

# **Pretreatment Variables for the Innovative Application of Urine Alarm Treatment for Young Children in Fourteen Outpatient Clinics in Israel**

Bettina Shapira  
Northcentral University

Pamela K.S. Patrick  
Capella University

The influence of specific pretreatment variables (i.e., age, gender, birth order, number of children in the family, and family history of enuresis) on outpatient urine alarm treatment outcomes was examined. A total of 186 Israeli children between the ages of 4 to 7 participated in the study, and of those, 55 children were 4 years old. The entire sample was used to test the age-related pretreated variable, and all other pretreatment variables were solely analyzed using the sample of 4-year-old children at the time of treatment. The data were derived from two different sources: (a) treatment files from a clinical psychologist, and (b) a six question telephone survey. Statistical analysis revealed evidence that family history is a positive predictor of urine treatment outcomes in young children. For young children with a family history of bedwetting, 71.9% were dry post-treatment, while only 43.5% of young children without a family history of bedwetting were dry post-treatment. Other statistical analysis showed no evidence ( $p > .05$ ) of pretreatment variables' (i.e., age, gender, birth-order, and number of children in the family) influence on urine alarm treatment outcomes in young children. The findings indicate that, in young children, a family history of bedwetting is a positive predictor for urine alarm treatment outcomes. Pediatricians and other pediatric health practitioners are encouraged to treat young children with a family history of bedwetting with a urine alarm treatment approach.

**Key Words:** bedwetting, alarm treatment, pre-treatment variables, young bedwetting children

Enuresis, more familiarly referred to as bedwetting, is one of the most widespread (Nappo et al., 2002; Rogers, 2002) and chronic childhood disorders affecting 7% to 22 % children by age seven (Butler & Holland, 2000). Boys are more affected by this disorder than girls of the same age. The cause of enuresis is variously understood as being multifaceted and multi-factorial (El-Radhi, 2005; Thiedke, 2003). Sources of causation for enuresis development include a low level of the antidiuretic hormone (ADH) vasopressin (Butler, 1994), reduction in functional bladder capacity (Kawauchi et al., 2003; Yeung, Chiu, & Sit, 1999), lack of sleep arousal (Neveus, 2003; Wolfish, 1999),

genetic factors (Eiberg, Berendt, & Mohr, 1995; Von Gontard, Hollmann, Rittig, & Lehmkuhl, 1997; Von Gontard, Eiberg, Hollmann, Rittig, & Lehmkuhl, 1998; Von Gontard, Eiberg, Hollmann, Rittig, & Lehmkuhl, 1999), delayed maturation (Fergusson, Horwood, & Shannon, 1986; Fritz et al., 2004), and psychological factors (Hagglof, Andren, Bergstrom, Marklund, & Wendelius, 1998; Theunis, Van Hoecke, Paesbrugge, Hoebeke, & Vander Walle, 2002).

Several treatment options are available for addressing bedwetting symptoms, including pharmacology, alternative therapies, and behavioral interventions with or without using a urine alarm system. To date, the urine alarm system remains the superior treatment modality for bedwetting symptoms (Boris, & Dalton, 2004; Houts, Berman, & Abramson, 1994) with successful outcome rates ranging between 65%-75% (Butler & Glasson, 2005). In the past, different outcome predicting pretreatment (OPP) variables for urine alarm treatment have been established (e.g., severity of wetting episodes, concurrent daytime wetting episodes, family stress, and lack of motivation) (Butler & Robinson, 2002). OPP variables can be instrumental in identifying existing conditions that either support or hinder urine alarm treatment (Moffat & Cheang, 1995), thus making OPP variables valuable from a clinical as well as a research perspective.

Earlier studies have been conducted on OPP variables (Butler, Redfern, & Forsythe, 1990; Butler & Robinson, 2002; Devlin & O’Cathain, 1990; Dische, Yule, Corbett, & Hand, 1983; Fielding, 1985). Comparing the results of these studies is complex because most studies vary significantly in outcome measures and age of study participants. Overall, in the cited studies, the age of the study participants varied from age 4.8 to age 17 and outcome measures to establish dryness varied from 14 consecutive nights to 6 weeks of consecutive dryness, with most studies defining initial treatment success at 14 consecutive dry nights (Butler et al., 1990; Butler & Robinson, 2002; Fielding, 1985), while other studies define treatment success as 21 consecutive dry nights during the treatment followed by 21 consecutive nights post treatment (Dische et al., 1983), or 42 consecutive dry nights (Devlin & O’Cathain, 1990).

