Estimating Risk Associated With Care in Alternative Settings

Deterioration Among Children Hospitalized

Kenneth M. McConnochie, MD, MPH; Charles M. Callahan, MD, MPH; Gregory P. Conners, MD; Klaus J. Roghmann, PhD

Background: Although managed care favors use of alternative settings in an attempt to avoid hospitalization, uncertainty about possible deterioration creates concern about their safety.

Objective: To derive preliminary estimates for the risk of adverse outcome in children hospitalized with acute illness who met criteria for admission to potentially less-expensive, alternative settings (eg, short-stay unit, home nursing).

Design: Description of hospitalization outcomes for a community-wide childhood population.

Setting and Population: All 11,591 hospitalizations for residents of Monroe County (Rochester), New York, aged 1 month to 18 years in 1991 and 1992.

Measurements: To identify potential adverse outcomes in alternative settings (numerator estimate), hospital medical records for admissions to regular inpatient units were examined. To ascertain deterioration among these admissions, detailed record reviews were conducted if the child died or was transferred to another hospital or to a critical care unit. To estimate the total number of admissions eligible for care in alternative settings (denominator estimate), hospital discharge files were analyzed.

Results: Deterioration was found in 83 medical admissions. Of these 83, major chronic problems (n=53) or severe illness at presentation (n=27) precluded alternative setting eligibility, leaving only 3 in whom alternative setting care might have been considered. The total number of admissions eligible for alternative setting care was estimated between 1661 (restrictive criteria) and 3322 (inclusive criteria) for the 2-year observation period. Based on these observations, best- and worst-case estimates for the risk of deterioration in candidates for care in alternative settings were 0.6 and 1.8 per 1000, respectively. For the 3 children for whom alternative setting care might have been considered, the shortest period from first indication of deterioration to arrival in the critical care unit was 3.0 hours.

Conclusions: These preliminary estimates suggest that alternative settings may be safe for the care of many children currently hospitalized. A randomized clinical trial to evaluate directly the potential benefits and harms of alternative setting care should be considered.


Editor’s Note: I’ve always believed the hospital is not a safe place unless you really need to be there, so I really like this thought-provoking study.

Catherine D. DeAngelis, MD

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SUBJECTS AND METHODS

STUDY POPULATION AND SETTING

This study is based on the entire experience with childhood hospitalizations for residents of Monroe County (Rochester), New York, during a 2-year period, from January 1, 1991, to December 31, 1992. All hospitalizations in county hospitals for county residents, ages 1 month through 18 years, were included in this analysis. Virtually all hospitalizations for county residents occur within the county. Travel times to hospitals outside Monroe County are relatively long. Strong Memorial Hospital is the only tertiary care facility and its CCU is the only one for children in Monroe County and its surrounding counties. Population estimates used in calculating rates were based on the 1990 US census. The county’s childhood population accounted for a total of 307,186 child-years at risk and 11,991 hospitalizations from January 1, 1991, to December 31, 1992. The overall, annual hospitalization rate was 29.2 per 1000 child-years.

DENOMINATOR ESTIMATES

Denominator estimates were determined by estimating the number of episodes that were candidates for ASC. The Figure shows the categories for hospitalizations that were used in estimating the probability of deterioration among illness episodes eligible for ASC. The denominator for this estimate was derived from a database maintained by the Rochester Healthcare Information Group, an agency created and finance by a consortium of the Rochester area hospitals. This database includes all county hospital admissions. Criteria applied to the database to estimate the number of potential ASC candidates were based on discharge diagnoses and included (1) medical admission, (2) classification of the hospitalization as discretionary, and (3) absence of major chronic problem. International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) codes were the principal source of information used in applying these criteria. Because ICD codes generally do not identify surgical admissions, diagnosis related group (DRG) codes were used for this purpose. Rationale and methods used to apply these criteria follow.

Restricting eligibility to medical admissions limited study hospitalizations to those for which pediatricians have a direct influence on developing care alternatives and on the decision to use these alternatives. To exclude nonmedical admissions, hospitalizations during the study period were first classified hierarchically as obstetric, surgical, psychiatric, or medical. Obstetric included pregnancy-related admissions in adolescents. Sexually transmitted diseases and other gynecologic problems commonly treated by pediatricians and family physicians were included in the medical rather than the obstetric category. Surgical admissions were included in those in which a surgical procedure was performed according to DRG classification. Included among psychiatric admissions were hospitalizations for psychiatric conditions, substance abuse, and eating disorders. Admissions not classified as obstetric, surgical, or psychiatric were considered medical.

