

# Evidence, Quality, and Waste: Solving the Value Equation in Neonatology

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Rising health care costs challenge governments, payers, and providers in delivering health care services. Tremendous pressures result to deliver better quality care while simultaneously reducing costs. This has led to a wholesale re-examination of current practice methods, including explicit consideration of efficiency and waste. Traditionally, reductions in the costs of care have been considered as independent, and sometimes even antithetical, to the practice of high-quality, intensive medicine. However, it is evident that provision of evidence-based, locally relevant care can result in improved outcomes, lower resource utilization, and opportunities to reallocate resources. This is particularly relevant to the practice of neonatology. In the United States, 12% of the annual birth cohort is affected by preterm birth, and 3% is affected by congenital anomalies. Both of these conditions are associated with costly health care during, and often long after, the NICU admission. We will discuss how 3 drivers of clinical practice in neonatal care (evidence-based medicine, evidence-based economics, and quality improvement) can together optimize clinical and fiscal outcomes.

## abstract

Health care-associated costs continue to dominate headlines as the United States strives to elevate itself out of the economic distress of the previous decade. Over the last 50 years, the United States and many other developed economies have experienced a rapid rise in medical expenditure as a percentage of gross domestic product with the United States owning the steepest rate of increase.<sup>1</sup> As a result, US health care spending is the largest in the world, in both relative and absolute costs. The \$2.7 trillion in annual expenditure would make the US health care sector the fifth largest economy in the world.<sup>2</sup> Even the approximate \$910 billion of annual US medical expenditure attributable only to waste<sup>3</sup> would constitute the 10th largest world economy.<sup>2</sup> Despite that level of spending, the United States still ranks poorly with respect to many aspects of quality, access, and

equity in care, particularly related to preventive care and population health, compared with countries that spend much less per capita.<sup>4</sup>

Given that nearly every sector (ie, hospital/other facilities, professional services, drugs and devices, administrative costs, investment, and public health) of US health care has experienced increased expenditure,<sup>5</sup> the underlying imperative to address cost affects all stakeholders. At the same time, there is pressure to improve care quality and patient safety, as morbidity data are made more available in the public domain (eg, reporting of central line associated infections).<sup>6</sup> Payers and providers alike face the challenge of meeting a higher expectation (or demand) of quality care, albeit with fewer dollars.<sup>6,7</sup> Similarly, all patient populations are impacted. Although the largest absolute health care

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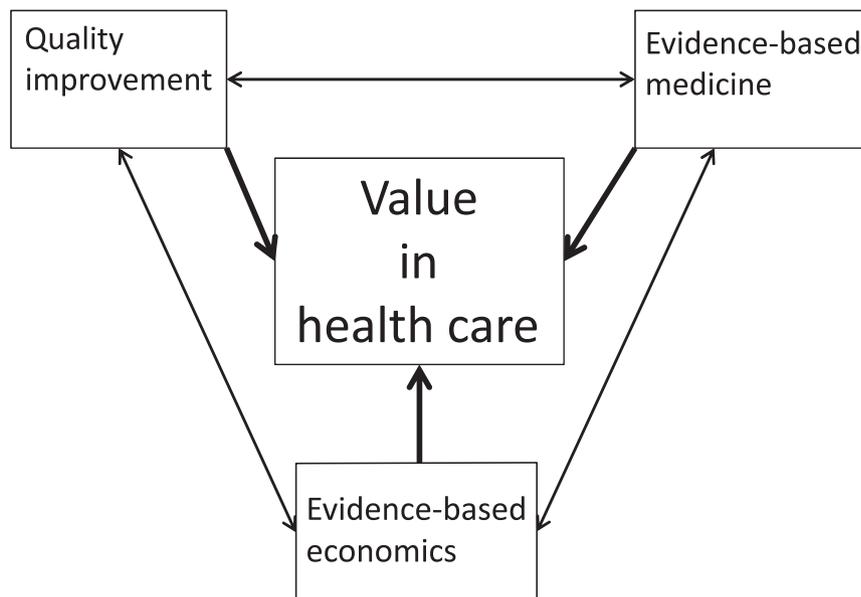
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expenditures are in adult medicine, spending on the very young is disproportionately larger compared with other age groups.<sup>8,9</sup> Indeed, despite some attenuation of the overall cost increase nationally,<sup>5</sup> costs of care for complicated newborns continue to rise, with the largest burden attributed to the preterm population.<sup>10</sup> Preterm birth, neonatal encephalopathy, sepsis, and other conditions of the newborn, and congenital anomalies contribute 4 of the 25 top causes of disability adjusted life years globally.<sup>11</sup> Thus, the economic implications of newborn care carry well beyond the NICU.

