

Unblinding the Urine Bag: a randomised controlled trial

Maneesh Deva

Paediatrics Department, Waikato Hospital, Hamilton, New Zealand

David Herd

Children's Emergency Department, Starship Children's Health, Auckland,
New Zealand

Introduction

Introduction

- Urine collection is paramount in the diagnosis of urinary tract infections^{1,2}

Introduction

- Urine collection is paramount in the diagnosis of urinary tract infections^{1,2}
- Under the age of 3, signs and history are unreliable^{3,4}

Introduction

- Urine collection is paramount in the diagnosis of urinary tract infections^{1,2}
- Under the age of 3, signs and history are unreliable^{3,4}
- Urinary tract infections thought to be related to renal scarring, hypertension and renal failure⁵

Introduction

- Urine collection is paramount in the diagnosis of urinary tract infections^{1,2}
- Under the age of 3, signs and history are unreliable^{3,4}
- Urinary tract infections thought to be related to renal scarring, hypertension and renal failure⁵
- Collection of urine by an appropriate and practical method is advisable⁶

Local practise

- In Waikato ED, bag urine collection is used as a directed screening tool in infants with fever

Local practise

- In Waikato ED, bag urine collection is used as a directed screening tool in infants with fever
 - Agrees with local guidelines

Local practise

- In Waikato ED, bag urine collection is used as a directed screening tool in infants with fever
 - Agrees with local guidelines
 - Positive screen results followed with 'definitive' urine samples due to contamination

Local practise

- In Waikato ED, bag urine collection is used as a directed screening tool in infants with fever
 - Agrees with local guidelines
 - Positive screen results followed with 'definitive' urine samples due to contamination



Local practise

- In Waikato ED, bag urine collection is used as a directed screening tool in infants with fever
 - Agrees with local guidelines
 - Positive screen results followed with 'definitive' urine samples due to contamination



- Other methods of collection include, 'clean catch', catheter urine collection and suprapubic aspiration

Hypothesis

Hypothesis

- 'Unblinding' the urine bag using modified nappy

Hypothesis

- 'Unblinding' the urine bag using modified nappy
 - allows for quicker urine collection

Hypothesis

- 'Unblinding' the urine bag using modified nappy
 - allows for quicker urine collection
 - Reduces the number of invasive urine collections

Hypothesis

- 'Unblinding' the urine bag using modified nappy
 - allows for quicker urine collection
 - Reduces the number of invasive urine collections
- Theory

Hypothesis

- 'Unblinding' the urine bag using modified nappy
 - allows for quicker urine collection
 - Reduces the number of invasive urine collections
- Theory
 - Urine is seen quicker

Hypothesis

- 'Unblinding' the urine bag using modified nappy
 - allows for quicker urine collection
 - Reduces the number of invasive urine collections
- Theory
 - Urine is seen quicker
 - Quicker processing

Hypothesis

- 'Unblinding' the urine bag using modified nappy
 - allows for quicker urine collection
 - Reduces the number of invasive urine collections
- Theory
 - Urine is seen quicker
 - Quicker processing
 - α less contamination

Hypothesis

- 'Unblinding' the urine bag using modified nappy
 - allows for quicker urine collection
 - Reduces the number of invasive urine collections
- Theory
 - Urine is seen quicker
 - Quicker processing
 - α less contamination
 - α less invasive urine collection