In the 1980s, Dische and associates (1983) and Fielding (1985) researched different variables associated with treatment outcome for alarm treatment. Dische’s et al. (1983) study included 113 children ranging in age from 4.8 to 13.2 years. Pretreatment factors related to treatment outcome included age, gender, birth order, family size, social class, child’s behavior rated by a parent, child’s behavior rated by a teacher, previous treatment for enuresis, secondary or primary enuresis, presence of urinary infection, diurnal wetting episodes, encopresis, family difficulties, unsatisfactory housing conditions, and severe financial hardship. The results of the study indicated only two OPP variables—unsatisfactory housing conditions and family difficulties—had an adverse effect on initial treatment success, while relapse and long term treatment outcomes were adversely influenced by deviant behavior scores on the teacher rating scale and family difficulties. All other tested pretreatment variables were found unrelated to treatment outcome.

Fielding (1985) studied pretreatment variables associated with enuresis treatment failure. The study accepted 52 children ranging in age from 5 to 17 years. Thirty different pretreatment variables, including variables deriving from socio-demographic data, enuresis history, family history of enuresis, social background, and behavioral problems, were researched. The findings indicated that only three variables had an

adverse effect on initial treatment outcome, including frequency of micturition, urgency of micturition, and a previous experience with enuresis alarm treatment.

Butler et al. (1990) investigated urine alarm treatment outcomes in 55 children ranging in age from 6.9 to 14.7 years. The researchers studied various pretreatment variables, including personal data, mother's tolerance, willingness of the child to change, resistance to change, family reaction, and secrecy. Findings indicated that positive treatment outcome was associated with the child understanding enuresis psychologically and showing no resistance to change, while treatment success declined where there was evidence of resistance to change. Devlin and O'Cathain (1990) analyzed predicting variables for urine alarm treatment in 96 children ranging in age from age 6 to 17 years. For this study, four different categories of pretreatment variables were used (socio-demographic data, history of enuresis, data about possible physical/psychiatric disorders and family stress were analyzed), and findings indicated that three stress related pretreatment variables (i.e., family stress, little or no distress of the child about the bedwetting, and developmental delay in the child) had a negative influence on urine alarm treatment outcome.

A third instructive study by Butler and Robinson (2002) analyzed pretreatment variables for enuresis alarm treatment in 66 children ranging in age from 6 to 16 years. Pretreatment variables included age, gender, severity of wetting, and functional bladder capacity. In this study, only functional bladder capacity was identified as a negative predictor for enuresis alarm treatment outcome.

In the reviewed studies, specific pretreatment variables, including age (Butler & Robinson, 2002; Butler et al., 1990; Dische et al., 1983; Devlin & O'Cathain, 1990; Fielding, 1985), gender (Butler & Robinson, 2002; Butler et al., 1990; Dische et al., 1983; Devlin & O'Cathain, 1990; Fielding, 1985), birth order (Dische et al., 1983; Devlin & O'Cathain, 1990; Fielding, 1985), family size (Dische et al., 1983, Devlin & O'Cathain, 1990), or family history (Fielding, 1985) were found to be unrelated to enuresis alarm treatment outcomes. Based on this inconclusive history of enuresis research, questions arise regarding the identification of urine alarm pretreatment variables especially for younger children. Research that provides a degree of clarity on the nature of enuresis pretreatment variables can inform key aspects of the intervention process including family settings, parent understanding of the nature of enuresis, parent and parent-child education regarding the treatment process that is developmentally appropriate. It also can provide pediatricians and other pediatric health practitioners with tools to better prepare families for the treatment regiment and help set appropriate expectations for treatment outcomes.

### **Focus of the Study**

This study focused on the analysis of interactions of five different OPP variables (i.e., gender, birth order, numbers of siblings in a family, family history of bedwetting, and age) and urine alarm treatment for 4-year-old children. While the OPP variables gender, birth-order, numbers of siblings in a family, and family history of bedwetting were solely analyzed on the study sample of children age four, the OPP variable age was analyzed utilizing the entire study sample including children age four to seven.

