

DEFINITIONS IN RESEARCH

Establishment of working definitions in nocturnal enuresis

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Studies of childhood nocturnal enuresis have traditionally used various criteria both to select children for treatment and measure its outcome. To make comparison possible among studies an agreed set of working definitions are needed.¹ The figure gives a flow chart by which the terms used in this paper are placed in context.

Inclusion criteria

The following characteristics of enuretics being studied should be included:

- Age, including the range for acceptance in the study, and the mean and actual age range of those children enrolled
- Number of boys and girls
- Presence or absence of organic disease
- Number of children with associated diurnal enuresis (such children may respond differently to treatment interventions).² 'Daytime wetting' requires definition and may be the occurrence of one or more daytime wetting incidents over a two week period
- The severity of bedwetting before treatment. In a review of 32 studies,¹ only 38% of papers reported severity: moreover the number of wet nights/week to be included in the study ranged from one to seven.^{2 3} A baseline period of observation is recommended: from

the patient's point of view four weeks is probably the maximum length. The suggested inclusion criterion for an individual child is 50% or more wet nights in a two week period.

When the emphasis of a study is focused on those children who wet less than 50% of nights and are more difficult to treat, the degree of severity of wetting should be clearly stated.

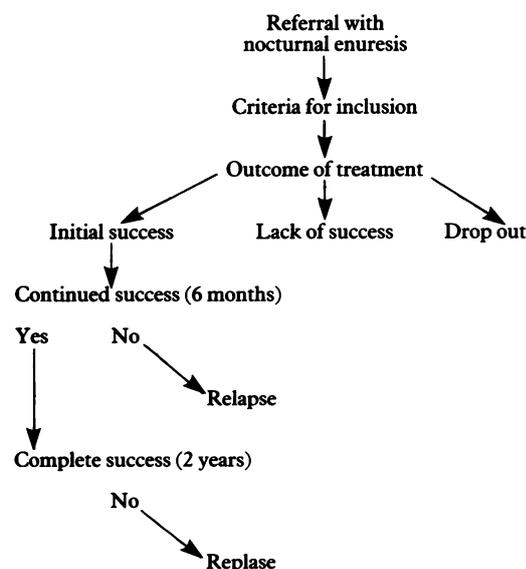
Initial success

Initial success is usually described as the achievement of 'an extended number of dry nights'. A working definition requires consideration of two issues: an agreement on what constitutes 'an extended number of dry nights', and the necessity to specify the duration of treatment. I reviewed a range of published reports to clarify the criteria used in practice (table 1). Reports were included in the analysis if they fulfilled the following criteria:

- They were published since 1969 (covering the last 20 years)
- At least 12 children in the study received treatment
- A definition of 'initial success' was included in the methods section
- Treatment was of a 'conditioning' nature (that is, pad and bell, body alarm or dry bed training). These were chosen because of their established effectiveness.

Thirty five studies (90%) used the completion of a particular number of consecutive nights to define initial success and 27 (69%) selected 14 as that number. Thus 14 consecutive dry nights seems to be an acceptable consensus definition of initial success.

A specified duration of treatment was considered important, as protracted treatment is increasingly influenced by spontaneous remission and thus less confidence can be given to treatment as the effective variable. Two measures of duration of treatment have been used: firstly, a number of trials of the treatment. An arbitrary number of 50 buzzer soundings was selected and if children failed to achieve the initial success criteria during this time they were considered to have failed.^{4 24} The limitation of such a measure lies in its specificity; it is only applicable to treatment with an enuresis alarm. Secondly, number of weeks of treatment. This is the most common method, and table 2 summarises the studies according to duration of



A flow chart of nomenclature.

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Table 1 Criteria for successful treatment of enuresis used in 42 studies