Aims

Aims

- To determine if 'unblinding' the urine bag

Aims

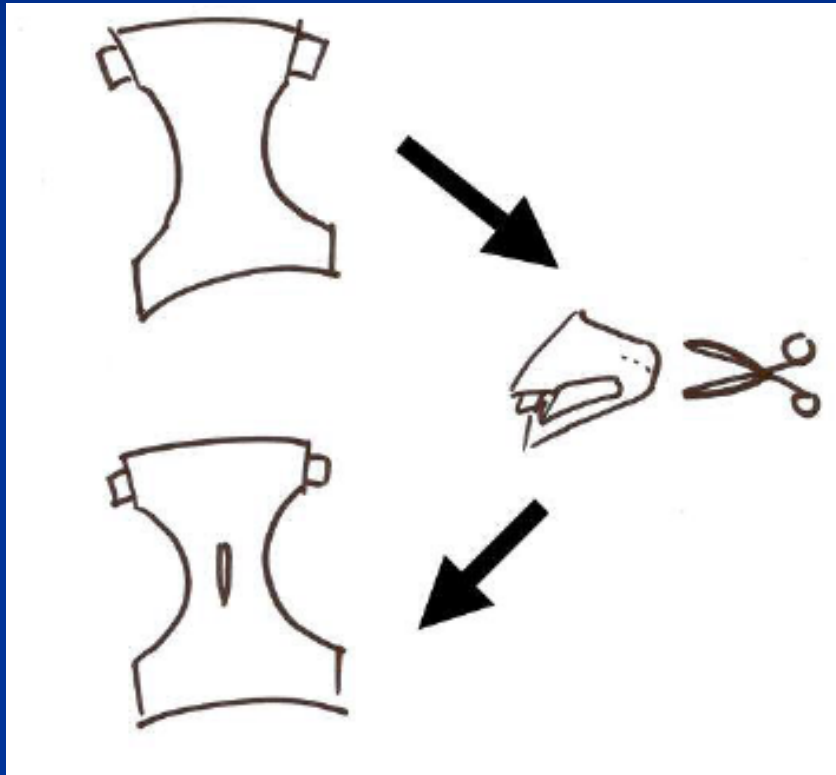
- To determine if 'unblinding' the urine bag
 - Reduces urine collection time

Aims

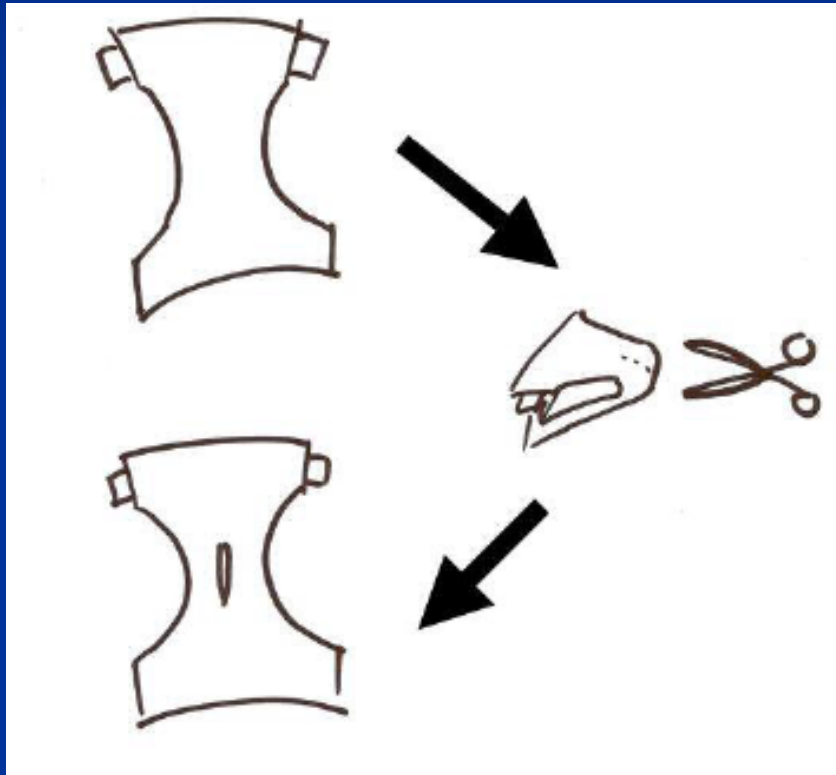
- To determine if 'unblinding' the urine bag
 - Reduces urine collection time
 - Reduces number of invasive urine collections