## Method

### *Participants*

In this study, 400 bedwetting children, aged 4-7 years, and treated by a clinical psychologist in Israel, were randomly chosen to be included in the study sample. These children were randomly selected from a population pool of 948 bedwetting children under treatment at fourteen urine alarm treatment offices in Israel. Inclusion criteria for participation in the study was determined by the following criteria: each child started treatment between June 1, 2003 and May 31, 2004; the child was receiving or had received urine alarm treatment only (i.e., no additional medication was prescribed) during the initial treatment session; the child was at least 4 years of age and not older than 7 years of age; the child was diagnosed with enuresis or the child was 4 years of age and met the criteria for enuresis described in the *Diagnostic and Statistical Manual of Mental Disorders, (DSM-IV-TR; American Psychiatric Association [APA], 2000)* with the exception of the age limit.

Of the 400 potential study participants only 265 could be contacted and of those 50 potential participants refused to participate in the study and 29 potential participants were excluded from the study for various reasons. Ultimately, the study sample was comprised of 186 participants, with 112 male participants and 74 female participants.

### *Treatment*

All children received urine alarm treatment from the same clinical psychologist in one of the fourteen bedwetting clinics in Israel. Each child participated in a combined assessment and treatment session. The initial session included diagnosis, a short and general education about the disorder, introduction to treatment, demonstration of the urine alarm device, explanation of the use of a daily progress chart, and discussion of arrangements for follow up. Follow-up treatment was made available in a face-to face format, via telephone consultation, or review and response to fax, letter, or e-mail inquires directed to the treating clinical psychologist. During follow-up sessions, progress was evaluated with the use of the daily progress chart combined with information from the child and the attending adult. When necessary, a multiple waking exercise was introduced with those children having difficulties waking up to the alarm. The treatment was considered to be successfully completed after the achievement of 21 consecutive dry nights. Parents were instructed to monitor the child for relapse, and when relapse occurred, to return to the office and restart the urine alarm treatment under clinical supervision.

### *Procedure*

Data for this study originated from two sources: the treatment files of the clinical psychologist and from a telephone survey of the clients (i.e., parents of the children receiving treatment). Treatment file data was generated by the clinical psychologist who recorded the information during the initial assessment and treatment session. Demographic data was also derived from this source and included: age of the child, gender, birth order, the family history of bedwetting symptoms [mother, father, sibling, uncle, aunt, grandparent having suffered (or are currently suffering) from bedwetting symptoms], and information about prescribed medication (e.g., Minirine or Elatrolet) used during the urine alarm treatment.

The second data source was derived using a telephone survey methodology. A survey was constructed that consisted of six questions inquiring about the number of

wetting episodes during the last month, supplementary enuresis medication, and possible additional enuresis treatment.

The telephone survey items were reviewed and subsequently revised by three clinical psychologists experienced in treating enuretic children with the urine alarm method in Israel to ensure the content validity of the instrument (Sproull, 2002). In addition, a pilot telephone survey was conducted using the survey instrument with 20 children to ensure that the text of the survey reflected content validity (i.e., it was easy to understand and used simple to follow questions). Following analysis of the pilot study data and completion of survey instrument revision, the study was implemented in spring of 2005.

The telephone survey was conducted by an agency specialized in data collection, and the data collection was supervised by the treating clinical psychologist. The interviewers made a maximum of four attempts to reach a parent of each study subject. Data derived from the telephone survey included: treatment success (defined by less than three wetting episodes during the previous month), treatment failure (defined by three or more wetting episodes during the previous month), identification of medication taken to control bedwetting symptoms during urine alarm treatment, and whether the child received additional bedwetting treatment after the urine alarm treatment.

### ***Data Analysis***

Descriptive statistics were employed for analyzing the study population. One-way analysis of variance [ANOVA] was used to ascertain the success rate of the urine alarm treatment for the total study population. The data of the 4-year-olds was then extracted from the data pool, and an analysis of pretreatment variables for this population was undertaken using logistic regression (birth order, number of children in a family, genetic predisposition) to examine a possible relationship between each of these variables and treatment outcome. Further, age as a pretreatment variable was examined by comparing the relationship of treatment outcomes in children ages 4 to 7 using a chi-square test of independence and an analysis of variance.

