Recommendation and Guideline

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Position Statements of the Emerging Trends Committee of the Asian Oceanian Society of Radiology on the Adoption and Implementation of Artificial Intelligence for Radiology

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Artificial intelligence (AI) is rapidly gaining recognition in the radiology domain as a greater number of radiologists are becoming AI-literate. However, the adoption and implementation of AI solutions in clinical settings have been slow, with points of contention. A group of AI users comprising mainly clinical radiologists across various Asian countries, including India, Japan, Malaysia, Singapore, Taiwan, Thailand, and Uzbekistan, formed the working group. This study aimed to draft position statements regarding the application and clinical deployment of AI in radiology. The primary aim is to raise awareness among the general public, promote professional interest and discussion, clarify ethical considerations when implementing AI technology, and engage the radiology profession in the ever-changing clinical practice. These position statements highlight pertinent issues that need to be addressed between care providers and care recipients. More importantly, this will help legalize the use of non-human instruments in clinical deployment without compromising ethical considerations, decision-making precision, and clinical professional standards. We base our study on four main principles of medical care—respect for patient autonomy, beneficence, non-maleficence, and justice.

Keywords: Position statement; Asian-Oceanian Society of Radiology; Artificial intelligence

INTRODUCTION

Artificial intelligence (AI) has pervaded daily life. Three-quarters of the 692 Food and Drug Administration (FDA)-approved AI solutions (software as a medical device) as of October 19, 2023, belong to the radiology domain [1]. Yet, the adoption and implementation of newly approved AI solutions in the majority of radiology practices have been

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slow, predominantly due to a lack of substantial clinically proven advantages, difficulties in integration into existing workflows, uncertain business models [2], and lethargic updates despite the vast number of approved AI solutions [3]. In addition, although the FDA has approved 692 AI solutions, updates to these solutions have been limited. In this series of position statements, we provide readers with a practical understanding of AI and answer important questions that guide radiologists' approaches toward the use of AI in clinical practice.

Several publications seek to advise clinicians on the implementation of AI in various disciplines, with some adopting a specialty-specific stance [4]. Health systems in the Asia-Oceanian region comprise a heterogeneous group. They are diverse in terms of clinical practice patterns and readiness to adopt radiology AI. These position statements represent a collective consensus among members and advisers of the Emerging Trends Committee of the Asian Oceanian Society of Radiology (AOSR). This document was approved by the AOSR Executive Council on January 24, 2024. The aim of producing this series of statements was to raise awareness among the general public, promote professional interest and discussions, clarify ethical considerations when implementing AI technology, and inform the radiology profession of a rapidly evolving field.

METHODS

The 10 authors include AI developers and AI users, all of whom are radiologists in the following countries: India, Japan, Malaysia, Singapore, Taiwan, Thailand, and Uzbekistan. Among us, two are also ethics administrators who have been previously involved in the clinical deployment of AI algorithms in their respective hospitals and have experience in the practical aspects and implementation of AI in Radiology.

The Emerging Trends Committee of the AOSR holds quarterly meetings, and the idea of creating recommendations and guidelines was formulated during one such meeting. Two authors (C.H.T. and K.A.G.) drafted several statements in point form, pieced together in prose by a third author (N.K.W.), and then presented them to the Emerging Trends Committee of the AOSR for discussion, refinement, and consensus. Subsequently, the paper underwent multiple revisions with input from the rest of the authors' group. There was ample room for discussion regarding the robustness and soundness of the points raised, with everyone reaching a consensus at the end of the process.

Thereafter, email correspondence between the authors and the Executive Council of the AOSR was conducted for editing. Revisions made by executive council members were integrated and considered in the final manuscript before submission. Therefore, this study presents consensus opinions from the Emerging Trends Committee of the AOSR, endorsed by the AOSR executive council.

RECOMMENDATIONS

We have divided the paper into three parts: the fundamentals of developing AI, key considerations for adopting AI, and overcoming barriers to the adoption of AI. These were constructed based on fundamental principles: the use of AI in radiology should follow ethical guidelines, and non-human decision-making should demonstrate features of human decision-making, including respect for patient autonomy, non-maleficence, justice, and beneficence.