Neonatologists are therefore left charged with what may appear as an improbable task: to improve care for the individual, and improve health of the population, while simultaneously reducing the per capita costs of care.<sup>12</sup> The continuously evolving US health care environment makes the related policy decisions even more difficult. Early evidence suggests that the implementation of certain aspects of the Affordable Care Act such as Accountable Care Organizations might improve quality and reduce costs.<sup>13</sup> However, new health policy for sick newborns may not optimally align financial incentives with appropriate regionalization of perinatal services given the missed opportunities for reimbursement associated with transfer.<sup>14</sup> Furthermore, shifting from fee-for-service to episode-based (and eventually to population-based) reimbursement may change both revenue and incentives. The pace of such changes will differ geographically and over time, making uniform recommendations for practice difficult.

In response to such challenges in health policy, conventional wisdom has held that doctors need not (perhaps “should not”) concern themselves with the economics of medicine, but focus solely on



**FIGURE 1**

This figure represents the interrelatedness of the 3 pillars of Value in health care: evidence-based medicine, evidence-based economics, and quality improvement. Although all 3 carry an independent effect on Value, there is complex interaction between the 3 that can be leveraged to improve Value in health care.

“clinical practice.” Others have even argued that it is unethical to think about such issues in the context of the care of an individual patient.<sup>15</sup> That dogma, however, ignores the interrelatedness of health, resources, and the constraints on a health care budget.<sup>16</sup> The most recent version of the American College of Physicians (AC) Ethics Manual proposes a different view: “Physicians have a responsibility to practice effective and efficient health care and to use health care resources responsibly. Parsimonious care that utilizes the most efficient means to effectively diagnose a condition and treat a patient respects the need to use resources wisely and to help ensure that resources are equitably available.”<sup>17</sup> Because resources are constrained, using them wisely should increase the level of health in the population. Thus, both the ACP and initiatives like Choosing Wisely<sup>18</sup> call for grassroots level effort at the individual provider level to support the shift required at the societal level.

In this article, we will emphasize that such “wise use” of resources may be

achieved by reducing expenditures, improving the quality of care, or by doing both. We will focus on 3 tools that should be in daily use in our clinical and administrative practice: evidence-based medicine, evidence-based economics, and quality improvement (Fig 1). We will review relevant health economic definitions and provide practical examples of how these 3 modern-day pillars of clinical practice can act independently and in synergy to address the dilemma of too much demand to too little resource.

### THE VALUE EQUATION

We conceptualize Value as a relation between resource use and health. This model can be illustrated by considering 3 different programs for 1 population (Fig 2). Each program costs \$1.5 million dollars. Program 1 yields an average of 0.25 U of health (eg, longevity or years of life); whereas program 2 yields 0.5 U of health and program 3 yields 1 unit of health. If we spend equally on all 3 interventions, we achieve

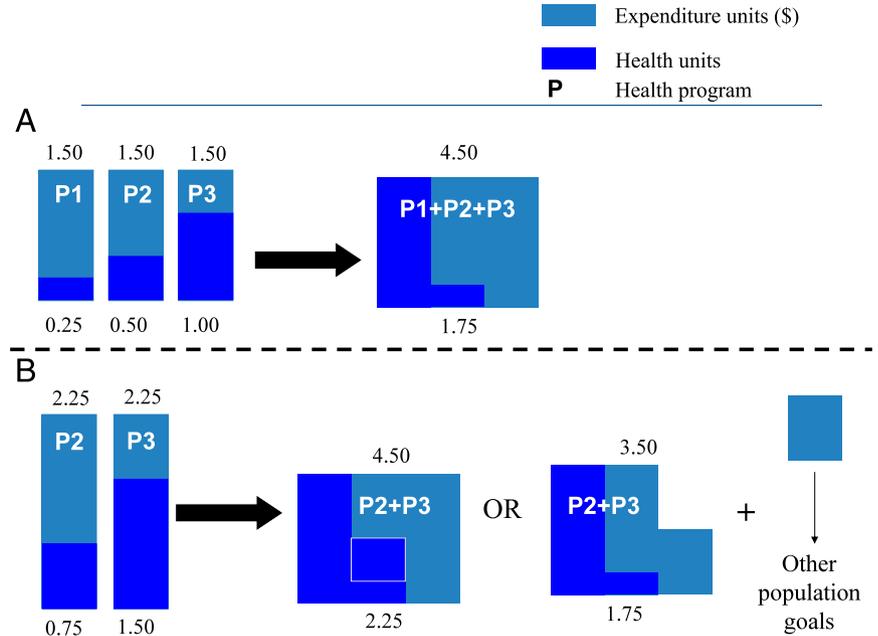
an average of 1.75 U of health for an expenditure of \$4.5 million (Fig 1A). If we instead identify and close down the program that yields the least health for the same expenditure (“the least efficient”), then redistribute that expenditure in the other 2 programs, we spend the same amount of money, but obtain a return that is now 2.25 health units. We might also decide that we have sufficiently targeted 1 particular area of health, and therefore choose to spend less money for the original 1.75 health units, while retaining those funds for other important goals in this population (Fig 1B). In either case, Value or efficiency (or more colloquially, “bang for the buck”) has been improved.

