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Validation of the Modified Vesikari Score in Children with Gastroenteritis in 5 U.S. Emergency Departments

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Abstract

Objective—The burden of acute gastroenteritis (AGE) in U.S. children is substantial. Research into outpatient treatment strategies has been hampered by the lack of easily used and validated gastroenteritis severity scales relevant to the populations studied. We sought to evaluate, in a U.S.

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Stephen Freedman participated in the conception and design of the study, analyzed the data, contributed substantially to manuscript revisions and approved the final manuscript as submitted.
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cohort, the reliability, construct validity and generalizability of a gastroenteritis severity scale previously derived in a Canadian population, the Modified Vesikari Score (MVS).

Methods—We conducted a prospective, cohort, clinical observational study of children 3-48 months of age with AGE presenting to 5 U.S. emergency departments (EDs). A baseline MVS score was determined in the ED, and telephone follow-up 14 days after presentation was used to assign the follow-up MVS. We determined reliability using inter-item correlations; construct validity via principal component factor analysis; cross sectional construct validity via correlations with the presence of dehydration, hospitalization and day-care and parental work absenteeism, and generalizability via score distribution among sites.

Results—218/274 patients (80%) were successfully contacted for follow-up. Cronbach's alpha was 0.63 indicating expectedly low internal reliability, because of the multidimensional properties of the MVS. Factor analysis supported the appropriateness of retaining all variables in the score. Disease severity correlated with dehydration (P<0.001), hospitalization (P<0.001), and subsequent day care (P=0.01) and work (P<0.001) absenteeism. The MVS was normally distributed, and scores did not differ between sites.

Conclusion—The MVS effectively measures global severity of disease and performs similarly in varying populations within the U.S. health care system. Its characteristics support its use in multi-site outpatient clinical trials.

Keywords

Gastroenteritis; Severity Scale; Emergency Department; Validity; Children

Introduction

Acute gastroenteritis (AGE) is a leading cause of death worldwide among children less than 5 years of age.[1] Although the rotavirus vaccine has been routinely adminsitered to children in the United States (U.S.) since 2006,[2] the burden of acute gastroenteritis (AGE) on children, their families and society continues to be substantial.[3-5] While treatment algorithms guiding the management of children with vomiting and diarrhea in the acute setting focus on the clinical assessment of dehydration severity,[6,7] in developed countries, where most children with AGE return home after their assessment in emergency facilities, there is an increasing focus on morbidity and costs associated with symptoms following discharge.[8-11]

Research into therapies has been hampered by the lack of easily used and validated, gastroenteritis severity scales in outpatient populations, because the success of proposed interventions cannot be assessed.[12-17] Although several scales integrate all gastroenteritis symptoms into a composite disease severity score, most are limited by the need for in-person follow up assessments, which renders them impractical for outpatient trials.[18-21] Over the past decade, a 20-point score often termed the “Vesikari Scale” has been widely adopted.[13,21-24]. A recent study prospectively evaluated 455 children in 11 Canadian pediatric emergency departments (ED) using modified version (“Modified Vesikari Score (MVS)) which did not obligate repeat visual assessment.[13] This scale effectively measured overall disease severity in children with AGE in that population.[13] However, the Canadian and U.S. health care systems differ significantly in coverage and access to care opportunities[25-28] and it is not clear whether a multidimensional global severity score such as the MVS, that includes healthcare utilization, would perform as well in the U.S. ED population. Hence, we evaluated the reliability, construct validity and generalizability of the MVS by studying its characteristics in a network of pediatric emergency departments in the U.S.

Materials and Methods

Study Setting & Design

We conducted a prospective cohort observational study between January and April 2012, in the EDs of 5 hospitals located in the Northeast (New York, Washington, D.C.) and Central (Missouri, Michigan, Illinois) U.S. The participating EDs are each in tertiary care pediatric centers with annual visit volumes between 55,000 and 93,000.