Study and method used	Year of publication	Country of origin	Definition of initial success (No of consecutive dry nights)	Duration of treatment unless otherwise stated
Pad and bell:				
Baker ⁴	1969	USA	14	10
Berg <i>et al</i> ⁵	1982	UK	On average <once a week in a four week period	16 (average)
Bollard and Nettelbeck ⁶	1981	Australia	14	20
Butler <i>et al</i> ⁷	1988	UK	14	16
Butler <i>et al</i> ⁸	1989	UK	14	16
Collins ⁹	1973	USA	10	8
Dische ¹⁰	1971	UK	21	52
Dische <i>et al</i> ¹¹	1983	UK	21	No limit
Fielding ²	1980	UK	14	12
Fielding ¹²	1985	UK	14	14
Finley <i>et al</i> ¹³	1982	USA	14	No limit
Fordham and Meadow ¹⁴	1989	UK	42	16 (extended to six months)
Forsythe and Redmond ¹⁵	1970	UK	28	30
Goel <i>et al</i> ¹⁶	1984	UK	<Four in 28	20
Houts <i>et al</i> ¹⁷	1986	USA	14	16
Jehu <i>et al</i> ¹⁸	1977	UK	14	16
McConaghy ¹⁹	1969	Australia	14	10
Netley <i>et al</i> ²⁰	1984	Canada	2 month	Not given
Sacks and DeLeon ²¹	1978	USA	13	Not given
Taylor and Turner ²²	1975	UK	No more than one accident in 28 nights	Not given
Turner <i>et al</i> ²³	1970	UK	14	4
Wagner <i>et al</i> ²⁴	1982	USA	14	14
Wagner and Matthews ²⁵	1985	USA	14	12
Young and Morgan ²⁶	1972a	UK	14	Not given
Body alarm:				
Arroe and Barner-Rasmussen ²⁷	1979	Denmark	14	1-11 (months)
*Butler <i>et al</i> ⁸	1989	UK	14	16
*Fordham and Meadow ¹⁴	1989	UK	42	16 (extended to six months)
Moffat <i>et al</i> ²⁸	1987	Canada	14	Not given
Shapiro ²⁹	1985	USA	21	5-36 (months)
Dry bed training:				
Azrin <i>et al</i> ³⁰	1974	USA	14	Not given
Azrin <i>et al</i> ³¹	1979	USA	14	Not given
Azrin and Thienes ³²	1978	USA	14	Not given
Besalel-Azrin <i>et al</i> ³³	1980	USA	14	6 (months)
*Bollard and Nettelbeck ⁶	1981	Australia	14	20
Bollard and Nettelbeck ³⁴	1982	Australia	14	20
Bollard <i>et al</i> ³⁵	1982	Australia	14	8
Bollard and Woodroffe ³⁶	1977	Australia	14	Not given
Breit <i>et al</i> ³⁷	1984	USA	14	Not given
*Butler <i>et al</i> ⁷	1988	UK	14	16
Doleys <i>et al</i> ³⁸	1977	USA	14	6
Griffiths <i>et al</i> ³⁹	1982	UK	14	22
Keating <i>et al</i> ⁴⁰	1983	USA	14	25

*Study design same as that in pad and bell study.

Table 2 Studies summarised according to number of weeks of treatment

No of weeks of treatment	Pad and bell	Body alarm*	Dry bed training*	Total
4-6	1	0	1	2
8	1	0	1	2
10	2	0	0	2
12	2	0	0	2
14	2	0	0	2
16	6	0	0	6
20	2	0	1	3
Other	2	2	3	7
Not given	7	1	5	13
Total	25	3	11	39

*The two studies comparing body worn alarm with pad and bell, and the two studies comparing dry bed training with pad and bell are included in the pad and bell column.

treatment. A third of the studies failed to specify duration of treatment. In the others a wide variety of treatment lengths (from four weeks to 36 months) were used, with 16 weeks as the most common.

An average course of treatment for the pad and bell is five to eight weeks.⁴¹ Thus studies in which treatment lasts less than eight weeks exclude all but the fast responders, and consequently underestimate the success rate. As the

average annual spontaneous cure rate between 5 and 9 years is 14%, however, and between 10 and 19 years is 16%, the longer the treatment the less confidence that can be attributed to the treatment itself. Duration of treatment might therefore be considered appropriate within a range of 12 to 20 weeks. As 16 has been used most frequently (nine studies from five different centres), this has been selected as the preferred option.

Thus a proposed definition of initial success is the achievement of 14 consecutive dry nights within a 16 weeks' treatment period. Conversely, lack of success would be accepted if treatment failed to meet these criteria.

'Drop outs'

A third possible outcome is premature stopping of treatment. This may occur for a number of reasons which have been classified as 'drop outs' for the reasons given below.

- (i) Failure to attend. This generally means that after an initial appointment, a number of subsequent appointments are missed without notice or explanation.

Reasonable clinical practice suggests that failing to attend on two consecutive occasions can be considered as dropping out. Research protocols need to specify the degree and type of contact. There is an assumption that missed appointments mean that the patient 'has voted with his feet'. There are, however, many variables associated with missed appointments, and it may be that some children stop attending because bladder control has been achieved and appointments are considered unnecessary. For example, in one investigation 19% of the children stopped treatment prematurely because they had become dry.⁴⁴ A further reason for non-attendance is the practical difficulty of getting to clinic appointments. Research investigations should attempt to delineate whether drop outs through failure to attend are successes (either using the initial success criteria or parent imposed criteria) or failures.