Furthermore, the contents of this position statement cover:

1) AI literacy: Understanding the basic methods used to generate an AI output by the general radiologist, requiring sufficient information and comprehension of the algorithms available, relevant training parameters that have been tested, and results that have been achieved prior to deployment within a clinical setting.

2) Integration: For AI to be used in radiological diagnoses and decision-making, AI tools can be clinically deployed and integrated into the workflow of radiologists and other healthcare providers during their decision-making processes [4].

3) Evidence: Multiple clinical trials with large sample sizes should be conducted, and outcome-based studies should be verified and published to ensure that the AI tools are adequately tested [5] prior to clinical implementation. These trials will need to ascertain whether AI can provide benefits not only to individual patients but also to the efficiency of the healthcare system, as it will be integrated into clinical workflows and protocols.

4) Governance: A set of rules and regulations that have been thoroughly discussed and verified with multiple experts coming together to achieve a consensus that will govern the use of training data. This will include establishing a governing body to regulate and supervise the use of AI tools in radiology and continuously monitor the safety of these tools throughout their clinical implementation [4].

5) Equity: All countries and healthcare providers should

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have fair and equal access and use, regardless of age, race, sex, income, social status, and ability to use technology. This will help overcome geographical barriers and facilitate the international implementation of AI.

Fundamentals of Developing AI

In this section, we review the fundamentals of AI, including common methods of machine learning, explainability, data access, and continuous learning. This will be useful for all radiologists to understand before deploying AI for clinical use.

Recommendation 1: **Machine learning methods are superior to rule-based AI methods, but greater care is needed to ensure clinical relevance.**

AI is a simulation of human decision-making, and two common methods are used: rule-based AI and machine learning methods.

A traditional machine learning method refers to a non-opaque pathway used to derive decisions, where each step is clearly understood. It uses several algorithmic models and statistical methods to solve problems and derive decisions without specialized programming. Several machine learning models are single-layered. Therefore, large components of feature extraction and data processing are typically performed before placing the data into the algorithm [6]. This has been the only available option for computer-aided diagnosis for many years and is still useful for simple tasks with objective parameters or in combination with deep learning methods. Such applications are not only used in medical imaging but have also recently accelerated testing and hospital responses in the battle against Coronavirus disease 2019 (COVID-19).

The deep learning method, a subset of machine learning, refers to a pathway, whereby a large set of weighting factors is arranged based on patterns observed in 'training data,' where the input and output factors are known [7]. These neural network models have several layers of features or variables that can predict outcomes. In healthcare, a common application of deep learning is the detection of malignant lesions in radiological images. This can also be applied in radiomics or the detection of clinically pertinent characteristics in imaging beyond what can be detected or diagnosed by the human eye, and is significantly more accurate than traditional methods. However, it is often unclear how each weighting factor contributes to the decision ("black box" phenomenon).

Recommendation 2: **Training data should be derived from a population that matches one's population as closely as possible. Where the target population is significantly different, as large as possible a training dataset should be acquired to ensure proper randomization. This will reduce population and sampling biases, and lead to greater accuracy with more representative results.**

Deep learning, a subset of machine learning, has higher flexibility than other machine learning approaches. This requires larger training sets for hidden layer(s) and more accurate labels for supervised learning. We recognize that the recent advent of foundation models with weakly supervised or unsupervised learning may change the way we develop AI models; however, this is beyond the scope of our review.

The premise of deep learning is to make predictions for new inputs, based on previous input-output combinations (training data) that it has already seen [8]. For this to be effective, the new input and training data should be obtained from similar populations.

Representations from one dataset can be useful, even when applied to a separate dataset. However, a large amount of training data is required to make the transfer learning as representative as possible. A deep learning system that has already been trained on huge datasets of natural images can through feature or representation learning automatically discover representations that are needed for the classification of a medical image, thereby enabling "computer vision." A medical image used for classification can be encoded by a pre-trained system that can utilize such representations [9].

Inaccuracy can sometimes occur when the new input varies significantly from the training data, or if the training data come from a very homogeneous source, leading to algorithmic bias [10] in machine/deep learning. However, the training data specific to a population may not always be readily available.