## **Results**

The pool of study participants totaled 186. This total was derived from an initial pool of 400 children randomly chosen for the study from the total population of 948 children treated for enuresis. Children taking medication to control bedwetting symptoms such as Minirine, Elatrolet, or any other medication in support of the urine alarm treatment were excluded from the study. From the 400 randomly chosen study participants, 135 could not be contacted via telephone and therefore were excluded from the study. A total of 265 children were contacted via the telephone survey. Fifty declined participation, while 215 participants consented to participate. Of this derived number of 215 participants, 29 were excluded for specific reasons (i.e., 21 were taking additional medication; 4 did not complete the questions; 2 did not start treatment; 2 were adopted children).

### ***Sample Description***

The mean age of the study participants ( $N = 186$ ) was 5.5 years ( $M = 5.45$ ,  $SD = 1.15$ ) with an age range from age 4 to age 7. Overall, 112 boys and 74 girls participated in the study, representing a male/female percentage ratio of 60/40. Participating children were largely first or second born children with 52.2% first born ( $n = 97$ ), 31.2% second

born ( $n = 58$ ), 11.3% third born ( $n = 21$ ), 2.7% fourth born ( $n = 4$ ) and 2.7% fifth born ( $n = 4$ ). The children had an average of 1.5 siblings with 9.7 % ( $n = 18$ ) of participating children having no siblings, 49.5% ( $n = 92$ ) of the children having one sibling, 26.5% ( $n = 49$ ) of the children having two siblings, 7.5% ( $n = 14$ ) of the children having three siblings, 6.5% ( $n = 12$ ) of the children having four siblings, and 0.5% ( $n = 1$ ) of the children having seven siblings. Children from families with a history of bedwetting symptoms totaled 123 (67%). Post treatment, 64.5% ( $n = 120$ ) of the participants achieved dryness, defined as not more than 0 to 2 wetting incidents in the last month, and 35.5% ( $n = 66$ ) participants wet their beds three or more times in a month, thus not achieving dryness.

#### ***Subset sample description of 4-year-olds***

Fifty-five children age four were included for the analysis of pretreatment variables. Of those, 52% ( $n = 29$ ) were male and 47.3% ( $n = 26$ ) female. With reference to birth order, the majority of study participants in the group of 4-year-olds were first born (61.8%,  $n = 34$ ), 29.1% ( $n = 16$ ) second born children, 7.3% ( $n = 4$ ) third born children, and 1.8% ( $n = 1$ ) a fourth born child. Most children (56.4%,  $n = 31$ ) had one sibling, while 16.3% ( $n = 9$ ) had no sibling(s), 18.2% ( $n = 10$ ) had two siblings, 7.3% ( $n = 4$ ) had three siblings, and one study participant (1.8%,  $n = 1$ ) had four siblings. Of the children in this age group, 58.2% ( $n = 32$ ) had a family history of bedwetting, and 41.8% ( $n = 23$ ) reported no family history. Children achieving dryness included 60% or 33 children in this subset of 4 year-olds, while 40% ( $n = 22$ ) children presented with bedwetting symptoms post treatment.

#### ***Variables associated with treatment outcome in 4-year-olds***

Gender was found to have no influence on treatment outcome in children age four receiving enuresis alarm treatment. The group of 4-year-olds consisted of 52.7% ( $n = 29$ ) male participants and 47.3% ( $n = 26$ ) female participants. Post treatment, 34.5% ( $n = 19$ ) boys and 25.5% ( $n = 14$ ) girls achieved dryness, while 18.2% ( $n = 10$ ) of the boys and 21.8% ( $n = 12$ ) of the girls still suffered from bedwetting. Logistical regression analysis was conducted with the treatment outcome as the dependent variable and gender as the independent variable. The logistic regression slope coefficient for gender was negative ( $B = -.488$ ) indicating that girls were less likely to be dry post-treatment. However, results of the Wald statistic = .77,  $p = .38$  showed that this slope coefficient was not statistically significant.