Classification of medical admissions as discretionary was based on previous work in which we developed a classification of childhood hospitalization decisions based on ICD and DRG codes in hospital discharge files. The classification was developed initially for infant hospitalizations and expanded for purposes of the present study to include older children. Discretionary admissions were defined as those medical conditions in which the decision to admit involves a substantial amount of physician judgment (ie, the physician exercises his or her discretion). Characteristically, discretionary conditions have a wide range of severity and are often managed at home. The discretionary group included 13 clinical problems (asthma, bronchiolitis, pneumonia, acute febrile illness, gastroenteritis and dehydration, croup, viral meningitis, seizures, urinary tract infections, other gastrointestinal tract disorders, skin and soft-tissue infections, acute otitis media, and upper respiratory tract infection) that met the definition of discretionary and also have been found to have hospitalization rates that vary widely among geographic areas. The validity of classifying these diagnoses as discretionary is supported by these geographic variation studies and also by the work of an expert panel. In addition to these 13, problems such as ingestions, lacerations, and minor fractures were included in the discretionary class on the basis of our clinical experience. In contrast to discretionary hospitalizations, mandatory hospitalizations were those for acute medical conditions for which withholding hospital admission would likely be deleterious to the child’s health (eg, bacterial meningitis, orbital cellulitis). Mandatory conditions are life threatening or have potential to produce candidates for ASC. In these episodes, deterioration that prompted transfer to a pediatric critical care unit (CCU) was used as a proxy for serious physiologic deterioration that would render management in an alternative setting unsafe. Risk for those episodes in which transfer occurred was further assessed by determining the period of time during which deterioration evolved. In patients whose condition deteriorates during ASC, adverse outcomes might be avoided if deterioration evolved over a period sufficiently long to allow timely return to hospital care.

Many important questions relating to care in alternative settings are not addressed. Use of deterioration with current inpatient care as a proxy for deterioration with ASC is valid only if ASC is equivalent to inpatient care in its ability to prevent deterioration. Equivalence in preventing deterioration is not addressed. We believe there are a substantial number of carefully selected acute illness episodes for which ASC can provide all the services presently provided to inpatients. We believe, for example, that carefully selected episodes of asthma exacerbation, bronchiolitis, soft-tissue infection, gastroenteritis, and urinary tract infection might receive equivalent care in alternative settings, but this study is not designed to address this issue. Specific services potentially provided in alternative settings are also not addressed, but we expect ASC would provide services that have successfully been provided in the home to people with chronic illness—intravenous fluids, parenteral antibiotics, and supplementary oxygen. Additional questions that should be addressed before any recommendation to adopt a specific form of ASC should be considered in-

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long-term disability without, or even with, immediate hospitalization. Inpatient hospital care is virtually always provided and ASC is considered inappropriate for initial management.

Children with major chronic problems were excluded because of the possibility that the chronic problem would increase the risk associated with ASC for the acute problem to an unacceptable level, or that the chronic problem, itself, could not be managed adequately with ASC. The presence of a major chronic problem was determined from a classification of all diagnoses for medical admissions as representing a major chronic problem or not. To identify children with major chronic problems who were hospitalized, this classification was applied to diagnoses among the first 5 listed in hospital discharge files.

Lower- and upper-limit estimates for the number of hospitalizations eligible for ASC were based on the number of discretionary admissions in which there was no morbidity classified as a major chronic problem. As an upper-limit or inclusive eligibility estimate, we used the total number of discretionary admissions without a major chronic problem. Using the inclusive eligibility estimate as the denominator provided a lower-limit (best-case) estimate for the probability of adverse outcome. For the restrictive or lower-limit eligibility estimate, we halved the inclusive estimate. Using the restrictive estimate in the denominator provided an upper-limit (worst-case) estimate for the probability of adverse outcome. The rationale for deriving inclusive and restrictive eligibility estimates using these methods is presented in the “Comment” section.