Recommendation 3: **Explainable AI should be reviewed such that features used for prediction are reasonable. The ultimate aim of explainable AI should be to achieve transparency, accountability, safety, and fairness.**

Explainable AI (XAI) is defined as the output from machine learning algorithms that allow users to understand and trust the results created by machine learning algorithms. These algorithms must be user-friendly, easily understood, and trustworthy. The emerging trends surrounding this research topic are primarily aimed at

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raising awareness of the inner workings of AI algorithms [11].

In medicine, an example of the drawback of this invisible reasoning behind a model's prediction is the inability to determine how a decision or choice was derived. Any XAI should help the deep learning model achieve the four aims: transparency, accountability, safety, and fairness [11].

XAI inspects the measures and models involved in decision-making or prediction and displays activation patterns in a manner that provides clues to the weightage of features. Users can then determine whether the model is sensitive to the choice of features on which the output is based. An example would be the use of XAI in creating a 'heat map' in a chest X-ray (CXR) image, that accompanies a probability score or prediction [12]. In some cases, the 'heat map' may lie outside the patient's chest on the CXR, indicating the potential for an inaccurate AI model for feature selection. As XAI is under continuous development, with room for improvement for practical commercial tools, this 'heat map' may serve as an interim tool prior to the launch of an ultimate XAI tool.

Recommendation 4: **Federated learning carries pros and cons which users should familiarize themselves with to maximize the benefits but minimize the risks that are associated with it.**

Rigorous regulations for the protection of patient data impede cross-institutional and international collaboration in AI development and evaluation. For example, the European General Data Protection Regulation (GDPR) and similar laws mandate strict adherence to methods of collection, storage, and exchange of personally identifiable data [13]. Ethical, moral, and scientific aspects of patient confidentiality and privacy are protected by "soft law." Because AI is fundamentally built on data, the aforementioned frameworks are necessary. These laws and regulations limit the pace at which AI can be developed and scaled.

Makkar and Santosh [14] were among the first groups to describe the concept of federated machine learning. Instead of requiring access to data sources (nodes), the algorithms are distributed and trained locally in an offline setting. Such a decentralized model allows models to be trained across institutional boundaries without submitting or pooling all data into one learning center or infringing on patient data and privacy. The degree of decentralization ranges from flexible (peer-to-peer or gossip strategies) to full (with or without the use of blockchain technology). However, federated learning suffers from cybersecurity vulnerabilities. This is particularly true if local algorithms are not rigorously encrypted. Thus, they are vulnerable to a variety of cyber-attacks, including backdoors, poisoning, inference, generative adversarial networks, and malicious model inversion attacks [15]. A mitigation technique is "differential privacy" whereby the outside observer is unable to infer if the result from the dataset was obtained from a specific patient [16] after noise is added to the data.

Recommendation 5: **To mitigate risks of model drifts, it may be prudent for users to deploy "continuous learning" models alongside "locked" algorithms before implementation, introduce protocols to log model updates so that reversal is possible, and conduct more frequent reviews of model performance.**

Model drift is a well-known phenomenon that impairs the performance of AI algorithms. This can be broadly classified into "concept drift" in which the statistical property of the target variable changes, and "data drift," when the statistical property of the predictor changes. An example is echocardiography, wherein the training data, the absence of a written impression of mitral regurgitation could mean either that the mitral valve was not visualized or that there was no regurgitation. If model deployment mandates the indication of either scenario, model drift may be introduced [17]. Changes in target variables may be due to variations in patient factors (demographic, genotypic, and phenotypic), other determinants of health (environmental, social, political, and cultural), and hardware and software used for data capture [18].

To mitigate the risk of model drift, which may arise as a result of changes to patient inclusion and exclusion criteria, clinical workflows, and actual patient population compared to the population of the training dataset, Singapore's Artificial Intelligence in Healthcare Guidelines (AIHGIe) recommend a yearly performance review of AI solutions [19].

The AIHGIe guidelines further recommend that the algorithm should be taken offline and rebuilt where necessary. However, other mitigation methods may also be incorporated into the design of the implementation models. For example, other than "offline learning" which may or may not be selected at appropriate points in time by the users, "discrete" change to the algorithm through learning either under the explicit direction of the manufacturer or user or "continuous" unsupervised learning by the model, can be designed [20]. While "continuous learning" appears to be

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preferable, this is an evolving domain, with attendant risks to the systems, such as when inappropriate initialization parameters are imposed. "Continuous learning" systems are also subject to maliciously introduced data, which limits the users' ability to fully confirm updates to the model's algorithms.