Birth order is not a predicting variable for treatment outcome in 4-year-olds. Logistical regression analysis was conducted with the treatment outcome as the dependent variable and birth order as the independent variable. This group of 4-year-olds consisted of 61.8% ( $n = 34$ ) first born children, 29.1% ( $n = 16$ ) second born children, 7.3% ( $n = 4$ ) third born children and 1.8% ( $n = 1$ ) fourth born children. Of the first born children post treatment, 40% ( $n = 22$ ) achieved dryness, while 21.8% ( $n = 12$ ) continued to suffer from bedwetting. In the group of second born children, 16.4% ( $N = 9$ ) achieved dryness post treatment, while 12.7% ( $n = 7$ ) persisted with bedwetting symptoms. In the group of third born children, 3.7% ( $n = 2$ ) achieved dryness post treatment, while 3.6% ( $n = 2$ ) did not. In the last group of fourth born children, none ( $n = 0$ ) achieved dryness post treatment, while 1.8% ( $N = 1$ ) still suffered from bedwetting symptoms. Overall, enuresis alarm treatment was most successful in first born children. The logistic regression analysis indicted a negative ( $B = -.478$ ) logistic regression slope coefficient for birth order in

children age 4, suggesting that latter-born children were less likely to be dry post treatment. However, as indicated by the results of the Wald statistic = 1.48,  $p = .23$ , the slope coefficient was not statistically significant.

The number of siblings in a family is unrelated to treatment outcome in children age 4. The group of 4-year-olds consisted of 16.4% ( $n = 9$ ) children without siblings, 56.3% ( $n = 31$ ) with one sibling, 18.2% ( $n = 10$ ) with two siblings, 7.3% ( $n = 4$ ) with three siblings, and 1.8% ( $n = 1$ ) with one sibling. The logistic regression analysis indicted a negative ( $B = -.322$ ) logistic regression slope coefficient, suggesting that children with the least number of siblings were more likely to be dry post treatment compared to children with two or more siblings. However, the Wald-statistic = 1.01,  $p = .23$  indicated that the coefficient slope coefficient was not statistically significant.

Family history of enuresis is a predictor for positive enuresis alarm treatment in children age 4. The group of 4-year-olds included 41.8% ( $n = 23$ ) children without a family history of enuresis and 58.2% ( $n = 32$ ) children with a family history of bedwetting defined as at least one of the following family members suffering or have suffered in the past from enuresis (i.e., father, mother, sibling, aunt, uncle, grandmother, or grandfather). The logistic regression slope for a family history of enuresis was positive ( $B = 1.201$ ), indicating that a child with enuresis in the extended family was more likely to be dry post treatment compared to children without a family history of enuresis. Wald-statistic = 4.35,  $p = .04$  showed statistical significance of the logistic regression slope coefficient.

To further understand the relationship between family history of enuresis and treatment outcomes, a cross-tabulation (see Table 1) and chi-square was employed to investigate the relative frequencies of treatment outcomes as a function of family history. The analysis showed that children age 4 with a family history of enuresis (71.9%) are more likely to be dry post treatment compared to children without family history of enuresis (43.5%).

**Table 1**  
**Cross-Tabulation of Genetic Predisposition and Treatment Outcome in 4-Year-Old Children**

	<i>Treatment Outcome</i>	
	Dry	Wet
No Family History	10 (43.5%)	13 (56.5%)
Family History	23 (71.9%)	9 (28.1%)

Age was unrelated to treatment outcome, indicated by similar treatment success rates of all age groups from the sample. Two different, yet complementary, statistical analyses were employed in support of this finding. First, a chi-square test of independence was used to test the relationship between age and treatment outcome variables. Second, ANOVA was utilized to compare mean success rates for all age

groups followed by a cross tabulation of the child's age in years and treatment outcome was performed (see Table 2) to summarize these observations. The chi-square test of independence analysis found no statistical evidence that the treatment effectiveness varied by age,  $\chi^2(3, n = 186) = .83, p = .84, \phi_v = .07$ . Overall, the percentage of children achieving post treatment dryness for the 4, 5, 6, and 7-year-olds was 60.0%, 66.7%, 68.0%, and 64.4%, respectively. The results of the ANOVA analyses, that compared the mean success rates for all four treatment groups, found no statistical evidence that the post treatment success rates varied by age group  $F(3, 182) = 0.27, p = .85$ .

