Ethical Framework for Risk Stratification and Mitigation Programs for Children With Medical Complexity

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abstract Those in hospitals and health care systems, when designing clinical programs for children with medical complexity, often talk about needing to develop and implement a system of risk stratification. In this article, we use the framework of an ethical evaluation of a health care program to examine what this task of risk stratification might entail by identifying specific and detailed issues that require particular attention and making a series of recommendations to help ensure that programs for children with medical complexity avoid potentially ethically problematic situations and practices.

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All the authors participated in the design of the study and interpretation of the data, drafting sections of the manuscript, revised the manuscript for key intellectual content, and read and approved the final manuscript as submitted.

DOI: https://doi.org/10.1542/peds.2017-1284J

Accepted for publication Nov 3, 2017

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PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

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FINANCIAL DISCLOSURE: The authors have indicated they have no financial relationships relevant to this article to disclose.

What ethical considerations should guide the design and evaluation of systems of care for children with medical complexity (CMC)? As we strive to improve clinical programs and policies for these children and their families (as illustrated by the articles in this supplemental issue of Pediatrics), we need to develop an ethical foundation for building and a framework for evaluating these programs and policies, which can range from a dedicated outpatient clinic for CMC to a home-based visiting clinician program, a variety of care management systems, or policies within or across health care systems. The need for this development arises from the inevitable tradeoffs that any complex health care system must confront, either explicitly or implicitly, when attempting to achieve multiple worthy ethical goals, including the following: benefitting individual patients and families, avoiding harming any patient or

family, respecting patient and family autonomy, securing a fair distribution of benefits across the population of children and families, ensuring a just process of appeal, and operating in a manner that is transparent and free from conflicts of interest.

However, performing an ethical evaluation of a risk stratificationbased program for CMC is challenging. In large part, the challenges are due to the difficulty of understanding exactly what these programs are doing, which is obscured by the technical, statistical, or computer-based algorithm aspects of these programs. Yet amid the technical details, a systematic evaluation of the various core components of these programs can reveal some important, ethically relevant data and decisions that warrant attention.

With these motivations guiding our approach, 1-4 we present a set of 8

ethically relevant considerations that are foundational for building and evaluating any program in which people aim to identify highrisk CMC (noting here that we will examine what high risk means later in this article) and enroll them in a clinical program to mitigate those risks (Table 1). As we develop these considerations, we integrate into the discussion the core components and attributes of any risk stratification and mitigation program (Fig 1) and examine how the ethically relevant considerations apply to the evaluation of these kinds of programs. We pay particular attention to the specific risk event or outcome that the program seeks to diminish (Table 2) and explain why the accuracy of identifying patients to enroll is important for program fairness and effectiveness. Throughout, we make specific recommendations regarding how to enhance the ethical appropriateness

TABLE 1 Key Ethical Considerations Regarding Programs for CMC

Ethical Consideration	Questions		
Transparency	 What is the underlying purpose and justification for the program? Is this purpose ethically appropriate? Our argument is that the chief justification should be that the program benefits patients and families, largely by lowering the risk of undesired events or outcomes. 		
	• From whose perspective is the program evaluated: patients, families, health care systems, payers?		
Clarifying potential benefit	• What is the specific undesired outcome that is being targeted when seeking to reduce the risk? The target might be a decline in a child's health, functioning, development, or quality of life; unmet health care needs; the parents' and family's function and quality of life; or excess health care use and cost.		
	 Whose values and priorities does the selection of the target risk or outcome reflect? 		
Benefit via effectiveness	 Is the program effective in reducing the risk and improving outcomes? Ineffective programs are ethically problematic. How is the program's effectiveness being evaluated? The program's effectiveness should be evaluated regarding how well the program lowers or otherwise improves the target risk. 		
Potential burdens and costs	 What are the costs of creating and maintaining an accurate risk stratification model? Who will bear the burdens and costs of the risk mitigation program? Will the burdens and costs be fairly distributed? 		
Fairness, effectiveness, and accuracy	 How accurate is the predictive model at estimating the probability that a given individual will, in the future, experience the specific event or outcome? Inaccuracies can threaten fairness and erode effectiveness. How is risk estimated? Is it by a clinician, an algorithm, or some other means? 		
Fairness of distribution	 Will the probability of risk be stratified fairly and not in an arbitrary fashion? Will the greatest risks or burdens align with the greatest potential for benefit from the intervention? Does the program unnecessarily burden families with less financial or social resources? 		
Fairness of processes and respect for autonomy	 Does the program have a formal, auditable complaint process and appeals process? How does the program inform parents about the program and obtain consent to enroll a patient? 		
Potential unintended harm	 Will a classification of medical complexity be used inappropriately, resulting in less or worse care? What are the potential consequences of program termination? 		