Because human work hours and equipment are needed to provide a health intervention, and these cost money, it follows that there is a relationship between financial input and outcome. Value simply refers to the efficiency with which those inputs yield a desirable clinical outcome. Some policy experts more explicitly define Value as “health outcomes achieved for patients relative to costs of achieving them.”<sup>19</sup> We can operationalize this relationship as the “Value Equation” (Fig 3):

$$\text{Value} = \text{Outcome} / \text{Cost}$$

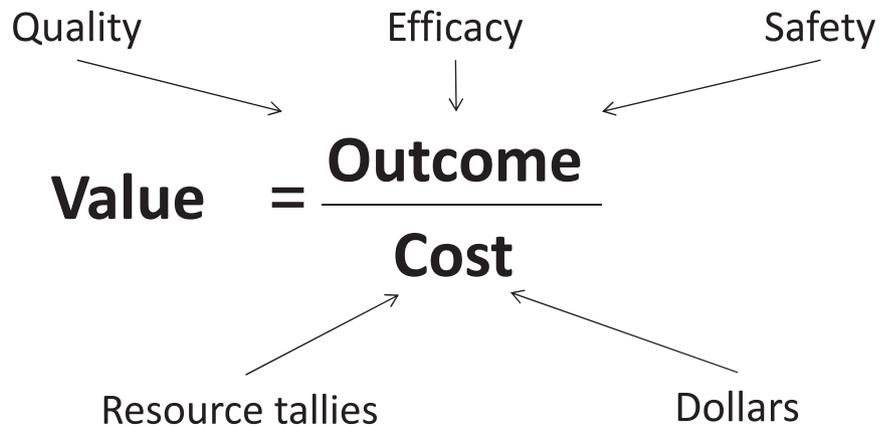
The numerator (Outcome) of this equation represents the results of our usual clinical activity expressed by the efficacy of an intervention. This can be derived from several sources: a clinical study, process and outcome measures reported in our institutions over time or in interinstitutional comparisons, or other markers of quality and safety.

The denominator (Cost) of the Value Equation includes all resources that constitute the inputs to the same clinical outcome. These fall into several categories. First, direct medical costs are those inputs that are a specific component of the



**FIGURE 2**

The figure demonstrates combining the cost of a program and outcome (eg, health units). A, The light blue represents the total area of the cost of each of theoretical 3 health programs (P1, P2, P3) of \$1.5 million dollars each. The dark blue represents the efficiency (eg, health units, life years, or quality adjusted life years). When combined together, the 3 programs yield 1.75 health units at an expenditure of \$4.5 million dollars. B, Demonstrates an example when the least efficient program (eg, one that leads the least health for the amount of dollars spent: P1) is eliminated and the money is redistributed equally between the other 2 programs and obtain a higher return of health unit. Alternatively, one can choose to spend less money to earn the same amount of health as previously and redistribute the additional spending on other social goals.