NUMERATOR ESTIMATES

Numerator estimates were determined by ascertainment and measurement of deterioration. Standard practice in this community is for all children having illness episodes with serious deterioration to be transferred to the CCU. To ensure complete ascertainment of serious physiologic deterioration, hospital records were reviewed if a patient was transferred from a community hospital inpatient unit to the tertiary care facility or was transferred within the tertiary care facility to the CCU. In addition, medical records were reviewed if a child was admitted to a regular inpatient unit and later died in a setting other than the CCU (non-CCU deaths). Non-CCU deaths were reviewed to ensure ascertainment of any apparent candidates for ASC in whom deterioration was so rapid that death occurred before transfer to the CCU. The database maintained by the Rochester Healthcare Information Group identified transfers and deaths.

Two steps were involved in ascertaining deterioration. As a first step, diagnoses and the names of the DRGs in hospital discharge files for events of interest (ie, transfers and non-CCU deaths) were examined to eliminate from consideration nonmedical admissions as well as children transferred for reasons unrelated to deterioration (eg, postoperatively). In the second step, medical records for illness episodes not previously eliminated were reviewed by investigators to provide judgments regarding eligibility for ASC at the time of admission and the occurrence of deterioration. Reviews were performed by 3 of the investigators (K.M.M., C.M.C., and G.P.C.) who were experienced clinicians. Because judgment was sometimes involved in step 2 reviews, the 3 clinicians reviewed independently all medical records for episodes reaching step 2 in the ascertainment process. Whenever determinations differed among members of this group, an attempt was made to reach consensus through discussion. If the child was judged ineligible for ASC at the time of admission, reasons were classified, in order of priority, as (1) limited physiologic resilience because of major chronic problem, (2) physiologic derangement too severe, (3) limited physiologic resilience because of the child’s young age, or (4) care required treatment that could not be administered in an alternative setting. If deterioration and transfer occurred, investigators estimated the transfer time. Transfer time was defined as the period of time from the first notation indicating deterioration to the time of the child’s arrival in the CCU.

ANALYSIS

Risk of adverse outcome was estimated as the rate with which children residing in Monroe County were admitted with a discretionary condition and subsequently deteriorated to the point that they died on a regular inpatient unit or were admitted to the CCU. Further information about risk included the probability of unsafe deterioration. Restrictive and inclusive eligibility estimates were used as denominators in estimating risk. Calculation of confidence limits (CLs) for rates of deterioration and unsafe deterioration were based on the Poisson distribution.

DENOMINATORS FOR RISK ESTIMATES

All 11,591 hospitalizations in 1991 and 1992 were evaluated to derive denominators for risk estimates (Table 1). Of the 11,591 hospitalizations, those not eligible for ASC included 2073 obstetric, 2873 surgical, and 701 psychiatric admissions. The remaining 9,342 admissions were medical. Among medical admissions, an additional 1322 were ineligible because admission was mandatory, and 1298 were ineligible because of a major chronic problem. The proportion of children admitted with major chronic problems underestimates the frequency of major chronic problems among all hospitalizations because many surgical admissions were for children with such problems.
The remaining 3322 medical admissions were discretionary in children without a major underlying chronic problem. The inclusive eligibility estimate was based on these discretionary admissions and accounted for 28.7% of all admissions and 55.9% of medical admissions. Among these 3322 discretionary admissions, 2382 (71.7%) were attributable to 1 of the 13 problems assigned to the discretionary class on the basis of variation observed in prior studies, whereas the remainder were assigned on the basis of investigator experience. The restrictive eligibility estimate (half the inclusive estimate) was 1661.

NUMERATOR FOR RISK ESTIMATES
To derive the numerator for risk estimates, non-CCU deaths and transfers were reviewed to eliminate episodes ineligible for ASC and to characterize deterioration, when it occurred, as to transfer time.

STEP 1 EXCLUSIONS
The vast majority of episodes were found in step 1 to be ineligible. As shown in Table 2, many transfers from community hospitals were unrelated to deterioration. Among the 41 community hospital transfers, those not eligible for ASC included surgical admissions (n=4), transfers for psychiatric care (n=7), or transfers for medical evaluation of complex problems (n=6). Most transfers within the tertiary care center were already in a state of severe physiologic derangement at the time of hospitalization and were admitted directly from the emergency department to the CCU (n=404) or were transferred to the CCU postoperatively (n=113). An additional 26 patients were transferred for ongoing management to the CCU from other intensive care units (eg, the burn unit) within the tertiary care facility. A total of 56 deaths were identified among patients not transferred to the CCU, but none of these occurred in patients eligible for ASC when presenting to the health care system. All occurred during or shortly after surgical procedures, in severely injured patients (eg, gunshot wound to head), or in surgical or burn intensive care units.