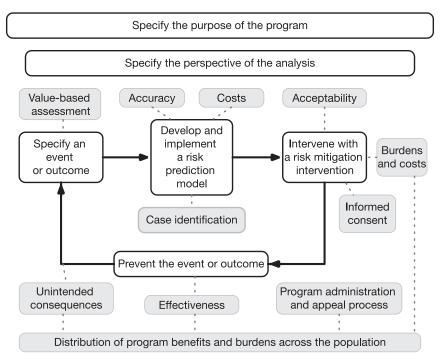


FIGURE 1 Characteristics of risk stratification and a risk mitigation program.

of these important programs for CMC (Table 3).

TRANSPARENCY OF THE PROGRAM RATIONALE, METHODS, AND PERSPECTIVE

Transparency is 1 of the cornerstones of good governance. The concept of transparency broadly encompasses an attitude of openness and clear communication on the part of the host organization regarding the program's goals, scope, processes, finances, and all other aspects of the program.⁵ Transparency enables persons served by and otherwise affected by the program to understand and support, or question and challenge, its operation. For these reasons, transparency is a prerequisite of ethical program development and an essential element of trustworthiness.6

For the sake of transparency, any evaluation of a program should be clear about the perspective from which the evaluation is

performed.³ For risk stratification—based programs for CMC, possible perspectives are those of the child, the child's family, clinicians, health care systems, government agencies, or payers.

In what follows, we strive to highlight issues that would particularly matter from the perspective of a child and his or her family, and we will point out situations in which other perspectives might differ.

CLARIFYING POTENTIAL BENEFIT

Program Purpose

Risk stratification can serve several potential purposes. One (which is the chief focus of this article) is to enable case identification, which is to say identifying particular CMC who could potentially benefit from a programmatic intervention. Other purposes of risk stratification include enabling risk-adjusted analyses of outcomes or costs, 7,8 or to identify a group whose predicted medical costs are substantially

different from the average to target for different insurance premium levels^{7,9} or for exclusion from coverage.⁷

Specific Risk Events or Outcomes

Whenever risk is discussed. the clarifying question "the risk of what?" should be asked and answered. There are many possible answers (Table 2). Any risk prediction model and risk mitigation program should specify the event or outcome that the program aims to prevent or minimize. For example, is the specific undesired event an emergency department (ED) visit or a hospital readmission or an outcome such as the onset of aspiration pneumonia or mortality? Is the focus any readmission or just preventable readmission, allcause mortality or just preventable mortality? These are different from each other and from other potential events or outcomes, such as prolonged hospital stays or receiving health care with total costs >95th percentile for the population. If a program aspires to provide additional services to the children and families who need it most, then the focus would be on predicting which children and families are likely to experience excessive levels of parental work of care, 10 unmet urgent or chronic care needs, preventable or remediable poorer health, or lower quality of life.

What about a program that sets out simply to identify CMC without focusing on a particular risk event or outcome? Aside from the problems that can arise from the circular reasoning of using a case identification process to both define and identify a group of patients (problems that we address below, such as how to determine the accuracy of such a scheme or determine the fairness

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TABLE 2 Possible Specific Risk Events or Outcomes to Be Targeted by Programs for CMC

Domains	Specific Risk Events or Outcomes	Comments and Questions
Health care use	ED visitsReadmissionsUnnecessary testingCosts	 These are common targets of CMC programs. Are all ED visits or readmissions targeted or just the preventable ones? How are preventable or unnecessary defined? Do costs include the potential costs shifted onto families?
Medical outcomes	 Patient death Specific patient morbidities Medication errors Hospital-acquired infections 	These are all important bad outcomes. However, care must be taken to not create perverse incentives whereby programs are disinclined to enroll patients who are at the highest risk of these outcomes.
Psychosocial outcomes	 Child-patient school absences Caregiver stress, anxiety, depression Family financial strain 	 A variety of adverse psychosocial outcomes are also important for the child, parents, and family overall. How is the program assessing this domain of outcomes?
Parental work of care	Hours spent providing hands-on care Disruption of nighttime sleep Absences, leave, or stopping work	 Parents perform most of the tasks required to care for CMC. Is the program monitoring the impact on parents' work of care and the consequences of changes in parental work of care?
Logistical tasks	 Approvals for equipment or services Scheduling multiple appointments Transportation difficulties 	 A sizable portion of the CMC work of care involves logistical tasks. How is the program measuring and evaluating the intervention's impact in this domain?