**Table 2**  
**Cross-Tabulation of Child's Age and Treatment Outcome**

Child Age in Years	Total <i>N</i>	<i>Treatment Outcome</i>	
		Dry ( <i>N</i> /%)	Wet ( <i>N</i> /%)
4.00	55	33 (43.5%)	22 (56.5%)
5.00	36	24 (66.7%)	12 (33.3%)
6.00	50	34 (68.0%)	16 (32.0%)
7.00	45	29 (64.4%)	16 (35.6%)

### Discussion

Data analysis indicates that for 4-year-olds, the studied pretreatment variables of age, birth order, and number of children in the family did not predict treatment outcome. The findings replicate the results of earlier studies on the same pretreatment variables in older children (Dische et al., 1983; Jensen & Kirstensen, 2001). However, a positive family history of enuresis was found to be an important predictor of positive treatment outcome in 4-year-olds, with results indicating that the treatment was most successful in 4-year-old children with a family history (72%) of bedwetting, while less effective for children age 4 without a family history (43.5%) of bedwetting. The reason for this discrepancy in treatment outcomes in 4-year-olds with or without a family history of bedwetting was not addressed in this study.

Superior treatment outcomes for children with a positive family history of bedwetting may be linked to parental attitudes toward bedwetting and/or greater parental involvement and compliance with the treatment regimen. Parents who have first hand experience with the issue might better understand the impact that involuntary wetting can have on a child. Such a personal history might lead to a greater sensitivity to the child's experience and encouragement for the child to comply with the treatment protocol.

Essential to a positive treatment outcome is use of the urine alarm treatment consistently (i.e., each night) for a time period of 2 to 6 months (Gimpel & Warzak, 1998). The length of the treatment regimen, combined with the demands of a nightly

routine, requires sustained motivation on the part of the child and his or her family. It is possible that parents who are familiar with the problem understand the significance of a positive treatment outcome and are therefore able to facilitate the child's motivation to comply with the treatment regimen until dryness is achieved.

Conversely, the marginal success rate for children without a family history of bedwetting might be related to the parent's role in understanding the problem and importance of treatment compliance. Further, parents unfamiliar with the problem might assume that the child has at least some conscious control over his or her bladder function and that the child is either too lazy or simply not willing to exercise control. On the other hand, parents with a family history of bedwetting tend to know that bedwetting is not intentional nor can it be controlled through cognition, desire, wish fulfillment, or trying harder to remain dry. As indicated, the difference in parental first hand experience identified in this study suggests a number of implications for treating enuresis; e.g., focused parent education that addresses parental attitudes toward the disorder and the potential impact these feelings may have on treatment compliance, persistence, and consistency.

While this analysis of the age related pretreatment variable indicated that age is not a predictor for urine alarm treatment outcomes in children age four, the study does suggest that the applied urine alarm treatment is similarly effective for children age 4 to age 7. Current pediatric (Boris & Dalton, 2004) and psychiatric diagnostic guidelines (American Psychiatric Association [APA], 2000) require a minimum age of 5 years for a diagnosis of enuresis implying that the earliest start of urine alarm treatment is set at age 5. However, research indicates prolonged suffering from symptoms of bedwetting increases the probability for a child to develop behavioral and emotional problems (Fergusson & Horwood, 1994). In addition, other research stipulates only a 6% probability for a 4-year-olds to become dry without intervention in the next year (Oppel, Harper, & Rider, 1968).

In view of the implied limits on use of the urine alarm system to treat enuresis for children, the present study provides some evidence that urine alarm treatment is successful for children age 4, especially for those who have a family history of this disorder. As a consequence of these findings, pediatricians and other health practitioners are encouraged to rethink treatment guidelines for bedwetting children and to offer urine alarm treatment to motivated parents with enuretic 4-year-old children.

Clinical implications for 4-year-olds without a family history of bedwetting are less clear. However, when confronted with the question of whether to start treating a child at age 4 with the urine alarm system, clinicians should take into consideration the finding that children without a family history of bedwetting have a 45% probability of success. While this probability is not as impressive as that for 4-year-old children with a family history of enuresis (i.e., 72% success rate), it does suggest the potential benefit of parent education about enuresis as a potentially effective strategy to increase parent sensitivity to the causative factors to childhood enuresis. With a heightened understanding and awareness of this information, parents without a personal history of enuresis may increase sensitivity to the child's needs for support during treatment for bedwetting.

Because this study was conducted in Israel through a single clinical psychologist, future research could explore the research questions across several practice settings; e.g.,

outpatient pediatric urologic clinics, multiple pediatrician practice settings. In addition, study of enuresis treatment outcomes in additional culturally diverse populations would be instructive. Further investigation of early age urine alarm treatment outcomes in the United States with children as young as 4 years of age is warranted based upon these results.

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