STEP 2 EXCLUSIONS
Among the 83 episodes remaining after step 1, 53 were judged ineligible because of limited resilience due to a major chronic problem, and 27 were judged ineligible because physiologic derangement was already too severe at the time of presentation, ie, admission was judged to be mandatory. No episodes were judged ineligible because of the inability to provide necessary care in alternative settings or because of limited resilience due to age. Two of the 83 were judged eligible for ASC at presentation. For 1 additional episode in which deterioration occurred, consensus on ASC eligibility was not achieved. (Case synopses for these 3 illness episodes are available from the authors.)

The 53 ineligible episodes with major chronic problems included some in which the coexisting acute problem, alone, was sufficiently severe to preclude ASC (eg, acute congestive heart failure, intractable seizures). In others, the acute problem itself had not yet become severe enough to preclude ASC, but the underlying chronic problem was judged to increase risk to a level that was unacceptably high (eg, asthma exacerbation in children with laryngeal stenosis or other head and neck anomalies). Although clinicians view asthma and diabetes mellitus as major chronic problems, acute exacerbations of these problems (eg, acute asthma episodes and diabetic ketoacidosis) in a child without additional major chronic problems were, for purposes of this study, grouped with children with no major chronic problem. As with other problems in this group, decision making regarding ASC admission for asthma attacks and diabetic ketoacidosis would focus largely on acute physiologic derangement attributable to a single problem, and many episodes would probably be eligible.

Among the 27 step 2 exclusions judged ineligible because of severe physiologic derangement, diagnoses at presentation (ie, bacterial meningitis, coma, dysrhythmia, or encephalitis) justified ineligibility for 4. For others, further justification is warranted. Two children presenting with possible “acute surgical abdomen” did not clearly have problems that required surgical intervention when they were admitted, although surgical consultation was obtained in the emergency department. Pulmonary function was severely impaired for 3 ineligible children with asthma, 6 ineligible children with bronchiolitis, and 2 ineligible children with croup. Two of the children with bronchiolitis, for example, were less than 2 months old and at presentation were having frequent, prolonged apnea episodes. An ineligible child with diabetic ketoacidosis had initial laboratory values that included a pH of 7.11 and a serum bicarbonate level of 8 mmol/L. An ineligible child with gastroenteritis was hypernatreemic and estimated to be 10% dehydrated. Six ineligible children with seizures were admitted because of intractable seizures or because close physician observation of seizure characteristics was sought.
ESTIMATES OF RISK

The best-case estimate for the number of eligible episodes that deteriorated counted only the 2 episodes for which eligibility was based on full consensus. The worst-case estimate for the 3 episodes that deteriorated included also the one case for which consensus was not achieved. The worst-case estimate for risk of deterioration, based on the restrictive estimate for the denominator and the 3 episodes with deterioration was 1.81 per 1000 children eligible for ASC (95% CLs, 1.72, 1.89 per 1000). The best-case estimate for risk of deterioration, based on the inclusive estimate for the denominator and 2 episodes with deterioration was 0.60 per 1000 children eligible for ASC (95% CLs, 0.58, 0.62 per 1000). Risk is further characterized by the fact that transfer times were 3 or more hours in every instance. Transfers for the 3 eligible episodes with deterioration all were completed safely, although transfers for the 3 eligible episodes with deterioration occurred in the inpatient setting. The transfer time that should be used to indicate whether transfer from ASC could be safely accomplished will vary with the proximity of the setting to the CCU and with local resources. Very short transfer times would be safe for a short-stay unit located on the campus of a hospital that includes a CCU. A CCU transport service, developed in this community subsequent to study observations, has demonstrated its ability to arrive at any of the other local hospitals within 30 minutes of notification and to provide relatively intensive intervention “in the field.” Given the availability of this service, it appears that this community has the capacity to provide safe ASC in off-campus sites as well. Transfers for the 3 eligible episodes with deterioration all were completed safely, although transfer times were 3 or more hours in every instance.