of the identification process), this "cut to the chase" approach does not clarify what the program is chasing after. What is the reason or justification for identifying CMC? If the reason is to help meet the unmet care needs of CMC, curb the costs of care, or prevent hospitalization, the program should make these underlying reasons clear. Furthermore, the program should acknowledge that there is likely to be a less-thanperfect correlation between being identified as CMC by the program's method of case identification and an elevated risk of the underlying problem that the program is supposed to be addressing, thereby threatening the ethical justifications for the program (as we discuss below).

Value-Based Assessment of the Risk Event or Outcome

The choice of which specific risk event or outcome to make the target of a program is a decision based on values that warrant clarification and examination. Care must be taken to explore how the value-based assessments of possible target risk events or outcomes might differ across stakeholder groups. For example, from the perspective of a family, a hospitalization may be viewed as an undesired event that imposes nosocomial risks on the child and disruption to family routines or, alternatively, as a desired event that provides respite or a desired level of therapy that could not be obtained at home, or a bit of

both. From the perspective of a payer, the benefits and harms of a hospitalization (which could include its costs) may be viewed differently from the family's view.

BENEFIT VIA EFFECTIVENESS

With the justification for the risk stratification—based program being to improve outcomes for CMC and their families, much hinges on whether the intervention effectively lowers the targeted risk event or outcome.

Risk Mitigation Intervention Effectiveness

To reiterate, the target risk might involve the child's health, functioning, development, or quality of life; the function and quality of life of the parents and family; unmet health care needs; or excess health care use and cost. Depending on which target was chosen, the program's effectiveness should be evaluated specifically regarding lowering or otherwise improving that target risk.

Currently, few data exist regarding the effectiveness, or lack of effectiveness, of programs focused on CMC; whereas researchers in some studies have presented encouraging findings, 11 others have not.12 Furthermore, most programs will have too few patients to have sufficient power to detect statistically significant differences in dichotomous outcomes (such as hospitalization events) and may equally lack power regarding continuous outcomes (such as costs) when the outcomes are distributed in a highly skewed manner. Those who administer programs may also lack the knowledge or resources to conduct and analyze rigorously designed studies regarding program effectiveness.

However, what those who administer programs should not do is rely on simple but potentially misleading evaluations in which they examine the

Recommendations	Explanation and Rationale	
Use systems thinking	CMC are part of a system of care that involves the parents, family, many aspects of the health care system, as well as othe systems (such as schools). Because all elements of these systems interact, an intervention focused on 1 part of the system may well have consequences,	
	intended or unintended, on other parts of the systems.	
Engage patients, parents, and families	 Because patients and parents are the key stakeholders regarding the health and well-being of the patient, their perspectives, values, and priorities should guide the value proposition of a program. 	
	Doing so helps ensure that the program serves the interests of	
	the intended beneficiaries. • Engagement also helps to ensure acceptability and feasibility.	
Specify program goals	 This action enhances the transparency of the program. Doing so also provides a basis for accountability. 	
Specify anticipated benefits, burdens, and costs	 Benefits and burdens are key ethical considerations. One goal is to promote fairness in the distribution of benefits and burdens. Cost is an ethical consideration regarding justice concerns and the stewardship of scarce resources. 	
Detail the intervention	 This enables stakeholders to evaluate the benefits and burdens of the intervention. This promotes voluntary and autonomous decision-making regarding participation. 	
Assess the accuracy of case identification	 This helps gauge an important aspect of the program's ability the benefit CMC in a fair manner. This ensures that the selection meets stated program goals and values. This helps identify and reduce bias in the selection of participants. 	
Adopt formal and auditable consent and appeal processes	 Informed consent is a cornerstone of ethical interventions. The appeals process promotes procedural fairness. 	
Make program features and performance metrics publicly available	Transparency is enhanced by open communication.Accountability is strengthened.	

outcomes and costs of patients before and then after entry into the program. We know that children who experience high levels of hospitalization in 1 year are the most likely to experience dramatically reduced levels of hospitalization the next year. ¹³ This regression to the mean underscores the need for a comparator group that is similar in terms of the risk of hospitalization or other outcomes but does not receive the program's risk mitigation intervention.