Children between 91 days and 48 months of age who presented to a participating ED with fewer than 7 days of AGE symptoms were screened for eligibility. Children with significant chronic gastrointestinal problems (e.g. short gut syndrome, inflammatory bowel disease) were excluded, because diarrhea in such children is less likely to be caused by an acute intestinal infection. We also excluded children with bilious vomiting, those who were previously enrolled in this study, and those for whom reliable telephone follow-up was highly unlikely 14 days after discharge (e.g. travel plans, language barrier, or lack of telephone).

Enrollment was based on the availability of trained research assistants in the EDs of the participating institutions. This resource varied between 20 and 60 hours per week across the collaborating sites. When present, research assistants screened and approached potentially eligible patients after triage, sought written informed consent, and, if provided, administered a standardized survey form to the caregivers to obtain information pertinent to the subjects' gastroenteritis symptoms. This information was used to calculate a baseline MVS, i.e. at ED presentation. In addition a baseline dehydration scale score was assigned by the treating physician, using a validated 4-item clinical dehydration scale, which consists of assessments of general appearance, and mucous membranes, and the presence of sunken eyes and tears.[29]

Follow up information was obtained via a separate interview administered by a research assistant or by the site investigator via telephone two weeks after the index visit. To enhance the accuracy of recall, caregivers were given a diary to record their child's symptoms on a daily basis. Information was collected regarding duration of symptoms, subsequent visits to health care providers, and hospitalizations attributable to AGE. This information was used to calculate the follow-up MVS. We also recorded diarrhea-related absences from day care and work by patients and parent, respectively. Caregivers who completed the telephone follow-up survey were sent a $10 check or gift card to acknowledge their time contribution. A chart review was performed to confirm caregiver report regarding revisits. The Institutional Review Boards of all participating institutions approved the study and written informed consent was obtained from all study participants.

Definitions

The MVS contains seven equally weighted variables (Table 1).[13] To maintain harmony with the cut-points employed by the original Vesikari Scale,[21-24] we defined scores from of 0-8, 9-10, and ≥ 11 as reflecting mild, moderate, and severe illness, respectively. AGE was defined by diarrhea (i.e. ≥ 3 watery stools in the preceding 24-hour period), for fewer than 7 days. “Watery” was defined as stool taking the shape of a container. Fever was defined as a temperature of 38.0°C documented by any method by any caregiver or professional. Because children were enrolled before physician assessment, only children with a final diagnosis assigned by the responsible ED provider consistent with an acute intestinal infectious process were included in the analysis. Scores assigned to future health care use and treatments provided included only the outcomes that occurred after the initial provider encounter.

Analysis

We analyzed reliability, construct validity and generalizability of the MVS according to the following methods and considerations.

Reliability—In keeping with prior research[13] MVS reliability was determined using inter-item correlations. Cronbach's alpha was used to measure the degree to which the items included in the score were related to the same construct as it generally increases as the inter-correlations among test items increase. Thus, it provides an estimate of the internal consistency of scale scores.[30]

Construct Validity—We performed principal component factor analysis which measures interdependence between variables, identifies possible redundancies between scale items and indicates the number of constructs that the scale measures.[31] This is achieved by developing a correlation matrix to assess the correlations between all possible pairs of variables and then calculating eigenvalues that represent the total variance explained by each factor.[32] We assessed cross sectional construct validity by calculating a two-tailed Spearman's correlation coefficient between the MVS score severity category at presentation and clinical factors of general importance to clinicians such as dehydration and admission to hospital). The follow-up MVS score severity category was correlated with other measures of the impact of the disease on the family (e.g. missed days of day care by the child and work by the caregiver).

Generalizability—we assessed score distribution and compared the mean scores between participating sites using ANOVA.

Results

Of the 282 enrolled patients, eight had diagnoses other than AGE (3%) and were excluded from further analysis. Participant mean age was 19 months (SD 11 months), and the median duration of symptoms before presentation was 3 (IQR: 2, 4) days. While only 24% of patients had any degree of dehydration (Table 2), 82% had moderate or severe disease according to the MVS at presentation. The rate of follow up of enrolled participants was 80% (218/274) with success varying significantly between sites (range: 52 – 96%; $P < 0.001$). We were able to calculate the MVS for 100% of patients that completed follow-up.

