all medical publications, than advancing the science and art of medicine and the betterment of public health. Today, and for the future, these goals will be accomplished by championing diversity, equity, and inclusion in all aspects of clinical care, biomedical research, health policy, and society.

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The Epic Sepsis Model Falls Short—The Importance of External Validation

Anand R. Habib, MD, MPhil; Anthony L. Lin, MD; Richard W. Grant, MD, MPH

Sepsis accounts for nearly 1 million hospitalizations annually and is a major contributor to hospital length of stay, health care expenditures, and in-hospital mortality (ranging from 12.5%-15%).[1] Early sepsis identification allows care teams to promptly implement goal-directed therapy to mitigate clinical deterioration. In this issue of *JAMA Internal Medicine*, Wong et al[2] report on their external validation of the Epic Sepsis Model (ESM), a prediction tool available within the Epic electronic health record that is designed to generate automated alerts that warn clinicians that patients may be developing sepsis. Based on their examination of 38 455 hospitalizations at the University of Michigan (Ann Arbor) between December 2018 and October 2019, Wong et al[2] found that the ESM had a sensitivity of 33%, specificity of 83%, positive predictive value of 12%, and negative predictive value of 95%, with an area under the curve of 0.63 (95% CI, 0.62-0.64). This falls short of the area under the curve of 0.76 to 0.83 that was jointly reported by Epic and University of Colorado Health.[3] Despite generating alerts on 18% of all patients, the ESM did not detect sepsis in 67% of patients with sepsis.

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What do the results of Wong et al[2] tell us about proprietary prediction models, like Epic's ESM, and the future of electronic health record–based clinical prediction tools in general? One simple lesson is that a model that is calibrated using data from one time and place (eg, data from 3 US health systems from 2013 to 2015 for ESM) needs to be validated and recalibrated in new settings and eras. To do so, health systems must support data scientists who can evaluate such models in the same way that health systems currently support clinicians in tailoring national clinical guidelines to their local patient populations. As the study by Wong et al[2] reveals, models with poor combined specificity and sensitivity, defined as less than 1.5 (in which 1 is a coin flip and 2 is perfect), must be incorporated into care with caution, particularly when a validation study is not published, as Epic failed to do.[4] Alerts that are generated based on an algorithm that

has only modest discriminant capacity threaten not only to exacerbate alert fatigue, but also to undermine value-based patient care by potentially increasing inappropriate triage, unnecessary diagnostic testing, and antibiotic prescriptions. Appropriate treatment depends on reliable models and clinical judgment.

Many currently available models are built on relatively straightforward logistic regressions. Therefore, they can be inspected by clinicians to better understand the key variables driving the results, which are analogous to tools, such as the Atherosclerotic Cardiovascular Disease Risk Estimator, that include such clinically informative variables as age, blood pressure, cholesterol, and diabetes.[5] However, more complex models that use machine learning methods that enable models to iteratively learn based on prior data and improve output without explicit human programming will pull in many different types of data (including free text from Natural Language Processing). These more complex prediction tools may present insurmountable barriers to local external validation, which will place more responsibility on model developers either to publish model performance characteristics, the variables included, and the settings in which they were obtained or to provide code and data on request to enable others to verify the model transferability to the local setting.[6]

Recognizing the "black box" nature of these future machine learning tools, health systems need to become adept at developing the correct workflows for use and governance of such models. Data scientists will need to work closely with operational and clinical leaders to match performance parameters and settings with clinical workflow needs and demands. Keys to the effective use of prediction models are: (1) moving toward open-access models or enjoining proprietary model creators to provide end users with validation studies that detail original data that are used and variable selection, (2) having the appropriate staff to evaluate performance in each hospital's own clinical setting, (3) developing well-considered workflows by collaborating closely with primary stakeholders and end users to focus on the optimal use strategy (eg, when is information presented, to whom, and how often?), (4) maintaining a culture of independent clinical thinking so that model results inform but do not supplant the clinician's interpretation of the patient's clinical presentation, and (5) designing a future-oriented governance strategy to iteratively recalibrate or retire models as they age beyond their initial validation. Ultimately, the quality of sepsis care will benefit not only from continued efforts to rigorously validate model performance in new settings but also from pragmatic randomized clinical trials that test the effect of such models on patient outcomes.

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High Mortality Rates in Medicare Patients After Peripheral Artery Disease Revascularization

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Peripheral artery disease (PAD) is common, affecting approximately 8.5 million people in the US, and associated with history of smoking, diabetes, and other cardiovascular risk factors.[1] Clinical practice guidelines[2] recommend that smoking cessation, supervised exercise, and guideline-directed medical therapy should be prescribed prior to recommending endovascular revascularization for patients with lifestyle-limiting intermittent claudication due to PAD. Yet Medicare claims for peripheral vascular interventions increased by 31%, from 227 091 to 298 127, between 2011 and 2017[3]; it is unlikely that there was such a large increase in the number of patients with PAD unresponsive to conservative measures during that time period.

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Paclitaxel drug-eluting stents or balloons were approved by the US Food and Drug Administration for PAD in 2012 and are associated with lower rates of restenosis after endovascular procedures[3] compared with bare metal stents. However, recent evidence, summarized in a systematic review and meta-analysis of randomized clinical trials (RCTs), reported increased mortality with paclitaxel-coated balloons and stents in the femoropopliteal artery of the leg.[4] Paclitaxel stents were associated with increased mortality at 2-year follow-up in analysis of 12 RCTs with 2316 patients (7.2% vs 3.8% crude risk of