Given these challenges, one might ask whether we should avoid getting

all tangled up in difficult evaluations about effectiveness and simply do the right thing, so to speak. Although this might seem tempting, we should regard what has occurred in adult care as a cautionary tale. For more than a decade, disease-management programs for adults have often been promoted by payers, hospitals, and other stakeholders on the basis of potential cost savings through greater uptake and adherence to relatively inexpensive preventative care, thereby (as the theory goes) reducing costs because of hospitalization and especially ED use. Although these programs have been shown to improve quality of care, ¹⁴ researchers have not consistently concluded that disease-management programs reduce costs, ¹⁵ and some have noted that standardized programs are a poor fit for complex patients with comorbid conditions, increasing burden but without adding benefit for some of the patients with the most severe cases. ¹⁶

Risk Mitigation Intervention Acceptability

If a program identifies a particular patient as being suitable for the risk mitigation intervention, will the child and family willingly (ie, voluntarily) agree to enter into the program and receive the intervention? Once enrolled and receiving the intervention, will they willingly remain enrolled?

The answers to these questions about acceptability relate to factors that we have considered above: do the patient and family place value on preventing the targeted risk event or outcome, and is the program effective at minimizing that risk? The answer will also depend on other factors, some pertaining to the program itself (eg, the burden the intervention places on the family in terms of additional clinic visits or phone calls) and nonprogram-specific issues (eg, a family's level of trust in the health care system or psychosocial factors that interfere with intervention adherence).

From an ethical point of view, the degree of acceptability of the program directly touches on issues of autonomy, voluntariness, and the role of informed consent when enrolling (and remaining enrolled) in the program. If the program is viewed by well-informed patients and families as highly acceptable, then no concerns on these fronts would arise. On the other hand, if the level of acceptability is lower for most families or is low for particular families, programs would need to ensure that participation is

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not encouraged via inappropriate inducements (eg, presenting only the potential benefits of the program while omitting the mention of burdens) or subtle forms of coercion (eg, negative financial repercussions for not participating).

POTENTIAL BURDENS AND COSTS

A full evaluation of a program must also consider the burdens that the program places on patients and families (as mentioned briefly above) as well as the broader costs of running the program.

Program Participation Burdens

From the family perspective, the burdens of participating in a program could include expenditures of time (eg, going to carecoordination clinic visits, engaging in phone calls, or completing paperwork), bearing certain expenses (eg, transportation costs for additional clinic visits or taking time off from work to attend these visits), or having more work to do (eg, care-coordination or other direct-care activities to mitigate risk). Although a family may view these burdens as being offset by the benefits accrued by participating in the program, nevertheless, the burdens need to be accounted for to ensure that they are indeed outweighed by the benefits.

Risk Mitigation Intervention Costs

From the perspectives of individual providers, risk mitigation programs will almost inevitably cost a great deal of time, with potential implications for their performance evaluations, compensation, and career advancement. From the perspective of a health system or payer, running the risk mitigation intervention will also have costs that need to be accounted for (eg, staff salaries and other resources to house and run the program, education

for staff and leadership, and lower reimbursement rates associated with more time-intensive patient care), although the reduction in other costs (eg, hospital stays) might offset the program's costs.¹⁷

Risk Stratification Model Costs

Other important drivers of program cost are the creation, implementation, and updates to the risk stratification model itself. These include the ongoing costs of acquiring and managing the necessary data, the costs of initial model development and validation, and periodic readjustments of the model (necessitated by changes in modes and the effectiveness of medical care).

Perspective and Standards for Evaluating Burdens and Costs

As discussed above, the evaluation of a program's burdens and costs can be performed from the perspectives of different stakeholders, including patients, families, health systems, payers, and even society. Given the possibility of cost shifting (whereby, for example, the payer costs associated with hospitalization are reduced but at the expense of greater costs for families), the evaluation needs to be clear about the perspective or perspectives taken and be able to justify the choice of perspective.

In practice, program evaluations employ different standards to determine if the program benefits are worth the program costs. Each of the various possible standards embodies a different stance regarding the value propositions of these programs, and these differences have ethical implications. For example, if the standard is that a program needs to be cost-saving or cost-neutral to be deemed worthy of continuation, regardless of the profile or magnitude of benefits, this stance would warrant ethical justification; in almost any other realm of health care, decreases in morbidity or improved outcomes justify some increase in spending.

