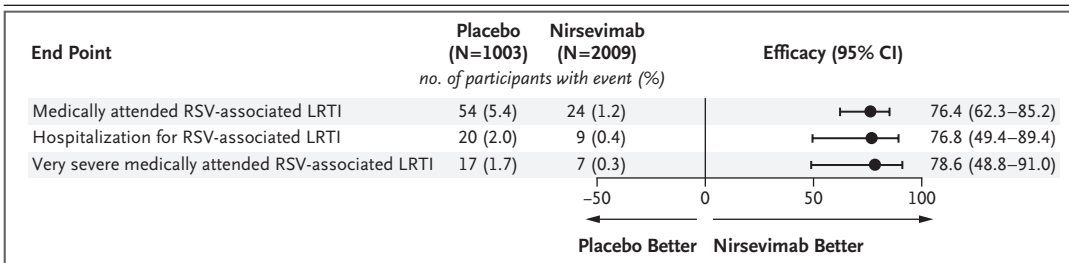

Figure 1. Incidence of Medically Attended Respiratory Syncytial Virus (RSV)–Associated Lower Respiratory Tract Infection (LRTI) through 150 Days after Injection and Efficacy of Nirsevimab as Compared with Placebo.

Very severe medically attended RSV-associated LRTI was defined as infection for which hospitalization and supplemental oxygen or intravenous fluids were warranted. Data are from the intention-to-treat population, which consisted of all infants who had undergone randomization.

demic,[5] the number needed to treat to prevent one hospitalization for lower respiratory tract infection of any cause was 53.1 (95% CI, 29.4 to 250.0), a number that was consistent with that in the primary cohort in the MELODY trial.[3] Furthermore, an estimated 57 days of hospitalization for lower respiratory tract infection of any cause were averted for every 1000 infants who received nirsevimab.

Adverse events related to nirsevimab or placebo were reported in 1.3% of the nirsevimab recipients and 1.5% of the placebo recipients through 360 days after injection. Data are shown in Tables S6 and S7.

In term and late-preterm infants, a single dose of nirsevimab provided a consistent level of protection against hospitalization for RSV-associated lower respiratory tract infection and very severe medically attended RSV-associated lower respiratory tract infection during an RSV season.

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Safety of Health Care in the Inpatient Setting

TO THE EDITOR: In their article on the safety of inpatient health care, Bates and colleagues (Jan. 12 issue)[1] describe events that should not surprise anyone for three key reasons. First, many in the health care field ignored a warning in 1997 that a focus on "human error" according to data regarding patient safety "would delay any real progress on safety for a decade or more."[2] Error-

related literature supports rejecting "human error as a cause of accidents and adverse events."[3] However, the patient-safety movement remains fixated on human error instead of complex sociotechnical systems as the cause of preventable harm. Second, research is needed on how clinical care is provided. Billions of dollars have been spent on efforts to understand the human body and to develop treatments, with little investment in understanding how to deliver care.[4] Third, the drivers of the patient-safety movement have excluded investigators who are trained in safety science. This action has forced a reliance on safety practitioners who work in health care with limited formal training in the broader science of safety rather than on investigators who are trained in safety science. Whereas the use of nonexperts to provide clinical care would be viewed as negligence, the use of nonexperts in patient safety is the standard of care.[5]

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TO THE EDITOR: Bates et al. provide an update to the Harvard Medical Practice Study from 1991,[1] the seminal research that launched the modern patient-safety movement. The study by Bates et al. follows two other recent studies — one by Eldridge et al.[2] and another by the Office of the Inspector General[3] — that evaluated the current state of patient safety. In these studies, investigators performed manual chart review and reported disappointing progress in the reduction of medical errors.

We think that 32 years is too long to wait for the next report. We posit that the major reason that more progress has not been made regarding safety is the absence of readily available, reliable, and automated measurements of medical errors and adverse medical events. We need the metrics before we can study the effects of interventions. In the era of electronic health records, these measures can be created automatically with the use of audit log data. Examples of this type of measure already exist.[4,5] Automating data collection would allow for updates on patient safety to occur every day in every hospital.

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TO THE EDITOR: Bates et al. discuss the continued prevalence of adverse events in medical care and highlight important opportunities for improvement, thereby furthering the observation that patient care is "still not safe."[1] However, we are surprised to see only cursory recognition of organizational practices and leadership as targets of improvement, despite substantial evidence linking these factors to patient safety.[1-3] Research in the organizational sciences investigates how these types of nonclinical structures, systems, and interpersonal behaviors contribute to adverse performance. Yet this work remains largely absent from discourse on patient safety (and medicine more generally),[3] which contributes to an overly narrow, clinical lens for interpreting adverse events.

Extending Berwick's call for a "constancy of purpose for improvement" in his accompanying editorial,[4] we think that improving organizational practices must be central to this purpose. Patient safety will remain elusive for as long as the focus remains on clinical solutions at the expense of organizational ones. As Bates et al. note, safety gaps endure despite "stunning advancements in medical science." It is past time to look to organizational science as a tool for addressing persistent challenges to patient safety.

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THE AUTHORS REPLY: Scanlon and Catchpole contend that there has been too much focus on human error in patient safety, which has slowed progress, and we agree. They point out that in other domains, improving safety relies on tracking and reducing of the rates of accidents (or adverse events), rather than on finding human error. We think that there is value in determining which adverse events are preventable, given what we know today, since such events are the most attractive targets to address first. However, this approach is still controversial. Next, the correspondents emphasize the need for exponentially more research on how care is delivered, which includes associated outcomes, and how it should be delivered. This is a key issue. In 2022, the budget for the National Institutes of Health totaled $45 billion as compared with only $488 million allocated to the Agency for Healthcare Research and Quality, which sponsors the most research on care delivery. These allocations should be much closer. Finally, the correspondents suggest that patient-safety experts have been excluded from operational safety, which we believe is debatable, although we agree that including these experts more broadly would be helpful.

Dietz et al. propose that safety could be measured much more effectively through automated extraction of data from electronic health records to identify adverse events and other safety issues, rather than by using traditional approaches such as spontaneous reporting. We completely agree — and believe this is how measurement should be done in the future.[1] Adelman and colleagues have led pioneering work in this area in describing how this improvement can be achieved for cases of "wrong patient" errors in which an order was documented in the wrong chart.[2]

Myers et al. underscore the importance of leadership in improving patient safety. We agree that this is vitally important, as underscored by Berwick[3] in the accompanying editorial. However, individual leadership alone is not sufficient for making progress. Organizations need to support safety teams as well as invest in the implementation of new systems to effectively track patient-safety events routinely, as described above. They also need to make investments in tracking adverse events and implementing interventions that have been shown to prevent harm, such as algorithms to identify patients at increased risk for adverse events and to detect any deterioration in a patient's condition.[4]

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Since publication of their article, the authors report no further potential conflict of interest.

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