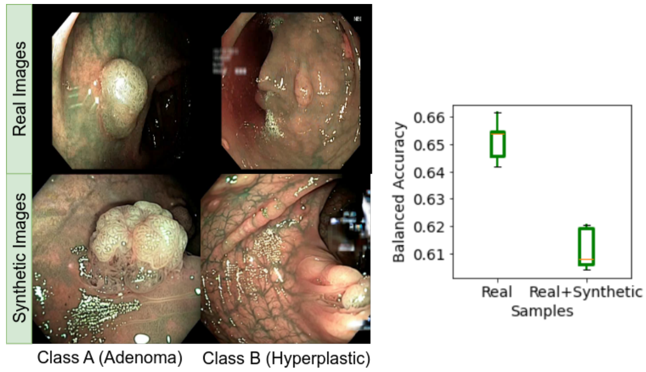

Fig. 3: The figure presents (a) real samples and synthetic samples generated using a diffusion model, and (b) a boxplot depicting the comparison of classification outcomes in two scenarios, one when only real images are used for training and the case when synthetic images were introduced in the training set. The results demonstrate how visually appealing synthetic images can reduce the performance of a classifier designed to identify pathological classes of polyps when combined with real ones.

2.1 Practical challenges

Data realism and generalizability. Biases in real patient data used for training can be amplified in synthetic images, potentially leading to models that underperform on diverse patient populations. It is essential to validate that these models capture the full range of disease presentations and must be established to avoid missed diagnoses. As shown in Fig. 3, the visually appealing synthetic images fail to capture the pathological aspect of medical images, degrading the classification results.

Transparency and explainability. Unlike traditional medical images, synthetic images lack inherent context. Understanding how the AI model generates a specific image is critical for healthcare professionals to assess its validity. A lack of transparency can limit trust and adoption among clinicians.

Validation and regulation. Existing validation processes for medical imaging tools need to be adapted to encompass synthetic images. Regulatory frameworks are necessary to guarantee the safety and efficacy of AI generated synthetic images before widespread clinical use. These frameworks should address both technical and ethical concerns, including data privacy and biases.

2.2 Ethical Challenges

Patient privacy. Synthetic image generation relies on real patient data, raising concerns about privacy and potential misuse. De-identification techniques might not be sufficient to guarantee anonymity, and the possibility of re-identification through advanced AI techniques necessitates robust data governance practices for protecting sensitive medical information.

Algorithmic bias. Biases inherent in the training dataset may persist in the synthetic images, resulting in misdiagnosis and unfair treatment, especially for underrepresented patients. It is particularly observed in cases where there are underrepresented patient groups. To mitigate bias, thorough data selection must be done, diverse and representative data must be included and continuous monitoring of generative AI models are required.

Misinformation and misdiagnosis. The realistic nature of synthetic images raises concerns about their potential to generate misleading medical information. Thus, clear communication strategies are crucial to ensure responsible use and accurate interpretation, particularly with a patient's medical history [1].

3 Effect of Adversarial Permutation

Fig. 4 shows the impact of adding adversarial perturbations on segmentation performance. We utilized the Fast Gradient Sign Method (FGSM) [11] to generate the adversarial examples and employed the UNet [30] model for T2-weighted Liver MRI segmentation. The UNet achieved a dice coefficient of 88.49%, mIoU of 82.54%, recall of 89.96%, precision of 90.80%, and Haudorff distance (HD) of 3.5421. However, when adversarial input was introduced, the model's performance significantly dropped, with a dice coefficient of 35.13%, mIoU of 27.95%, recall of 31.49%, precision of 60.41%, and HD of 6.60.

The experiments were carried out using the PyTorch framework [27]. For the segmentation tasks, a batch size of 16 and a learning rate of 1e-4 were considered. The network was set to train up to 500 epochs of training with an early stopping set to 50 to fine-tune the parameters. To further enhance network performance, we utilized a hybrid loss function that combined binary cross-entropy and dice loss, along with an Adam [17] optimizer for parameter updates. The data was partitioned into three subsets: 80% for training, 10% for validation, and 10% for testing. To balance the training time and model complexity, we resized the image to a resolution of 256×256 pixels in plane resolution. All experiments were conducted on the A100 GPU server.