**FIGURE 3**

The Value Equation is represented as Value = Outcome/Cost. The numerator (“Outcome”) includes components such as quality, efficacy, and safety, whereas the denominator (“Cost”) includes things such as resource tallies and actual dollars.

medical intervention, including medical and nursing personnel hours, equipment, or doses of medication. Direct nonmedical costs are those inputs that are triggered by illness but do not directly relate to health; for example, families might incur

out-of-pocket expenses for travel to hospital. Finally, illness and its indirect consequences have an impact on productivity: the ability of the family or patient to contribute to society through work, now or in the future. From a practical

perspective, the resources in any of these categories might be considered in terms of dollars to facilitate comparison.<sup>20</sup>

In our formulation, “Waste” might be defined as the degree to which potential increases in the Value equation are not realized. Approaches to reducing waste and improving Value therefore target the components of the equation. Increasing the numerator (Outcome) while holding the resource inputs constant addresses “Quality Waste.”<sup>21</sup> In fact, improving outcomes in neonatology almost always reduces the denominator (Cost) as well, because adverse outcomes are often long-term and generally involve long-term costs that far exceed the cost of the original intervention.<sup>22</sup> A prominent example of quality waste was the underuse of antenatal corticosteroids, which resulted in higher rates and severity of adverse (and costly) consequences of preterm birth.<sup>23,24</sup>

Waste might also be reduced and Value improved by reducing the denominator (Cost), while holding the outcomes in the numerator (Outcome) constant. If 2 therapies have equivalent efficacy and side effect profiles, but 1 requires more resource inputs, it is sensible to choose the less expensive option, because the resources saved can be applied elsewhere to improve health. Besides the obvious example of more versus less expensive antibiotics, this “Inefficiency Waste”<sup>21</sup> also includes therapies that have been shown to have no or minimal efficacy, such as acid blockade for treatment of apnea of prematurity.<sup>25</sup>

Finally, Value may be improved even when both the numerator (outcome) and denominator (cost) move in the same direction, provided that the relative improvement in outcome exceeds the change in cost. Cost-effectiveness does not imply that an intervention saves money, or even that it is

cheap.<sup>26</sup> If a new intervention has a high price, but yields substantial improvements in outcome relative to the next best alternative, it might still be an appealing option. In neonatology, prominent examples include surfactant for treatment of respiratory distress syndrome,<sup>27</sup> and extracorporeal membrane oxygenation for term respiratory failure.<sup>28</sup> Indeed, neonatology itself, despite its large expenses, has been shown repeatedly to have a cost-effectiveness ratio in line with other acceptable interventions.<sup>29-33</sup>

There are situations (eg, orphan diseases or rare cancer treatments) where the bang for the buck would be unfavorable when compared with other disorders or public health interventions. Thus it is critical to incorporate additional considerations beyond dollars and health units into the decision to invest in a particular program.

### EVIDENCE-BASED MEDICINE

Because improving outcome is a key approach to optimizing the Value equation, the first pillar described of practicing value-conscious care is evidence-based medicine. Therapies with unequivocal positive effects free of any potential adverse consequences are rare in medicine<sup>34</sup>; therefore, almost all interventions should be subject to experimental confirmation of their efficacy and safety. The accuracy of this efficacy information will determine the outcome in the Value equation, and will therefore drive Value in health care. Randomized, controlled studies that minimize bias and have large enough collective sample sizes to provide reliable estimates are therefore critical. Neonatology has had a long tradition of conducting such rigorous trials and synthesizing the results in systematic reviews and meta-analyses.<sup>23,24</sup> Even with these efforts, however, failure to replicate findings<sup>35</sup> or to adopt lessons from

rigorous meta-analyses<sup>36</sup> can lead to misleading conclusions and failure to optimize Value. Moreover, the failure to transfer knowledge from trials into practice will likely lead to ongoing but preventable adverse consequences. For example, the lack of adoption of antenatal corticosteroids for impending preterm delivery was delayed for some 20 years after evidence of efficacy had been firmly established in meta-analysis.<sup>24</sup> This delay may have resulted in as many as 31% excess deaths,<sup>37</sup> as well as likely higher rates of expensive acute and chronic conditions such as respiratory distress syndrome, bronchopulmonary dysplasia, interventricular hemorrhage, and cerebral palsy.