Key Considerations for Adopting AI

In this section, we discuss the key considerations for deploying AI in mainstream radiology practice: the appraisal of model performance, technical integration, ethics, and medicolegal concerns. This is crucial for radiologists involved in the implementation of AI in clinical practice.

Recommendation 6: **A careful review of research papers should focus on discovering gaps that need to be addressed prior to adoption, rather than simply accepting reported performance attributes.**

Published deep learning research falls broadly into two categories, namely technical papers, and clinical papers. Peer-reviewed studies detailing the real-world performances of models using sound statistical methods may not always be available.

As the name suggests, technical papers describe the technical aspects of a model and often include some degree of internal testing. Details such as the training data (source and how it was used), use of transfer learning, model design, and training and tuning methods are available. A limitation of such studies is the lack of available technical expertise on the part of radiologists, which is needed to appraise them. In contrast, clinical studies have described the performance of models in simulated or actual clinical practice. Biostatistical descriptors, such as accuracy, sensitivity, specificity, and area under the receiver operating characteristic curve, are often used. However, studies on image quality improvement are often limited to subjective assessments by experts.

Recommendation 7: **Integration is a critical step to enhance end-user buy-in and satisfaction, and its implementation should be based on users' needs and the clinical workflow.**

Clinical integration of the AI model into the imaging chain is preferred; however, the output should contribute effectively to the institution's clinical workflow, considering variations in practices. For example, an AI model that highlights critical findings during wet reading is useful in places with limited radiologists but may not be as useful in places where radiologists are always available. If used as a double-reader model, it may increase the workload, requiring a radiologist to counter-check the output of the AI model. Therefore, it is essential to survey the needs of users before implementing the AI model.

The deployment of AI models entails seven key considerations: 1) image delivery, 2) quality control, 3) result database, 4) result processing, 5) result presentation and delivery, 6) error correction, and 7) a dashboard for performance monitoring [21].

In the majority of instances, the AI model is required to ingest images automatically, usually in a commonly used standard format such as DICOM or HL7, and produce outputs in those formats. In the former, standards-compliant DICOM can present AI measurements, lesion detection, results, and findings to the radiologist in a clinical context. This will hasten the clinical decision-making processes by allowing the reporting radiologist to accept or reject results more efficiently. The system also implements a feedback mechanism for post-processing technologists to correct results as directed by the radiologist [22].

An AI model completely enclosed within a single entity (such as a scanner acquisition or radiology information system, RIS) does not require further technical integration. It would be prudent to engage the expertise of imaging informatics professionals to ensure the seamless technical integration of the AI model.

Recommendation 8: **Both local and cloud-based inference are acceptable, so long as data privacy and security concerns are addressed.**

Although deep learning models require sophisticated computer systems for training, the process of inferencing (producing a prediction) often requires considerably less computing power. This often allows a purely local deployment within institutions without the need for cloud computing. Local (on-premise) deployments typically pose less security risk but may be difficult to maintain and update, in addition to increased cost. In some cases, institutional policies prohibit the use of cloud computing. Cloud computing is safe to use as long as reasonable care is taken to ensure the privacy and security of patient data. It has the advantages of scalability while allowing for continuous model updates and more efficient training methods, such as federated learning.

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Recommendation 9: **Ethical considerations on the use of AI are well-described internationally. While differences exist, there is general agreement on the need to ensure data and patient privacy and the careful application of the technology for clinical settings.**

"The Ethics and Governance of Artificial Intelligence in Health Care" by the World Health Organization provides guidance on the use of AI in Healthcare. Radiology and Informatics societies across the world have similarly provided consensus guidelines on ethical use of AI in medical imaging [23,24]. National guidelines, such as those from Australia, Canada, Singapore, France, and United Kingdom have also emerged [20,25-28]. One notable example is the European Union's "Ethics guidelines for trustworthy AI," in which the principles of lawfulness, ethics, and robustness are deemed cornerstones for adoption [29].