The 'unblinded' nappy

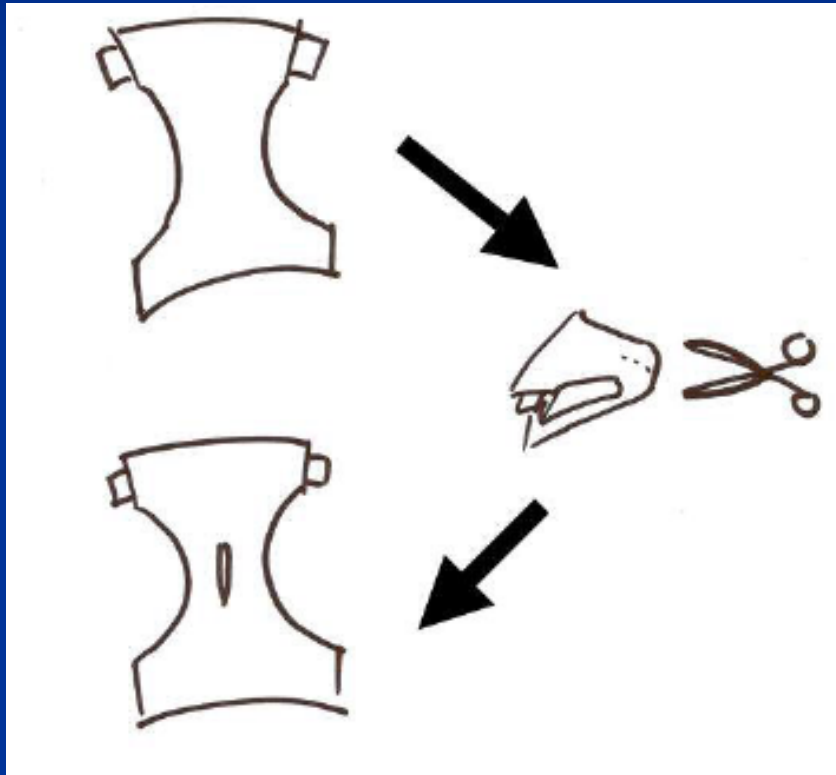
The 'unblinded' nappy



The 'unblinded' nappy



The 'unblinded' nappy



Method

Method

- Parallel, randomised, non- blinded controlled study

Method

- Parallel, randomised, non- blinded controlled study
 - Waikato Hospital, Hamilton, NZ

Method

- Parallel, randomised, non- blinded controlled study
 - Waikato Hospital, Hamilton, NZ
 - February- June 2007

Method

- Parallel, randomised, non- blinded controlled study
 - Waikato Hospital, Hamilton, NZ
 - February- June 2007
 - Students t- test/ Chi square analysis

Method

- Parallel, randomised, non- blinded controlled study
 - Waikato Hospital, Hamilton, NZ
 - February- June 2007
 - Students t- test/ Chi square analysis

- To authors knowledge no previous publications on this method

Method

- Parallel, randomised, non- blinded controlled study
 - Waikato Hospital, Hamilton, NZ
 - February- June 2007
 - Students t- test/ Chi square analysis