- (ii) The family wishes to discontinue treatment. For whatever reasons, if the child and parent wish to withdraw from treatment this is considered a drop out.
- (iii) The doctor wishes to discontinue treatment. There may be instances where the doctor takes a clinical decision to stop treatment. This too constitutes a drop out.
- (iv) The parents or the child may not accept treatment.¹² It might be argued that as treatment has yet to be initiated it cannot be viewed as 'premature stopping of treatment' and does not therefore constitute a drop out. Thus a proposed definition of drop out is that, after an initial appointment, two consecutive appointments are missed without notice, or treatment is discontinued by agreement by parent, child, or doctor. Protocols should endeavour to differentiate drop out successes from drop out failures.

Relapse

Relapse is generally accepted to mean a return to regular bedwetting after a period of being dry.⁴² What, however, constitutes 'regular wetting'? Adoption of the stringent criterion that relapse was a single wet incident in the six months after a treatment success resulted in an 80% relapse rate.⁴⁵ This suggests that only a small number of children will remain completely free of bedwetting accidents once treated, a result that has been replicated in several studies.^{9 46} It has been argued, however, that occasional bedwetting accidents after initial success should not be considered relapse on the grounds that (i) occasional bedwetting occurs among 'normal' or non-enuretic children, and (ii) bladder control may continue to be 'vulnerable' for some time and bedwetting may occur at times when the child is ill or under stress. Such lapses of control remit spontaneously and do not predict further relapse, suggesting that a definition of relapse should take this into account.⁴⁶

Table 3 Definitions of relapse used in 24 studies

Study	Definition of relapse
Azrin <i>et al</i> ²¹⁻³³	More than three consecutive nights of bedwetting
Bollard <i>et al</i> ^{6 34-36}	One wet night/week over a 4 week period
Breit <i>et al</i> ³⁷	Two wet nights in any seven day period
Butler <i>et al</i> ^{7 8}	Two wet nights in any one week
Collins ⁹	More than one wet in two weeks
Dische ^{10 11}	One or more wet night in four consecutive weeks
Fielding ^{2 12}	Two wet nights in any one week
Finley <i>et al</i> ¹³	More than three wet nights/week for two weeks
Griffiths <i>et al</i> ¹³⁹	More than one wet night in a month
Houts <i>et al</i> ¹⁷	At least one wet night in two consecutive weeks
Keating <i>et al</i> ⁴⁰	Three consecutive wet nights
Sacks and DeLeon ²¹	One wet night/week for four weeks
Taylor and Turner ²²	More than one wet night/week at any stage
Turner <i>et al</i> ²³	At least one wet night/week in any two consecutive weeks
Wagner <i>et al</i> ^{24 25}	Three wet nights in any period of 14 nights
*Williams <i>et al</i> ⁴⁷	Three wet nights or more a month

*This is a follow up of the study by Doleys *et al*.³⁸

The acceptance of occasional wet nights into a definition of relapse has, however, resulted in a wide variety of definitions (table 3). The 16 centres reported 10 different definitions. To examine these, a number of hypothetical cases were put forward. Table 4 shows to what extent relapse was accepted for six different cases using each definition. There was: (i) no unanimity for accepting relapse; (ii) a range of acceptance from more than three wet nights/week for two weeks—indicating no relapse—to more than one wet night/month, in which case relapse was judged to be universal; (iii) difficulty in applying some definitions because of ambiguity.

The most popular definitions were: more than one wet night/week (four centres), and one wet night/week over four weeks (three centres). The creation of an acceptable definition depends on agreeing about: the duration of monitoring, the elapsed time—that is, the length of time for which wet nights are observed—and the number of wet nights.

DURATION OF MONITORING

Nearly all relapses, however defined, occur within the first six months of treatment.^{11 21 42 46} Thus regular monitoring of progress for six months after initial success seems to be good practice.⁴³ Relapse during this six month period usually indicates the need for retraining, whereas an absence of relapse might be considered to be continued success. As relapse is uncommon after six months, a two year period of monitoring has been advocated during which the follow up would be less intensive than during the first six months.¹⁵ Complete success has been suggested to describe those children who do not relapse within two years of their initial success.^{1 46}

ELAPSED TIME

The options considered could be number of weeks, number of days, or number of consecutive wet nights.