Specifically, these ethical guidelines highlight the need for human regulation and supervision, technical robustness and safety, privacy and data governance, transparency, responsibility, accountability, diversity, nondiscrimination and fairness, and societal and environmental sustainability. Several guidelines have been published [30] and summarized into the following requirements: 1) humans should have autonomy over the system and possible ability for intervention to monitor decisions made by the system, 2) the AI system will be able to withstand adversarial attacks, 3) data privacy and clinical governance will not be compromised and are routinely regulated, 4) all data algorithms generated by the AI system should be transparent and can be easily audited, and decisions made by the AI system are fair and equitable, and 5) the output of the AI system should be sustainable to allow for positive social change.

Currently, regulatory bodies regard AI as a medical device that can be approved for use in clinical practice. The United States (US) FDA "Regulatory Framework for Modifications to AI/Machine Learning-Based Software as a Medical Device – Discussion Paper and Request for Feedback" outlines the approach to approval of algorithms for clinical use [1]. This has been updated with the most recent update published in March 2024 entitled "Artificial Intelligence & Medical Products: How CBER, CDER, CDRH, and OCP are Working Together." This seeks to outline more specific focus areas on the development and use of AI across healthcare, further consolidating, and streamlining the agency's work in AI [31]. The European Commission published a white paper "On Artificial Intelligence - A European Approach to Excellence and Trust," detailing a policy framework setting, as well as key elements of future regulatory framework for AI in Europe, to establish ecosystems of excellence and trust [20]. Particularly for healthcare, the European Coordination Committee of the Radiological, Electromedical, and Healthcare IT Industry (COCIR) has counter-proposed that the existing requirements imposed by the European Union Medical Device Regulation (EU MDR) and EU In Vitro Diagnostic Medical Device Regulation (IVDR) in combination with the GDPR are adequate for establishing stated goals [32].

Recommendation 10: **The use of AI in clinical settings is largely now still determined by healthcare providers who may bear the brunt of failure. Concerns over medicolegal liability still limit widespread use. It is essential to ensure that practicing clinicians are fully aware of the risks and limitations of AI products before implementing them, to ensure long-term successful adoption of AI solutions in clinical practice.**

Regarding the complex issue of medicolegal liability, physicians, the organizations in which they operate, and software developers may all be liable for product failure that culminates in harm to patients. Physicians may be charged with failing to critically evaluate AI recommendations. Healthcare organizations may be liable for their decisions to implement improper AI solutions. This may change as AI systems continue to develop and become more widely implemented, whereby the developers of AI solutions can be charged with designing less-than-optimal products. Owing to the relatively low prevalence of real-world clinical adoption of AI and the lack of precedent cases, the issue of who bears the liability for misdiagnosis due to AI has yet to be fully established.

However, physicians are likely to bear the brunt of failure [33]. In instances where harm resulted from physicians who had acted based on insufficient information or errors made by manufacturers, most courts allowed malpractice claims to proceed [34]. As such, it becomes even more crucial that decision-makers, who can be considered to assume vicarious liability for practicing clinicians, are fully aware of the risks and limitations of AI products before implementing them as a standard of care. Unfortunately, this has hampered the pace of AI adoption in clinical practice [35]. Specialized adjudication systems that exempt AI products from traditional liability systems can mitigate this problem. "Locked" algorithms, particularly if they are explainable, would be more easily defensible and consequently adopted, as compared to "continuous" algorithms that operate within a "black box." To gain a better handle on implementing

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regulations, the US FDA for example, has designated a sandbox "Predetermined Change Control Plans for Machine Learning-Enabled Medical Devices: Guiding Principles" to better study and thereafter inform policymakers on standards related to the conduct and safety of AI solutions [36].

Overcoming Barriers to the Adoption of AI

In this section, we highlight the major barriers to the adoption of AI, namely trust, balance, and timeliness. Developers and hospital administrators should be aware of these present-day challenges to ensure the adoption of effective AI solutions in clinical practice.