The qualitative results demonstrate that both original and adversarial modified images appear identical to human observers and even radiologists. However, segmentation output on contrast enhanced abdominal MRI images (T2-weighted Liver MRI) was affected significantly. This highlights the need to develop robust deep learning strong models and defense techniques to withstand minor but powerful pixel-level alternations. Some techniques to enhance the model's robustness are strong data augmentation, adversarial training, smooth activation function, advanced regularization, and distillations.

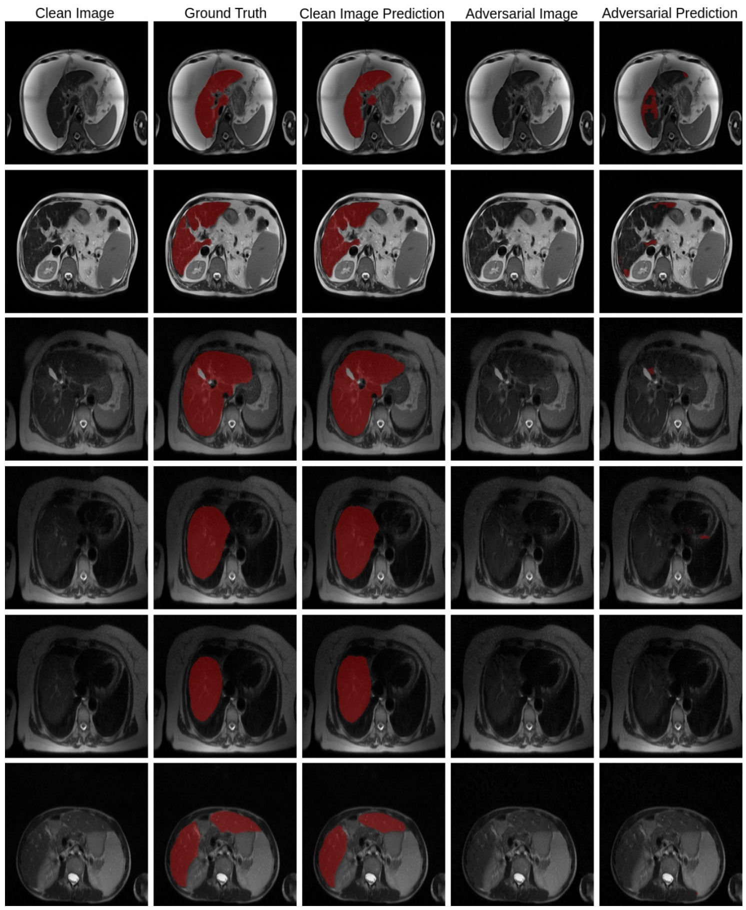

Fig. 4: The figure shows (a) Clean T2-weighted Liver MRI image, (b) Ground truth, (c) Clean image prediction by UNet [30] model, (d) Adversarial image generated by using Fast Gradient Sign Method (FGSM), and (e) Adversarial Prediction.

4 Regulations on synthetic medical data

Synthetic data addresses the current challenges of medical data availability. Training AI models using such datasets also complies with medical privacy regulations such as the Health Insurance Portability and Accountability Act (HIPAA) and General Data Protection Regulation (GDPR). *Ensuring compliance, privacy, and data protection regulations* is paramount when generating and utilizing synthetic medical data to prevent unauthorized disclosure of sensitive patient information. In response to these challenges, researchers and developers are exploring innovative approaches to synthetic data generation that prioritize patient privacy and comply with regulatory requirements.

Techniques such as *federated learning (FL)* [28], *differential privacy* [37], and *data anonymization* [32] are being investigated to mitigate privacy risks while enabling the development of robust generative AI models.