- To authors knowledge no previous publications on this method

- Ethical approval granted

Method

Enrolment

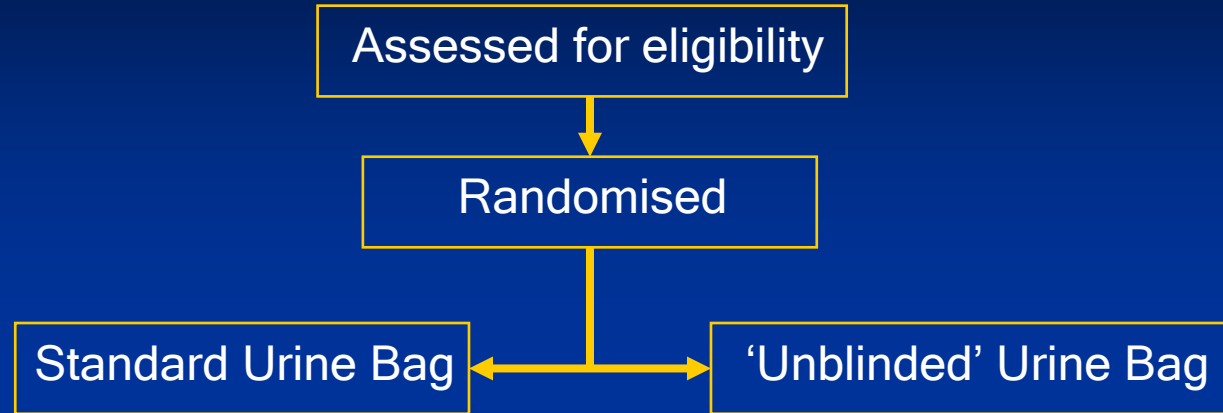
Method

Assessed for eligibility



Allocation Enrolment

Method



Allocation
Enrolment

Method



Assessed for eligibility

Randomised

Standard Urine Bag

'Unblinded' Urine Bag



Method

Enrolment
Allocation
Follow-up



Assessed for eligibility

Randomised