Reliability and Construct Validity

Item total correlations were all > 0.2 and the Cronbach's alpha was 0.63 indicating low internal reliability.[33] Factor analysis supported the appropriateness of retaining all factors in the score (see table 3 for individual test results and interpretation; Figure 1 for scree plot of eigenvalues). The presentation MVS score category correlated with the presence of any degree of dehydration ($\rho=0.24$; $P<0.001$) and the likelihood of hospitalization ($\rho=0.23$; $P<0.001$) (Figure 2). The severity of disease following discharge (follow-up MVS score category) was correlated with post-visit day care ($\rho=0.34$; $P = 0.01$) and work ($\rho=0.49$; $P < 0.001$) absenteeism (Figure 3).

Generalizability

The MVS was normally distributed, with a mean of 6.4, a SD of 3.1, skewness of 0.36 (SE 0.16) and kurtosis of −0.21 (SE 0.33) (Figure 4). The overall distribution of the MVS between severity categories following discharge was: mild – 76%; moderate – 14%; and severe – 10%. Further, the variation between participating institutions was not statistically different ($P = 0.82$).

Discussion

We sought to determine if the MVS is a valid tool when applied to a population within a health system that is structured differently from the one in which it was developed. Such confirmation is important, because the validity of a clinical tool varies according to its purpose as well as the population and setting in which it is applied.[34] This is particularly important for a disorder such as AGE, which rarely requires hospitalization, and for which the venue of medical evaluation could vary according to access to, and payment incentives or disincentives for care. Our study, which is the first to evaluate the MVS in a U.S. cohort of ED children with AGE, found that the MVS was reliable, valid and generalizable within a population that includes a broad geographic and demographic sample of children. Combined with previous data from Canada, it appears that the MVS is suitable for use in different healthcare systems and populations.

The most fundamental consideration faced by researchers when selecting a patient-based outcome measure is to choose a metric that is most appropriate to the aims of the particular trial. This determination is based on the fit between the specific objectives of the trial and the content of the instrument. Over the past decade, use of the Vesikari Scale in AGE research has become commonplace.[13,22-24] However, because this score relies on the variable of “percent dehydration”, its use in the outpatient context, where follow-up is often not feasible, is a significant and understated limitation. Even when in-person follow-up is achieved, percent dehydration is difficult to assess, especially in the low to moderate range of volume loss commonly seen in high income countries among children with AGE.[35-38] Furthermore, despite the broad acceptance of the Vesikari Scale by the medical community, its reliability and validity have not been tested. Our current work in the U.S. extends a prior Canadian study that demonstrated the reliability, validity and feasibility of using the MVS in children in outpatient settings.

Some of our data warrant elaboration. Reliability can be divided into the two key constructs of internal consistency and reproducibility. These properties, however, are not fixed but, instead, depend on the context of their use and the population studied.[30] Internal consistency is most commonly evaluated via Cronbach's alpha calculation, which, in our cohort, was slightly higher than previously reported. Nonetheless this variable remained low (0.63).[33] The reason for this low value in our study context is that the Cronbach's alpha estimates the average level of agreement and homogeneity of all the items in the scale. The rationale for this is an underlying assumption of unidimensionality where more than one scale item measures a dimension or construct. When the unidimensionality assumption is violated, reliability might be underestimated.[33,39] Thus, for the MVS, it is not surprising to find an overall low Cronbach's alpha in both studies because the cardinal signs and symptoms of AGE (i.e. diarrhea, vomiting and fever) are heterogeneous and do not always correlate in all patients (i.e. one patient may have mostly vomiting, while another one may have mostly diarrhea with or without fever). Because the goal of the MVS is to integrate all multidimensional symptoms into a composite score that can be used with all patients with any combination of signs and symptoms, internal consistency is sacrificed in favor of construct validity and generalizability. In fact, in both the Canadian and U.S. studies, factor analysis supported retaining all items in the scale, and the distribution of the score did not differ between sites or populations.