Table 4 Diagnosis of relapse for each definition for six hypothetical cases

Definition	No of wet nights/week for four weeks					
	Case 1 (1, 1, 1, 1)	Case 2 (1, 0, 6, 0, 0)	Case 3 (0, 0, 2, 0)	Case 4 (1, 3, 0, 0, 0)	Case 5 (2, 2, 0, 2)	Case 6 (1, 1, 2, 0)
More than one wet night/week ^{2 7 8 12 22 37}	No	Yes	Yes	Yes	Yes	Yes
One wet night/week over four weeks ^{6 10 11 21 34-36}	Yes	Uncertain	No	Uncertain	Uncertain	Uncertain
At least one wet night in two consecutive weeks ^{17 23}	Yes	Yes	No	Yes	Yes	Yes
More than three consecutive wet nights ³¹⁻³³	No	Uncertain	No	Uncertain	Uncertain	No
More than one wet night in two weeks ⁹	Yes	Yes	Yes	Yes	Yes	Yes
More than three wet nights/week for two weeks ¹⁵	No	No	No	No	No	No
More than one wet night/month ³⁹	Yes	Yes	Yes	Yes	Yes	Yes
Three consecutive wet nights ⁴⁰	No	Yes	No	Uncertain	Uncertain	Uncertain
Three wet nights in any 14 ^{4 5}	No	Yes	No	Yes	Yes	Yes
Three wet nights or more/month ⁴⁷	Yes	Yes	No	Yes	Yes	Yes

Number of weeks

This is the most popular, the possibilities being one week (first definition), two weeks (third, fifth, and sixth definitions) or four weeks (second definition) (table 4). Two definitions (the seventh and tenth) give a month as the elapsed time but this suggests a less precise measure, because of the variable number of days in a month. Extending the time over which the definition applies introduces further complexity. For example, the second definition (one wet night/week over four weeks) might mean that a child who had one dry week but then wetted severely during the other three weeks would not be considered to have relapsed. This indicates that wet nights/week over a number of weeks should be avoided.

Number of days

Two examples are two wet nights in any seven day period,³⁸ and three wet nights in any 14.^{25 26} Such definitions seem to emphasise the number of wet nights over a shifting period of time (any seven or 14 consecutive nights), which avoids the problem of number of wet nights/week over a specified period of time. This might provide a more clear cut criterion of relapse.

Number of consecutive wet nights (fourth and eighth definitions)

The merit of this option is that it avoids the need for an elapsed time. Using a number of consecutive nights, however, suggests that a child might be wetting four or five times a week and were these not on consecutive nights a relapse would not have been diagnosed.

The preferred options (without specifying the number of wet nights) might therefore be considered as: more than wet night/week (first definition); more than wet night in two weeks (fifth definition); or one wet night in any 14 (ninth definition).

THE NUMBER OF WET NIGHTS

The number of wet nights beyond which relapse is indicated must at this stage be a somewhat arbitrary choice. Taking the preferred options the maximum number of wet nights allowed before a relapse would be judged is: first definition—one wet night a week; fifth

definition—one wet night over two weeks; or ninth definition—two wet nights in any 14.

It seems therefore that the first and ninth definitions are in agreement in allowing two wet nights over two weeks or 14 nights. The options then look like this: more than one wet night a week (first definition); more than two wet nights in two weeks; or more than two wet nights in any 14 (ninth definition).

The first option is the most commonly used, but the second and third are consistent with the initial definition of success in using 14 consecutive nights. All three options are sensitive in detecting relapse in the six hypothetical cases (table 4), and indeed options 2 and 3 give identical results.

Taking note of the lack of agreement between workers, the appropriate view might be to adopt option 2, a succinct yet easily applied definition that accepts the occurrence of occasional wet nights. Thus a proposed definition of relapse is more than two wet nights over two weeks.

Summary of definitions

SEVERITY

For inclusion in a research study a child should have 50% or more wet nights in two weeks.

INITIAL SUCCESS

The achievement of 14 consecutive dry nights within a 16 week treatment period. As a measure of the effectiveness of treatment the average number of weeks taken to reach the initial criteria of success might be a useful variable.

LACK OF SUCCESS

Failure to meet the initial criteria of success excluding drop outs.

DROP OUTS

After an initial appointment, two consecutive appointments are missed without notice, or treatment is discontinued by agreement by parents, child, or doctor. The clinician should endeavour to discover whether the drop out was a success or a failure.

RELAPSE

More than two wet nights in two weeks. The

time between initial success and relapse should be stated.

CONTINUED SUCCESS

No relapse in the six months after initial success.

COMPLETE SUCCESS

No relapse in the two years after initial success.

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