Recommendation 11: **Sandbox environments with local datasets will become useful adjuncts in radiology practices, to allow for controlled measurement of value of AI in simulated workflows.**

To address the issue of trust in the systems by the users, it is recommended that deep learning solutions providers need to demonstrate the real-world and local efficacy of their algorithms, beyond the claims of regulatory approval and other "headlines." A clear articulation of the model development process, such as the source and quality of the training datasets, would increase confidence in the product. Beyond the accuracy of data reported by the vendor to regulatory bodies, one should consider that model performance may degrade with local institutional datasets [37]. This makes it necessary for adopters to develop their own annotated ground-truth datasets that can be easily passed through the algorithm to validate the vendors' claims. A "sandbox" or "staging" environment that is distinct from the production RIS-PACS systems would be ideal, so as not to compromise routine clinical workflows during the test-bedding phase. This would also allow the verification of claims in a more controlled environment.

Recommendation 12: **The choice of AI solutions to be deployed will much depend on the regulatory and practice patterns of each health system, but it will be prudent for users to prioritize clinical use cases that have the greatest impact on practice. This includes settings where there is a shortage of healthcare providers, resulting in a need for non-radiologists to interpret imaging studies, although this is neither ideal nor recommended.**

Given the abundance and rapidly growing number of AI solutions in the market, it is prudent for users to prioritize clinical use cases that have the greatest impact on their clinical practice. In settings where radiologists are in shortage, algorithms with high sensitivity, such as for detecting tuberculosis on CXRs [38,39] and for breast cancer on mammography [40] would add tremendous value in screening out the "normal" imaging studies. Usually, a radiologist is still necessary to assess the studies labeled as "positive," but where the pre-test probability is low, AI would have been able to eliminate a significant portion of the workload. For example, in the quantification of spinal canal stenosis, the use of AI may not replace radiologists, but hasten the process of clinical reporting [41]. Frontline scenarios in which non-radiologists are required to interpret imaging studies due to a lack of appropriate manpower from board-certified radiologists will also benefit from the democratization of radiologist expertise. For example, the interpretation of brain CT for infarction or hemorrhage in the emergency department or ultrasound performed in the primary care setting. However, a formal evaluation of imaging findings by radiologists is ultimately required by most health systems.

Recommendation 13: **Consensus on the optimal approach to testing before deployment of AI solutions will enable healthcare providers to adopt them more readily into clinical workflows to enhance patient care.**

We advocate that radiologists test and trial the use of various market-ready AI solutions to quickly gain experience in augmenting their practice with this technology [42]. In this process, one would better appreciate the strengths and limitations of the modality and select the most appropriate application to suit one's clinical workflow. One example is the American College of Radiology (ACR) AI-LAB, a platform that has been designed to make AI algorithms more accessible and user-friendly for radiologists, without the need to share patient data externally [43,44]. Subsequently, issues related to reimbursement and willingness to pay for the use of AI in practice must be addressed for sustained deployment.

CONCLUSION

Healthcare practice considers four main principles namely, respect for patient autonomy, non-maleficence, justice, and beneficence, and trust between care providers (clinicians) and care recipients (patients). If the use of AI in radiology is to be successfully implemented within a clinical setting, it needs to be seen as an equitable and just system and as

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an integral part of the healthcare infrastructure.

As AI technology continues to advance, our working group believes that these principles must be implemented with a governing body to supervise and ensure that they are upheld. Deploying AI technology without considering human factors would damage the doctor-patient relationship. Our paper will be useful to policymakers, professional bodies, and the general public as we introduce AI into radiology. Some underlying broad principles may also apply to other clinical specialties.

Conflicts of Interest

The authors have no potential conflicts of interest to disclose.

Author Contributions

Conceptualization: Kwan Hoong Ng, Cher Heng Tan. Data curation: Nicole Kessa Wee, Kwan Hoong Ng, Cher Heng Tan. Formal analysis: Nicole Kessa Wee, Kwan Hoong Ng, Cher Heng Tan. Investigation: Nicole Kessa Wee, Kwan Hoong Ng, Cher Heng Tan. Methodology: Nicole Kessa Wee, Kwan Hoong Ng, Cher Heng Tan. Project administration: Nicole Kessa Wee, Kwan Hoong Ng, Cher Heng Tan. Resources: Cher Heng Tan. Supervision: Kwan Hoong Ng, Cher Heng Tan. Validation: Nicole Kessa Wee, Kwan Hoong Ng, Cher Heng Tan. Visualization: Kwan Hoong Ng, Cher Heng Tan. Writing—original draft: Nicole Kessa Wee, Kwan Hoong Ng, Cher Heng Tan. Writing—review & editing: all authors.

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