A systematic and timely process for evaluating evidence and recommending for or against its use is therefore necessary. Organizations in the United States such as the American Academy of Pediatrics (AAP) Committee on Fetus and Newborn have this mandate, but have not explicitly considered costs. Recently, the Choosing Wisely campaign of the American Board of Internal Medicine Foundation highlighted the pursuit of Value as defined by evidence of effectiveness. This national movement aims to stimulate discussion between providers, patients, and payers to promote care that is “supported by evidence, not duplicative of other tests or procedures already received, free from harm, and truly necessary.”<sup>18</sup> Since its inception in 2012, over 60 professional organizations have developed lists of therapies that do not meet these criteria<sup>38</sup>; the AAP and its Section on Perinatal Pediatrics, pediatric hospitalist medicine,<sup>39</sup> rheumatology,<sup>40</sup> and ophthalmology<sup>38</sup> are among these organizations. Neonatology has recently completed a 2-year process of clinician survey, evidence review,

and expert consensus to identify its own “Top Five” lists of therapies and procedures to reconsider.<sup>41</sup>

## EVIDENCE-BASED ECONOMICS

The second pillar of practicing value-conscious care is evidence-based economics. Even if the neonatology community insists on first establishing that a clinical practice improves outcomes before adopting it, explicit cost considerations are still necessary to demonstrate Value. First, most interventions in medicine are not free, or their economic implications are not obvious to the provider. The adoption of all therapies with any demonstrated efficacy might lead to very high expenditures if the incremental gain in outcome comes at a high price. Conversely, therapies that appear to be very expensive might actually enhance Value. Such therapies might have large effect sizes, or they might address a disease state lacking any better or less expensive alternative, or 1 with long-term expensive adverse outcomes. Outcome and cost will often move simultaneously in the Value equation, and they must therefore be measured together to guide clinical practice.

A second situation occurs when 2 clinical approaches have similar efficacy and safety demonstrated in clinical studies. If clinical equipoise exists, then a decision regarding adoption might sensibly rest on differing costs (inputs) for each therapy.

Formal economic evaluation informs such decisions by simultaneously assessing the cost and efficacy of therapies; this is best performed, with least risk of bias, in randomized controlled trials (RCTs). Costs are measured either directly using hospital cost-accounting systems to assign a best estimate of cost to each patient over the course of treatment, or indirectly by tallying resource utilization and assigning a

price to each item. An incremental cost-effectiveness ratio (ICER) is then calculated as the difference in costs between 2 interventions, divided by the difference in effects.<sup>42</sup> The ICER (the additional cost for each increment in outcome) is thus very closely related to our more conceptual Value Equation. Once ICERs are available for multiple therapies, it is possible to rank those therapies according to their cost-effectiveness, and to spend our resources on those highest on the list until our budget is exhausted. This minimizes waste by choosing a portfolio of therapies that have the best tradeoffs between costs and effects. Although previous attempts to undertake a formal ranking of a large panel of therapies<sup>43,44</sup> have been hampered by public acceptance and the quality of available economic data,<sup>45,46</sup> such rankings would be expected to improve with time and could be undertaken in the context of a broader societal discussion of the therapies. Given a limited budget, the rational approach is to include economic considerations for priority setting in health care.

By measuring the ICER alongside RCTs, we take advantage of inherent protections against bias afforded by rigorous study designs and prospective data collection. Unfortunately, such evaluations are uncommon in neonatology, constituting only 1% of RCTs in 1 systematic review.<sup>47</sup> When they have been performed, they have confirmed that expensive therapies may represent good Value,<sup>28,48,49</sup> and that economic outcomes might facilitate decision-making when clinical outcomes are equivalent.<sup>50</sup>

To perform economic evaluation ancillary to RCTs or other clinical studies, additional data are necessary. Although every additional piece of information collected during an RCT or clinical project adds a research cost burden, the incremental requirement is modest

in this case relative to the substantial clinical data already collected for secondary outcomes. Existing guidelines provide a roadmap for investigators on how to perform such analyses.<sup>20,51,52</sup> When prospective economic evaluation alongside an RCT is infeasible, cost-effectiveness can be assessed in retrospective analyses of RCT data,<sup>22,49,53</sup> decision analysis by using RCT efficacy information,<sup>54</sup> or carefully performed observational investigations.<sup>55</sup> Similar concern for bias exists for economic evaluations as for efficacy outcome when there is a lack of randomization and an a priori hypothesis.

## QUALITY IMPROVEMENT

Once an evidence base for efficacy and cost is established, and recommendations by professional societies (eg, AAP Committee on Fetus and Newborn) or governing bodies (eg, Centers for Disease Control and Prevention) are made for adoption or rejection of interventions, these recommendations must be transmitted to the bedside. The third pillar of value-focused care is thus the application of improvement science.<sup>56</sup> In addition to implementing evidence and recommendations to the bedside, standardization of practice itself can lead to improved outcomes and reduced costs.