FAIRNESS, EFFECTIVENESS, AND ACCURACY OF RISK CLASSIFICATION

Now, we must address the accuracy of the method used to identify children who are at heightened risk.

Risk Estimation Model

Within any risk stratification program, some model serves to estimate the risk level for every individual. These models can employ different methods. For example, some programs have clinicians nominate patients for participation in a high-risk disease-management program, whereas other programs use computer software to estimate a patient's risk level on the basis of that patient's diagnoses and other characteristics. 18

Model Accuracy

Models should be assessed regarding their predictive accuracy because inaccurate or systematically biased models raise many concerns, ethically and otherwise. When assessing accuracy, the task is to determine how closely the model estimates the probability that a given individual will, in the future, experience the specific event or outcome. The word "future" is underscored because the model can only be evaluated by using longitudinal data, whereby data from 1 time period is used to predict events in some subsequent time period. Cross-sectional data should not be used to assess the accuracy of or validate predictive models because this type of data can only confirm cross-sectional associations.

To evaluate the accuracy of a predictive model, several statistical measures could be used. The area under the receiver operator curve, which is calculated as the C-statistic, provides a summary measure of how

well a predictive model works (with a built-in tradeoff of sensitivity and specificity, weighing each equally). Because this measure evaluates the entire sample of individuals, it is not from the perspective of a given group of CMC, but rather from an analyst or program manager perspective.

The program's analysts and manager would also want to know how well the risk prediction model is calibrated; across the continuous range of predicted probabilities from 0 to 1, how closely do the predicted probabilities match the observed probabilities, moving across groups of children from those with the lowest to those with the highest predicted probabilities? The calibration can be formally tested by using the Hosmer-Lemeshow test.

From the child or family perspective, important questions about the fairness of the risk prediction model would be better answered by knowing the model's sensitivity ("If I truly should qualify for the program, how likely is this model to correctly identify me as eligible?"), falsenegative rate ("If the model says that I do not have an elevated risk, how likely is it that the model made a mistake?"), or positive predictive value ("If I am identified as needing this program, how likely am I to really be at an elevated risk of the event or outcome?").

Accuracy should be evaluated with an eye on the overall purpose of the program and a sense of whether the identification of patients will lead to a fair distribution of additional resources. For example, if a risk stratification algorithm based on diagnoses identifies a group of patients with cancer as being at risk for higher levels of resource use, costs, and mortality, but this group is already well known to have these risks and is already provided high levels of care coordination, should the algorithm be praised for this accomplishment? Conversely, if an algorithm is designed such that a

specific condition (such as type 2 diabetes) is not included among the high-risk conditions that confer eligibility for program services, yet a particular patient with that condition would benefit from the program despite being ineligible on the basis of the algorithm score, how should the algorithm's performance be judged?

FAIRNESS OF THE DISTRIBUTION OF PROGRAM BENEFITS AND BURDENS

Now, we move on to consider, from a population perspective, whether the program would fairly distribute its benefits and burdens across the population of CMC (and more broadly, across all other children) because fairness and justice are important ethical considerations.

Risk Distribution and Risk Categories or Groups

Risk stratification requires dividing the underlying probability (ranging from 0 to 1) of an undesired event happening into categories or groups, such as low, medium, and high risk. A program must define cut-points by dividing the range of probabilities from 0 to 1 into 1, 3, or more subranges and then place individuals into risk groups depending on where their estimated probability falls within those subranges. For example, among children with neurologic impairment and swallowing dysfunction, the risk of microaspiration with feeding, the development of aspiration pneumonia, and being hospitalized all can, during a given period of time, range from 0 to 1. A program might classify children with risk in the 0 to 0.1 range as low risk, from 0.1 to 0.3 as medium risk, and from 0.3 to 1 as high risk.

The fairness of this scheme will depend in part on how, across the population of patients, the level of probabilistic risk is distributed; if the risk is distributed in 2 dominant modes, with most of the people

having either a risk probability of close to 0 or close to 1, then dividing the population into 2 groups will seem sensible, whereas if the risk is distributed more evenly, drawing any given cut-point may seem arbitrary, raising the potential for perceived or real unfairness.

