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Many medical AI developers in Asia, UK lack regulation awareness: study

An NTU Singapore study suggests that addressing this gap will be key to safe AI integration in healthcare systems.



Although developers of medical AI tools in Asia generally feel responsible for the technology they build, many remain unaware of regulatory frameworks, according to a new study from Nanyang Technological University in Singapore.

Researchers surveyed 122 medical AI developers from Singapore, China, Hong Kong, and the United Kingdom to assess their awareness of, familiarity with and views on medical AI regulations.

FINDINGS

The study, whose findings were published in npj Digital Medicine, found that more than half of respondents (57%) knew of at least one regulatory framework, with senior developers reporting greater familiarity with these frameworks than their junior counterparts.

About a third of respondents worked for organisations that had formally adopted at least one recognised framework. Singapore's Artificial Intelligence in Healthcare Guidelines were the most widely adopted, but only 18% of respondents said their organisations had adopted them.

Respondents described regulatory implementation as "complex," "difficult" and "laborious."

Three-quarters of the respondents recognised that they have greater responsibility for implementing regulatory standards in medical AI development than regulatory bodies, institutional ethics offices, and data providers. They also highlighted the need for adaptability, balance and flexibility when implementing regulatory frameworks.

To increase AI regulation awareness, the researchers proposed incorporating regulatory frameworks into developer training and establishing training sessions between junior developers and senior mentors.

The researchers also recommended that governments and regulators "actively encourage" organisations to adopt medical AI frameworks. They also called for a harmonised global regulatory framework to streamline compliance across jurisdictions and facilitate international collaboration.

WHY IT MATTERS

According to NTU, the study's findings point to a greater need to engage medical AI developers to improve the effectiveness and safety of AI implementation in healthcare, particularly as countries increase investment in digital innovation. Limited awareness of regulatory safeguards, it said, could affect patient outcomes and erode public trust in medical AI.

Dr Anindita Santosa, co-founder and CEO of AIGP Health, a Singapore-based developer of an agentic AI platform, said regulation should never be viewed as the enemy of innovation.

In an interview with MobiHealth News, she said medical AI companies must view regulation and clinical governance "not as hurdles to overcome at the end of product development, but as design principles from day one."

"Patient safety, evidence generation, and regulatory compliance should never become secondary to speed of deployment or commercial pressures," she said.

Dr Santosa, a private rheumatologist, emphasised that AI developers, like doctors, bear responsibility for safeguarding the lives entrusted to them.

"If we keep patient outcomes – not technology itself – as our north star, then innovation and regulation cease to be opposing forces; they become partners in delivering safer, better healthcare."

She also argued that healthcare organisations should not treat AI as a plug-and-play solution.

"Institutions need governance structures to evaluate, implement, monitor, and continuously audit AI systems in real-world practice, while ensuring clinicians remain appropriately trained and accountable for clinical decisions."

Still, Dr Santosa said understanding clinical workflows, cognitive load, accountability, and the realities of healthcare delivery is equally important as understanding regulations. Many problems in healthcare do not stem from technology itself, but from deficiencies in workflows, communication, and systems, she noted. Beyond regulatory compliance, she reminded doctors to uphold their ethical obligations, as AI changes how they practice medicine.

The healthcare AI leader added that "clear, risk-based, and adaptive regulatory frameworks" will become increasingly important as AI systems evolve beyond static software towards systems that continuously learn and operate with greater autonomy.

<https://www.mobihealthnews.com/news/asia/many-medical-ai-developers-asia-uk-lack-regulation-awareness-study>