Nearly half of all very low birth weight infants either die or survive after experiencing during their NICU hospitalization 1 or more major morbidities, such as infection, chronic lung disease, brain injury, retinopathy of prematurity, and necrotizing enterocolitis.<sup>57</sup> These morbidities expose infants to additional diagnostic, therapeutic, and surgical interventions, cause psychological and financial distress for families, increase length of stay and the risk of rehospitalization,

and are associated with long-term neurodevelopmental disabilities. Yet, we can markedly reduce the rates of these major morbidities by applying what is already known. In the decade 2003 to 2012, improvements have been made in all of these morbidities without the discovery of any novel breakthrough clinical interventions. A particularly compelling example is the rate of catheter-associated bloodstream infections (CLABSIs), which have declined dramatically in neonatal, pediatric, and adult intensive care units as a result of quality improvement interventions focused on placement, maintenance, and removal of lines,<sup>58-60</sup> not on novel medical interventions. Many NICUs now report hundreds of days between CLABSIs. In addition, the overall hospital acquired infection rates for very low birth weight infants have declined from 23% in 2003 to 13% in 2012, translating into 5500 fewer late onset infections in US NICUs in 2012 than in 2003.<sup>61</sup>

Such improvement over time is variable, however. Risks of the major morbidities often vary markedly among NICUs, with those in the worst quartile having risk-adjusted rates 2 to 4 times higher than those in the best quartile. Although the maternal and patient demographic base may explain some of this, there remains a strong argument that the implementation of effective interventions varies as well.<sup>62</sup> If serious neonatal morbidities other than CLABSI were to match those of the best quartile, thousands of infants and families would be spared their damaging consequences. The corollary would be to spare the system of unnecessary expenditures. To do this will require understanding that the NICU is a complex socio-technical system, in which technical interventions often fail because inadequate attention has been paid to the social and behavioral aspects of interdisciplinary care. Improvement science, applied locally and within the

broader community of neonatology practice, accomplishes exactly that task, and has the potential to impact the Value equation.

This approach has been demonstrated to successfully address the Value Equation in multiple settings in neonatology.<sup>63</sup> The Neonatal Intensive Care Quality (NICQ) Collaborative is a program of the Vermont Oxford Network (VON) in which interdisciplinary teams, including parents, work under the guidance of expert faculty to identify, test, and implement potentially better practices designed to improve outcomes across multiple domains in the NICU.<sup>56</sup> In NICQ7 and NICQ8 (the seventh and eighth NICQ collaborative conducted by VON since 1995), VON sought to more explicitly add Value to the goals of the collaborative, to address waste while continuing to improve care quality. Each of the 50 participating teams developed a Clinical Aim, as well as corresponding Value and Family Aims. The Value Aims were focused on waste resulting from inefficient processes, underused effective technologies, and overused ineffective technologies. A group working toward reduction of necrotizing enterocolitis, for example, might target a Value Aim of reduction of days of parenteral nutrition support. Teams used familiar tools, such as the Plan-Do-Study-Act Model for Improvement<sup>12,56,64</sup> and measured resource outcomes in simple tallies, which could later be converted to costs. Over the course of the 3-year collaborative, the teams were able to demonstrate impacts on both the outcome and cost components of the Value Equation. Collectively, teams documented 93 fewer cases of bronchopulmonary dysplasia, 1168 fewer days of hospitalization, 245 fewer chest radiographs, 1480 fewer days of parenteral nutrition, 191 fewer transfusions, 420 fewer central

venous lines days, and 34 fewer blood stream infections.

Many states have now established neonatal and perinatal improvement collaboratives for interdisciplinary teams from NICUs in their geographic areas.<sup>65</sup> These collaboratives have achieved significant improvements in both quality and cost. For example, the Ohio Perinatal Quality Collaborative standardized the approach to neonatal abstinence syndrome, showing an almost 10-day length of stay reduction (33% decline) for infants in centers that had a morphine weaning protocol versus those that did not.<sup>66</sup> In the longer run, such successes might be expected to be leveraged to even better Value, as partnership with hospital administration and payers allows sharing of the gains and reinvestment into ongoing quality improvement work.