The use of the transfer time as a measure for the speed of deterioration assumes that ASC would allow identification of deterioration in eligible episodes as rapidly as occurred in the inpatient setting. The transfer time that should be used to indicate whether transfer from ASC could be safely accomplished will vary with the proximity of the setting to the CCU and with local resources. Very short transfer times would be safe for a short-stay unit located on the campus of a hospital that includes a CCU. A CCU transport service, developed in this community subsequent to study observations, has demonstrated its ability to arrive at any of the other local hospitals within 30 minutes of notification and to provide relatively intensive intervention “in the field.” Given the availability of this service, it appears that this community has the capacity to provide safe ASC in off-campus sites as well. Transfers for the 3 eligible episodes with deterioration all were completed safely, although transfer times were 3 or more hours in every instance.

The use of the transfer time as a measure for the speed of deterioration also assumes that intervention not appropriate in ASC would not be required until arrival in the CCU. As noted, none of the 3 children included in the numerators for risk estimates underwent such a procedure prior to arrival in the CCU.

INSENSITIVITY TO DENOMINATOR ASSUMPTIONS

It should be emphasized that estimates for risk of deterioration remained low across a broad range of estimated values for the number of episodes eligible for ASC.
This lack of sensitivity supports the validity of preliminary estimates for risk of deterioration. Holding the number of adverse events constant at 3, a large change in the estimate of eligible episodes (from 1661 to 3322) causes the risk estimate to decrease from 1.81 to 0.90 per 1000.

Many barriers exist to providing more precise estimates of the number of eligible episodes. For example, eligibility criteria might vary among alternative settings. Development of detailed eligibility criteria would require substantial experience with specific alternative settings. Considerable time and resources would be required to perform precise estimates.

In contrast, risk estimates are relatively sensitive to the number of adverse events (numerator events) observed. If the number of eligible episodes is held constant at 3322, it requires a change of only 3 adverse events (from 3 to 6) to change the risk estimate from 0.90 to 1.81. Because risk estimates are relatively sensitive to the number of adverse events, detailed reviews of clinical records were conducted for hospitalizations in which adverse events were expected to be found, and judgment about the occurrence of adverse events was based on the consensus of 3 experienced clinicians.

DENOMINATOR ASSUMPTIONS

As the denominator for risk estimates, we used discretionary admissions without major chronic problems. The validity of this denominator is based on the assumption that services equivalent to those currently provided for these children on regular inpatient units could be provided in alternative settings. While ensuring that such services are made available promptly is a logistical challenge, the common use of nurse home care18 for technology-dependent patients19-22 as well as patients requiring intravenous infusions9-13 and other forms of “intermediate level” technology (eg, transcutaneous oximetry, home oxygen, peripherally inserted central catheters [PIC lines], and broad-spectrum, long-acting antibiotics that can be given intramuscularly)23 suggests that this is a reasonable assumption. This assumption is further supported by the observation that no episodes were judged ineligible for ASC because required care could not be provided in an alternative setting.

Best- and worst-case estimates for the denominator based on discretionary admissions appear to provide reasonable upper and lower bounds for risk estimates. Be-

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<th>Table 2. Derivation of the Numerator for Estimates of Risk</th>
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<td>Not transferred</td>
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<td>Non-CCU deaths</td>
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<td>Exclusions</td>
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<td>Step 1 exclusions</td>
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<td>Nonmedical admission or no deterioration</td>
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<td>For psychiatric care</td>
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<td>For medical evaluation</td>
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<td>Transferred within the tertiary care facility to the CCU</td>
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<td>Admitted directly from emergency department to CCU</td>
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<td>Died in operating room postoperatively or in surgical or burn intensive care units</td>
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<td>Total step 1 exclusions</td>
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<td>Episodes remaining after step 1 exclusions</td>
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<td>Step 2 exclusions</td>
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<td>Admission for medical problem, child’s condition deteriorated, but not eligible for ASC because of</td>
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<td>Major chronic problem producing limited resilience</td>
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<td>Mandatory admission (physiologic derangement too severe when admitted)</td>
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<td>Total not excluded</td>
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* Based on the total of 11,591 admissions for Monroe County (Rochester), New York children in 1991-1992. Ellipses indicate not applicable.
† Based on 3322 admissions eligible for alternative setting care (ASC), derived as shown in Table 1.
‡ Lower-limit estimate for probability of deterioration among eligible episodes.
cause of the nature of discretionary admissions, the best-case estimate probably underestimates risk. Asthma admissions, the most common discretionary hospitalization, may be used to exemplify this point. Although asthma admissions as a group fit the definition of discretionary, severe acute asthmatic attacks would not be appropriate for ASC. To the extent that severe asthmatic attacks are found among all asthma hospitalizations, asthma admissions overestimate the number of ASC-eligible illness episodes and, in turn, reduce the estimate of risk. Our recent study of asthma hospitalizations in this community found that more-severe asthma attacks, defined as episodes in which the worst oxygen saturation level in the first 24 hours of hospitalization was less than 90%, constituted 49.7% of hospitalized episodes.24