Reproducibility, which evaluates the ability of an instrument to yield the same results repeatedly, is another component of reliability. It is most commonly applied to laboratory tests or examination findings and assessed by calculating test–retest reliability by different assessors. We did not seek such data in our study because all variables were historical in nature. In contrast, validity assesses the extent to which a scale measures what it claims to

measure. Face, content, and criterion validity were not determined in the current study, because we did not test a specific survey or questionnaire. Our data were obtained via bedside or telephone interviews, which allow clinicians and interviewers to repeat or rephrase questions until they are satisfied that they are well understood and that the answers are related to the question asked. However, we did address the issue of construct validity by examining possible redundancies between score items and the appropriateness of retaining all items of the score. Finally we assessed cross sectional construct validity by quantifying the relationships between the MVS and a set of *a priori* clinically and family relevant outcomes, namely the presence of dehydration, hospitalization and day care and parental work absenteeism. We detected a statistically significant correlation between the MVS and these important outcomes.

There were several limitations to the MVS. Although the score was felt to be easy to apply, there were considerable differences in follow-up rates between the sites. This variance is probably related to research assistant and site investigator availability which varied by site as did their degree of engagement. Indeed, the only site with a full-time, dedicated research assistant had the highest follow-up rate. Alternative strategies to improve follow up rates in future studies should include greater dedicated research assistant time, more frequent and scheduled calling (e.g. daily until symptoms resolve) and/or the use of electronic media and reminders to gather the information. This is particularly important in studies of AGE treatment, where value might relate to multiple post-discharge actions and not merely to the easily quantifiable clinical variables of readmission rates and days to first formed stool.

Conclusion

We evaluated and validated the MVS in U.S. ED children 3-48 months of age with AGE. Our findings confirm that the MVS score performs similarly in a different population within a different health care system from the derivation study. Its characteristics support its use in future trials in such settings.

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Abbreviations

AGE	Acute gastroenteritis
ED	Emergency Department
D	Days
Hr	Hours
IQR	Interquartile range
Mo	Months
MVS	Modified Vesikari Score
SD	Standard deviation
SE	Standard error
U.S.	United States