In particular, the FL-based FedSyn method [2] allows AI models to be trained across multiple decentralized synthetic data sources without directly accessing raw patient data. Each participating healthcare institution retains control over its data, ensuring compliance with medical privacy regulations like HIPAA and GDPR. By aggregating model updates rather than raw data, FedSyn can enable the training of robust generative AI models while preserving privacy and copyright regulations. *Differential privacy* techniques add noise to individual data points before they are used for training generative AI models. This ensures that no single patient's data can be inferred from the model's outputs, thereby protecting medical privacy and copyright regulations. *De-identifying and Anonymizing medical images* by removing or obfuscating identifying information such as patient names, dates of birth, medical record numbers, etc., can help protect patient privacy while allowing synthetic data to train generative AI models. Additionally, strategies such as *consent for medical data* and *intellectual property* should be examined when developing and deploying generative AI models in medical imaging.

5 Measuring fairness, bias, and diversity

Fairness metrics assess whether the generative AI model produces *unbiased results* across different patient demographics, such as age, gender, ethnicity, or socioeconomic status. Equal opportunity is a critical aspect of fairness, which entails ensuring that the generative AI model provides equitable access to accurate medical image generation for all patients, regardless of their demographic characteristics [31]. This means the model should not exhibit realism and correctness based on factors like race or gender. On the other hand, procedural fairness ensures that the processes involved in medical data collection, model training, and decision-making are *transparent, accountable, and unbiased.* This includes transparent documentation of medical data sources, model architectures, and evaluation metrics, as well as mechanisms for addressing and mitigating biases at each stage of the AI pipeline [12].

Bias assessment involves identifying and mitigating biases in the generative AI model's training data or algorithms that may lead to skewed or inaccurate image generation [8]. Firstly, *biases may originate in the datasets* that are used to train AI models and might inadvertently reflect societal prejudices or inequalities present in the data sources. For instance, historical biases in medical records or imaging datasets can lead to skewed representations of certain demographic groups, potentially resulting in biased AI predictions. Secondly, *biases can be introduced during the algorithm design*, where choices made in AI model architecture, feature selection, or optimization techniques may reinforce or increase existing biases within the data. Lastly, *biases can also emerge from user* *interactions* with generative AI systems, where feedback loops or reinforcement learning mechanisms may reinforce and exacerbate biases present in the system's outputs. Therefore, it is imperative to identify, mitigate, and address biases at each stage of the machine learning pipeline to ensure the development of fair, transparent, and unbiased AI systems.

Diversity of medical image generation encompasses the ability of the AI system to generate medical images that represent a *wide range of clinical scenarios, anatomical structures, imaging modalities, and disease presentations*, ensuring that the AI system can effectively capture the heterogeneity present in clinical practice. It ensures the AI system's *robustness, generalizability, and clinical relevance*. Additionally, diversity of generation enables AI models to adapt to diverse patient populations and imaging settings, facilitating their broader applicability and adoption in healthcare settings. To evaluate and promote diversity in generative AI outcomes for medical imaging, researchers may employ metrics based on the entropy of neural network encodings [16]. Overall, generation diversity ensures that the AI system can effectively capture the complexity and heterogeneity of real-world clinical data, thereby enhancing its utility and impact in medical imaging applications.

6 Conclusions

This study highlights the ethical complexities of deploying generative AI in medical imaging. Our study emphasizes fairness, patient privacy, accountability, algorithmic and data bias, and transparency, emphasizing the need for the responsible use of generative AI in medicine. We have identified practical and ethical challenges, from data realism and generalizability to transparency, validation, and regulation, emphasizing the need for continuous scrutiny and improvement. Additionally, with some qualitative examples, we showed the effect of adversarial perturbations on medical image segmentation performance and the effectiveness of diffusion models in generating realistic medical images. Moreover, we also provide some standard regulations on synthetic medical data and discuss ways to ensure fairness and mitigate bias problems and diversity challenges. We advocate for collaboration between academic researchers, ethicists, clinicians, and regulatory bodies to ensure ethical considerations are met for developing responsible generative AI in medicine.

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