The worst-case estimate probably overestimates risk. The decision to generate the restrictive denominator estimate (used in calculating the worst-case estimate) by halving the inclusive denominator was arbitrary. We expect that more than half of discretionary hospitalizations could be managed entirely with ASC. This view is based on additional findings of our study of asthma hospitalizations,24 and it takes into consideration technological developments that simplify treatment and monitoring for discretionary admissions of intermediate severity. The first 24 hours of hospitalization in the asthma hospitalization study included the period spent in the emergency department. For 45.9% of episodes classified as severe in this study, room-air oxygen saturation levels below 90% were confined to the time spent in the emergency department.24 Thus, the asthma admissions that could safely be cared for in alternative settings probably include many of those classified as severe in this study, and the proportion eligible for ASC probably is substantially greater than 50%. The actual number of illness episodes manageable with ASC can only be determined on the basis of extensive experience with ASC of various types, but for this community it probably lies between the best- and worst-case estimates.

VALIDITY OF NUMERATOR ASSUMPTIONS

Completeness in ascertaining episodes that appear eligible for ASC at presentation, but later deteriorate to the point that ASC would be unsafe, is critical to the validity of findings. Ascertainment should be complete if the assumption is correct that all such episodes are found among non-CCU deaths and transfers. Both clinical experience in this community and study findings support the validity of this assumption. Prudent clinical practice dictates that all children whose condition is deteriorating be transferred to the setting that allows the most intensive monitoring and intervention. In this community, for children with medical problems this setting is the CCU. Our clinical experience is that all severely ill children are admitted to the CCU, and that some children who never require ventilatory or cardiovascular support are sometimes admitted to the CCU as a precautionary measure. The fact that all non-CCU deaths occurred in other intensive care settings (eg, operating room, surgical intensive care unit) suggests the health care system does, indeed, consistently provide care for critically ill children in intensive care settings.

Another assumption is that transfers judged to be ineligible in this study would, in fact, be judged ineligible by clinicians at the time of presentation if ASC were available. Eligibility judgments for this study were made in retrospective medical record reviews by investigators who were aware of transfer events or outcomes. Details of the episodes judged ineligible have been presented to allow the reader to assess the validity of our judgments. The objective of this study was to provide preliminary, “ballpark” estimates of risk. For purposes of meeting this objective, unblinded record reviews were considered adequate. A prospective study would be necessary to guarantee both that they are made on the basis of precisely the same information that is available to providers responsible for patient care and that eligibility judgments are not influenced by awareness of illness outcome. It should also be recognized that a prospective study also has limitations if the eligibility judgments do not actually determine management. Eligibility judgments that actually determine ASC admission might vary from judgments made in hypothetical circumstances. Only a clinical trial with random allocation of eligible illness episodes will determine the actual impact of ASC on adverse outcomes.

IMPLICATIONS

Although limitations in study design have been noted, the probabilities for deterioration and for unsafe deterioration derived from this study are useful as ballpark estimates. This study does not attempt to provide information to allow one to predict which children with acute medical problems will experience deterioration of their condition, but it provides strong evidence that the probability of rapid deterioration is low in children admitted for a discretionary condition who have no major chronic problems. Findings suggest a clinical trial of ASC would experience 1 transfer from ASC to inpatient care for every 600 enrolled episodes, and that adverse outcome would not result if an effective CCU transport service were available. A randomized clinical trial to further evaluate the potential benefits and harms of ASC would be appropriate.

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Corresponding author: Kenneth M. McConnochie, MD, MPH, Department of Pediatrics, Box 777, University of Rochester Medical Center, 601 Elmwood Ave, Rochester, NY 14642 (e-mail: hmim@uhura.rochester.edu).
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