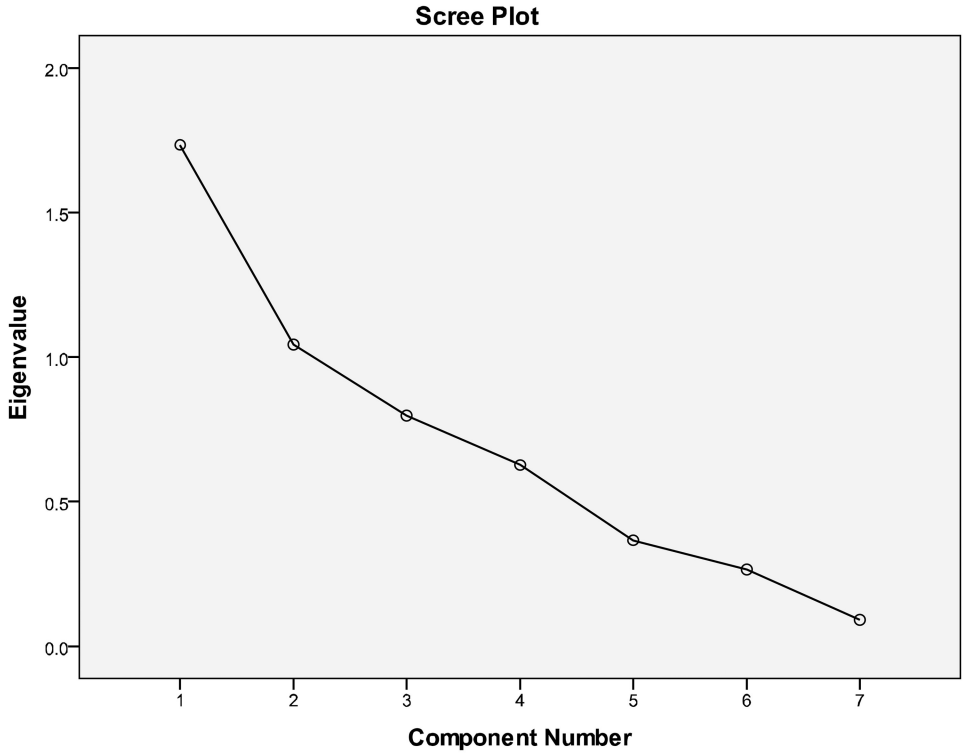

Figure 1. Scree Plot of eigenvalues versus component number

Scree plot of eigenvalues (y-axis) versus component number (x-axis). The plot demosntrates eigenvalues versus the number of factors, in order of extraction.

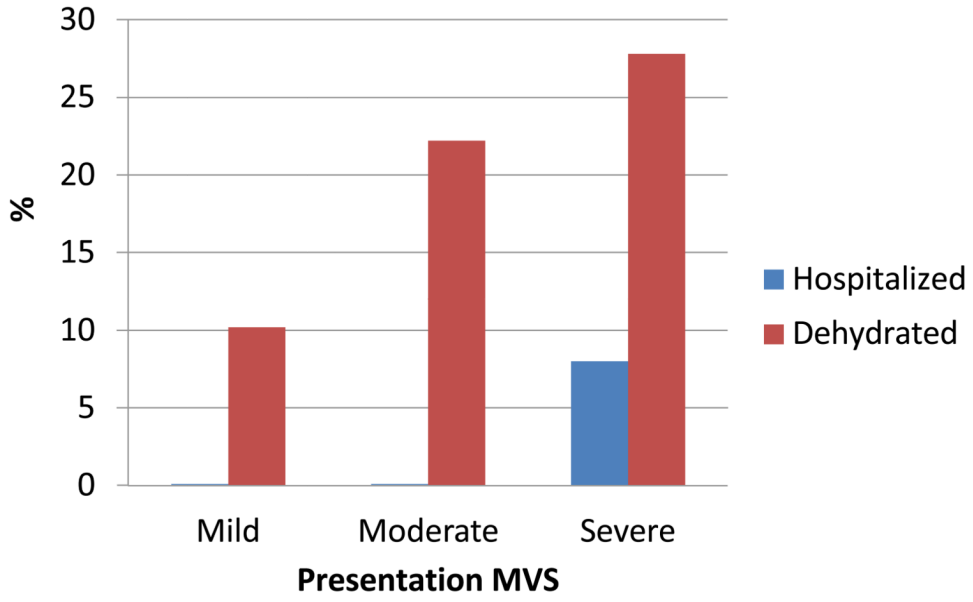

Figure 2. Dehydration and Hospitalization by presentation MVS score severity

Association between presentation MVS and dehydration and hospitalization. Disease severity at presentation, as determined with the MVS (mild, 0–8; moderate 9-10; severe ≥11), is presented on the x-axis and the proportion of children within each disease severity category in our cohort who experienced any degree of dehydration and hospitalization on the y-axis. MVS, Modified Vesikari Scale.