Benefit and Burden Distribution Across Risk Categories or Groups

Fairness will also depend on how the distribution of risk matches up to, for each and every individual, the distribution of potential benefits and burdens of participating in the program. Let's clarify what this means: one might suppose that the CMC who are at the greatest risk of having an undesired event or outcome are also the same CMC who would be the most likely to benefit from the program and have the greatest benefit-to-burden ratio, but these suppositions may not hold. For example, in a program intended to reduce hospitalizations among CMC with neurologic impairment, a particular child who is at high risk for aspiration pneumonia might nonetheless face an unfavorable benefit-to-burden ratio because of the potentially refractory process of microaspiration in a child with severely impaired airway protective reflexes, and thus limiting the potential benefit.

FAIRNESS OF PROCESS, APPEAL PROCESS, AND INFORMED CONSENT

Fairness is a consideration not only about how benefits and burdens are distributed but also about how programs are administered and the degree of justice afforded by any appeal process.

Program Administration and Appeal Process

We know from studies of other child-oriented programs (specifically regarding educational programs) that parents differ substantially regarding the amount of financial resources or other forms of cultural capital at their disposal to advocate

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for their children's inclusion or exclusion from a program.¹⁹ Programs need to consider how they will ensure against providing, wittingly or unwittingly, preferential treatment to more empowered families.

For similar reasons, to ensure equity of treatment, programs should have a formal and auditable process in place for handling complaints and appeals from patients or families.

Informed Consent

As a cornerstone of medical ethics, obtaining informed consent before performing any procedure is a fundamental method for respecting a person's autonomy. Programs should scrutinize how they are informing and educating potential participants in the program about exactly what will be done and why and how they are ensuring that voluntary consent to participate has been granted. Similar to other interventions that unfold over time, programs should recognize that participants have the right to withdraw their consent and should have in place steps to enable participants to stop being part of the program if they so choose.

POTENTIAL UNINTENDED HARMS FROM THE PROGRAM

Finally, the ethical evaluation of any intervention or program (and in particular, a risk stratification–based program) must consider potential unintended consequences.²

Adverse Risk Selection

In the arena of adult health care, payers have employed a variety of tactics to reduce the expenses associated with complex medical

conditions. A common scenario involves efforts to create a pool of relatively healthy, insured individuals by refusing coverage directly or indirectly to those who are sick or intentionally recruiting healthier policyholders. For example, after the passage of the Patient Protection and Affordable Care Act, the majority of insurers who offered policies through exchanges were found to be using adverse tiering to discourage certain groups of patients from enrolling in any of their plans.²⁰ Insurers have also been found to target advertising toward wealthier and healthier potential policyholders by, for example, sponsoring advertisements in health clubs.

Program Failure

Risk mitigation programs may not be equipped (financially, structurally, politically, or otherwise) to operate indefinitely. Some risk mitigation programs may bring considerable benefit to CMC and their families, but the prioritization of other outcomes (most commonly, cost reduction) that are not achieved might mean that the programs are considered failures and ultimately terminated by the host organization. Other programs may never fulfill their initial promises because of mismanagement, funding shortfalls, or political challenges and may disenroll CMC haphazardly or precipitously.

Disenrollment from programs may induce harms that would not have arisen had some CMC or their families never been enrolled in the first place because families may make important choices (eg, where they live, how their work is structured, or where they seek health care) on the basis of ongoing enrollment and then

struggle to find similar services after they are terminated. Even when families are able to manage the end of a program with relative ease, they may feel disappointed and lose trust in their providers or the health care system. Some of these potential harms might be avoided with careful planning on the part of the host organization or intervention providers, who may owe participant families appropriate support or referral.

CONCLUSIONS

CMC and their families deserve the best health care possible, as do all children and families. To the degree that risk stratification and risk mitigation programs can optimize the care of and outcomes for CMC in a manner that is fair to all, we support these programs. Yet as we have highlighted here, these seemingly straightforward programs are complex and must be designed and evaluated regarding key ethical considerations to ensure that they indeed are fair to all and that they do not wind up serving the best the interests of health care organizations or payers as opposed to children and families.

ACKNOWLEDGMENTS

We thank the Lucile Packard Foundation for Children's Health for organizing and hosting the Designing Systems for Complex Care symposium in December 2015, which served as the impetus for writing this article.

ABBREVIATIONS

CMC: children with medical complexity

ED: emergency department

FUNDING: No external funding.

POTENTIAL CONFLICT OF INTEREST: The authors have indicated they have no potential conflicts of interest to disclose.

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