Although we have described the tools of evidence-based medicine, evidence-based economics, and quality improvement individually, such a distinction is to some extent artificial. Indeed, in the ideal case, the same study or improvement process will address more than 1 of the issues simultaneously. This approach has already been demonstrated in neonatology, for example, in cluster randomized trials of quality improvement interventions,<sup>67-69</sup> as well as in clinical trials with economic outcomes.<sup>70</sup> Integrated care delivery systems such as Intermountain Healthcare have similarly demonstrated success by using quality improvement to drive cost reduction.<sup>71</sup>

## OTHER CONSIDERATIONS

Certain characteristics particular to neonatology will affect how the above approaches are applied. First, just as the assessment of clinical outcomes well beyond NICU discharge has become the norm in RCTs, Value must be considered over a

relevant time horizon. Expenditures for interventions typically accrue in the NICU, but they may reduce disability and chronic disease over a life-time. The cost implications of several conditions, including cerebral palsy, mental retardation, hearing loss, and visual impairment, have been well established.<sup>72</sup> In addition, there are general costs absorbed by the public sector in preterm infants compared with term throughout the first 18 years of life.<sup>73</sup> And finally, it is becoming apparent now that prematurity might have subtler, but potentially costly, impacts on other morbidities, including behavioral, cognitive, and mental health conditions,<sup>74</sup> as well as obesity, adult onset heart disease, and type II diabetes mellitus.<sup>75</sup> The fragmentation of the US health care system does not lend itself to measuring such impacts<sup>76</sup>; indeed, there may be a tendency for parties to transfer responsibility of costs to another part of the health care system. However, failure to recognize these issues might introduce important bias into the Value equation. This area warrants close collaboration between providers, government, and other payers to understand how current interventions (and the reimbursement to support them) will provide downstream health and savings.

Similarly, the value of the “family voice” in the NICU should be considered in targeting Value.<sup>77</sup> Families shoulder a significant economic burden in both the acute and postdischarge periods. As previously noted, these costs include direct medical costs such as equipment, direct nonmedical costs such as child care, travel, accommodations, and meals, and productivity losses such as parent work absence. Specifically targeting

any of these would improve Value when viewed from a societal, rather than narrow hospital or payer focus. In addition, families may inadvertently have their economic burden increased by initiatives that target other aspects of care, such as transition to home. Given that a large proportion of NICU costs are fixed daily hotel and personnel fees,<sup>78</sup> there is tremendous pressure to reduce length of stay. Earlier discharge may shift costs to families, who might be required to make more frequent ambulatory visits or take additional time from work to care for a still-convalescent child.<sup>79,80</sup> More generally, there is a tendency for Value in our system to be a zero-sum game, in which one party’s cost is another’s profit. To optimize both quality and Value, it is important to align the experiences of the patient, hospital, ambulatory providers, and society. Certain aspects of the Affordable Care Act, including incentives for creation of Accountable Care Organizations, do just this.

Finally, we acknowledge that the conceptualization of Value as an economic and clinical objective does not fully reflect other aspects of the Value of care as they may be defined by either clinicians, families, or society. For example, equity in distribution of resources, or even targeting of resources preferentially to different groups, may be a goal in itself that is not incorporated in the Value Equation. The Value Equation measures and communicates 1 important aspect of care delivery, but our discussion of the goals of medicine must go well beyond this.

## CONCLUSIONS

External pressures to be more cost-conscious in providing neonatal intensive care are likely to increase

as national health policy and payer practice shifts financial risk to providers. By focusing on optimizing Value rather than exclusively on cost reduction, both outcomes and the overall patient experience can be improved rather than threatened. The 3 approaches to practicing Value-focused care discussed in this review (optimizing the conduct and dissemination of rigorous efficacy studies; undertaking economic evaluations ancillary to clinical trials; and inclusion of Value Aims in local, regional, and national quality improvement collaboratives) are closely related to activities that have long been at the core of neonatal intensive care practice. In concert with the broader tools of national health policy, these bedside interventions can provide the foundation for a new paradigm of clinically and fiscally responsible neonatal care.

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## ABBREVIATIONS

AAP:	American Academy of Pediatrics
CLABSI:	catheter-associated bloodstream infection
ICER:	incremental cost-effectiveness ratio
NICQ:	Neonatal Intensive Care Quality
RCT:	randomized controlled trial
VON:	Vermont Oxford Network

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