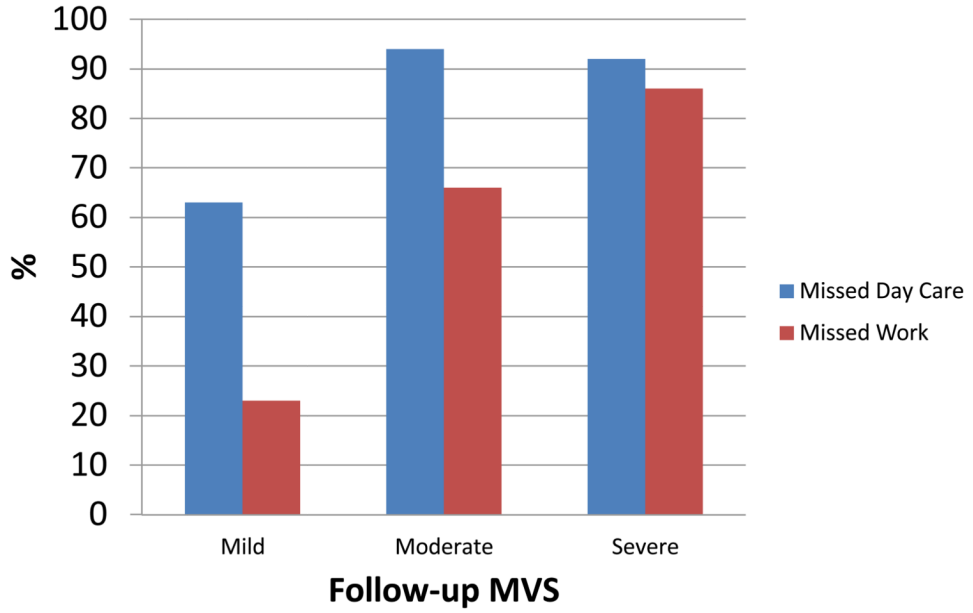

Figure 3. Missed Daycare and Work by Follow-up MVS score severity

Association between MVS and absenteeism from day care or work. Disease severity, as determined with the MVS (mild, 0–8; moderate 9-10; severe ≥11), is presented on the x-axis and the proportion of children within each disease severity category in our cohort who experienced the outcomes (day care and work absenteeism) on the y-axis. MVS, Modified Vesikari Scale.

