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Executive order promotes investment in women's health research and could profoundly advance clinical AI use

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The Buzz This Week

On Monday, President Biden signed an executive order aimed at advancing women's health research. This latest action from the White House introduces new standards and requirements for government-funded research to include a higher proportion of women in studies and prioritize more studies focused on diseases that disproportionately affect women.

The order calls on Congress to invest \$12 billion in women's health research, which would be disbursed through the National Institutes of Health (NIH).

Women currently represent more than half of the US population, but, only comprise 41% of overall study participants, according to a review of more than 1,400 drug and device trials. Study findings can suggest inaccurate conclusions when research under-represents certain populations.

However, this executive order is different from past policies in two ways. First, it extends standards and requirements to any federally funded research, not just research funded through the NIH. It also extends beyond basic research and clinical trials to translational research. Second, the order introduces stronger data standards related to women's health, which will impact study design, as well as data collection, analysis, and reporting.

Why It Matters

President Biden's executive order has come during a period of transformation in healthcare. While this investment has the potential to advance women's health research and improve women's health status, its impact potential is far greater. For years, healthcare entities have been incorporating more advanced digital

technologies to improve outcomes, enable population health management, increase efficiency, and reduce menial task workload. As digital transformation rapidly accelerates, few organizations are still in the nascent stages of incorporating digital solutions into their clinical and administrative operations.

The pace of change in healthcare is accelerating. The industry is at a new inflection point, with the potential to spur radical change and exceptional impact for healthcare entities and the populations they serve. Artificial intelligence (AI) has introduced a plethora of new possibilities in advancing the practice of medicine and healthcare delivery.

Some healthcare leaders believe AI introduces the potential to go beyond a transformation. The keynote speaker at the recent HIMSS conference, Robert Garrett, CEO of Hackensack Meridian Health, stated that “AI and industry partnerships have the potential to improve health for billions...of people. We cannot reach our highest aspiration to redefine healthcare without a revolutionary approach.”

When AI is applied in the clinical setting, errors can misinform a physician's diagnosis and treatment, potentially impacting the health and life of a patient. Accuracy, therefore, is crucial. However, some current AI tools have exhibited unreliable, inconsistent, and erroneous output in clinical settings—particularly for women and minority groups. This causes an appropriate level of skepticism and caution among clinicians and hospital administrators. As a result, organizations are cautious about adopting AI in the clinical domain.

In machine learning AI models, the output is only as good as the input. If the AI tool used biased data or exclusionary data to “learn” and build its algorithm, output data could be just as biased.

For instance, a recent study found that an AI-powered liver screening tool missed 44% of the cases of liver disease among women, compared to 23% for men. Even when an AI diagnostic tool is developed for a condition that affects only women (and therefore learning data came exclusively from women), bias can appear on racial and ethnic dimensions.

One study found that when an AI algorithm was trained with a dataset that lacked non-white racial and ethnic representation, the tool performed most accurately with white women. Hispanic women had a high rate of false positives, and Asian women had a high rate of false negatives. The algorithms used in each of these cases were based on skewed data, unrepresentative of the broader population. The result is a propagation of gender and/or racial biases in healthcare that could lead to dangerous consequences.

Including a more diverse group of study participants will help balance future study cohorts. In turn, the data that AI tools use to develop their algorithms will be more representative of the broader population and enable more accurate output for specific cohorts within the population.

While initially hesitant, more healthcare institutions are not only developing plans to incorporate AI into clinical practice but are also actively piloting AI-powered solutions. With better data input and improved accuracy in outputs, AI could potentially ignite a revolutionary approach to healthcare and make meaningful improvements to population health.

With all of this in mind, and despite the rapid change in digital health, the timeline to realize the full effect of the AI revolution will be somewhat longer. Research can take years from grant application to publication of results and subsequently, the release of underlying data that could be used to train an AI tool. Any AI application that directly connects to a patient will require extensive piloting, vetting, training, and education.

The recent advances on research policy and digital health capabilities are exciting, but patience will be needed to see the impact come to fruition. Challenges and potential delays could also arise, should officials overturn policies or roll back funding. Biden's executive order will improve the accuracy of clinical AI tools when applied to women. But to make AI tools truly representative of the US population, policies should be formed to promote minority healthcare research as well.

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