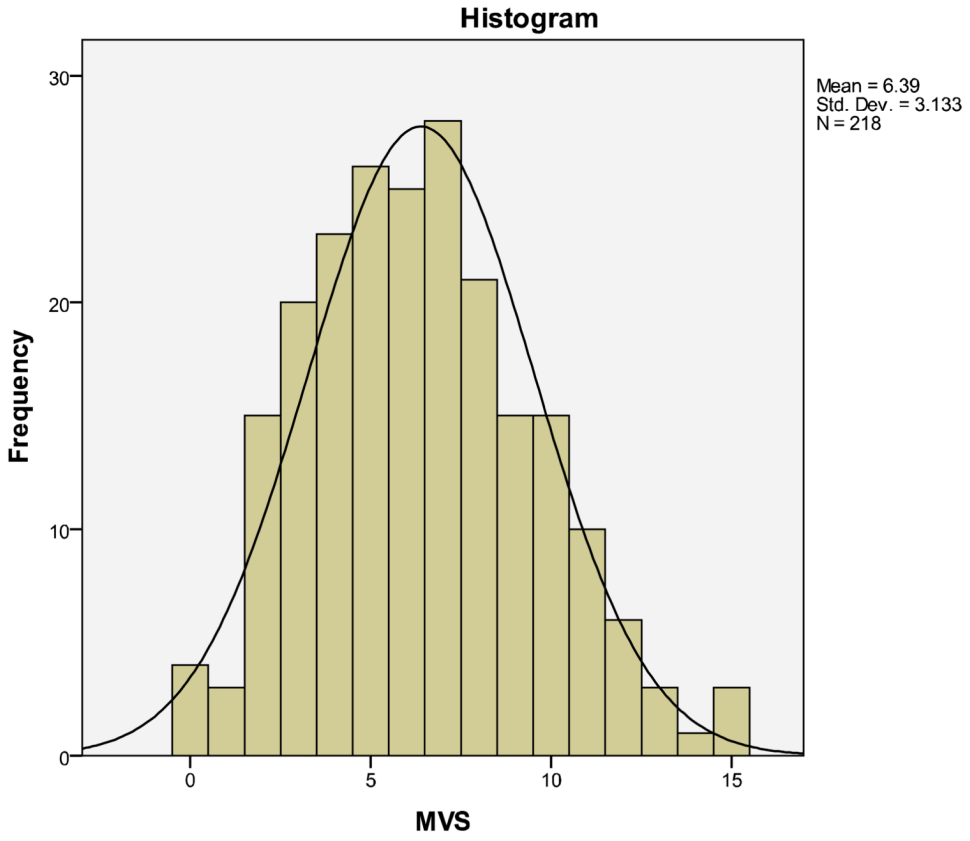

Figure 4. Follow-up MVS distribution

Histogram of MVS distribution, with standard normal distribution shown. The y-axis (frequency) indicates the number of children experiencing each outcome (i.e. total MVS). MVS, Modified Vesikari Scale.

Table 1

Modified Vesikari Score

Points	**0**	**1**	**2**	**3**
Diarrhea duration (hr)	0	1-96	97-120	≥ 121
Max no. of diarrheal stools/24 hr period (in the course of the disease)	0	1-3	4-5	≥ 6
Vomiting duration (hr)	0	1-24	25-48	≥ 49
Max no. of vomiting episodes/24 hr period (in the course of the disease)	0	1	2-4	≥ 5
Max recorded fever	< 37.0°C	37.1-38.4 °C	38.5-38.9°C	≥ 39.0°C
Future healthcare visit	0	-	Primary Care	Emergency Dept.
Treatment	None	IV Rehydration	Hospitalization	-

Table 2

Demographic and Clinical Characteristics of Children with Acute Gastroenteritis (N = 274).

Characteristic	Cohort Value
Age at entry, mean (SD), mo	18.6 (11.2)
3.0 – < 24, n (%)	189 (69)
24.0 – < 48, n (%)	85 (31)
Male gender, n (%)	136 (50)
Race, n (%)	
White	91 (33)
African American	75 (27)
Other	22 (8)
Not provided	86 (31)
Ethnicity, n (%)	
Hispanic	108 (40)
Non- Hispanic	154 (56)
Not provided	11 (4)
Number of days with diarrhea, median (IQR)	3 (2,4)
Maximum # of diarrheal episodes in 24h period, median (IQR)	5 (4, 8)
Number of days with vomiting, median (IQR)	1 (1, 3)
Maximum # vomiting episodes in 24h period, median (IQR)[†]	3 (1, 5)
Fever in previous 48h, n (%)[‡]	115 (42)
Difficulty feeding, n (%)[*]	188 (69)
Decreased urine output, n (%)[*]	168 (61)
Triage heart rate, mean (SD)	132 (18)
Triage temperature °C, mean (SD)	37.3 (1.0)
Triage respiratory rate, mean (SD)	29.2 (7.1)
Dehydration score,[29] median (IQR)	0 (0-0)
No dehydration (0), n (%)	210 (77)
Mild (1 – 4), n (%)	62 (23)
Moderate – Severe (5 – 8), n (%)	2 (1)
Baseline MVS[$], mean (SD)	11.0 (2.5)
Mild (0 – 9), n (%)	49 (18)
Moderate (9 – 11), n (%)	63 (23)

Characteristic	Cohort Value
Severe (11 – 20), n (%)	162 (59)

† Numbers of vomiting episodes in the preceding 24 hours includes all children, even those who had no episodes in the preceding 24 hour period.

‡ Fever was defined as a documented temperature of > 38.0°C measured by any method.

* Questions regarding difficulty feeding and decreased urine output were asked as is routine during clinical history taking and responses were left to the caregiver's interpretation.

$ MVS at ED presentation

Table 3

Results of Factor Analysis

Test	Result	Interpretation
Matrix determinant	0.31	No colinearity
Kaiser-Meyer-Olkin measure Bartlett's test of sphericity	0.59(P<0.001)	Relationships between individual variables and the data are acceptable for factor analysis
Scree plot eigen values (Figure 1)	1 value above 1 (1.7), no plateau or tailing off	Appropriate to retain all factors in the score