Standard Urine Bag

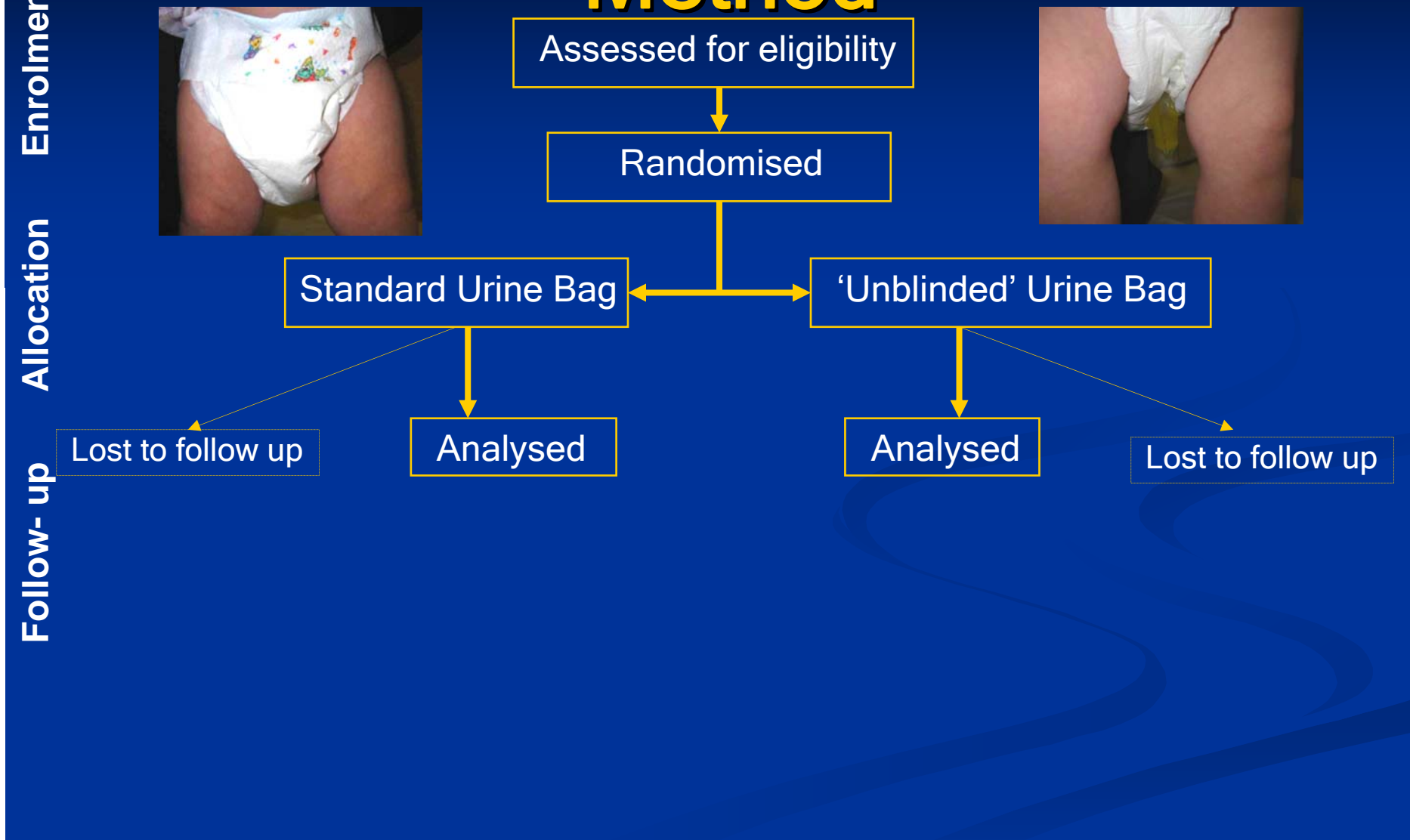
'Unblinded' Urine Bag

Lost to follow up

Analysed

Analysed

Lost to follow up



Method

Enrolment
Allocation
Follow-up
Analysis



Assessed for eligibility

Randomised

Standard Urine Bag

'Unblinded' Urine Bag

Lost to follow up

Analysed

Analysed

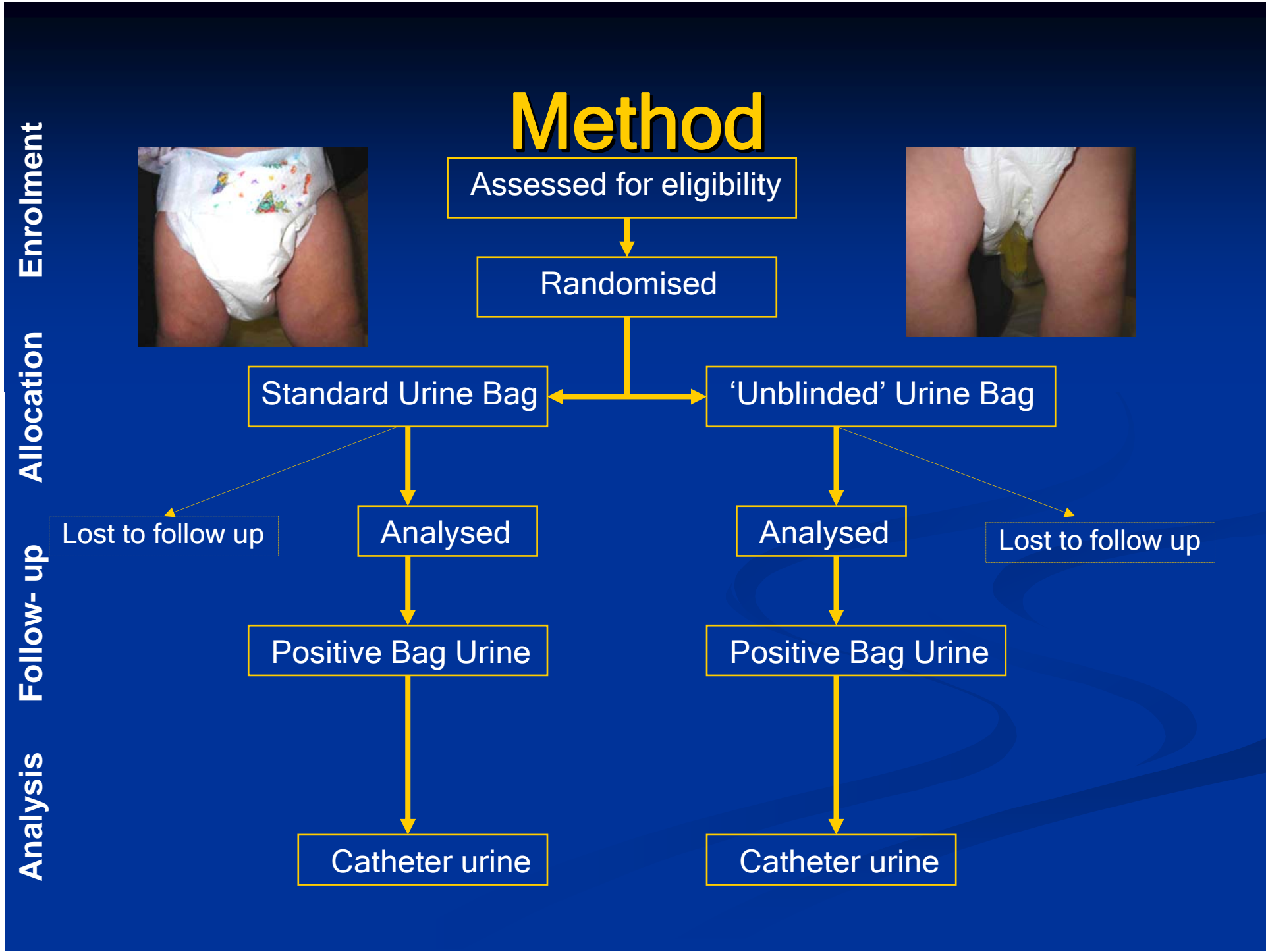
Lost to follow up

Positive Bag Urine

Positive Bag Urine

Catheter urine

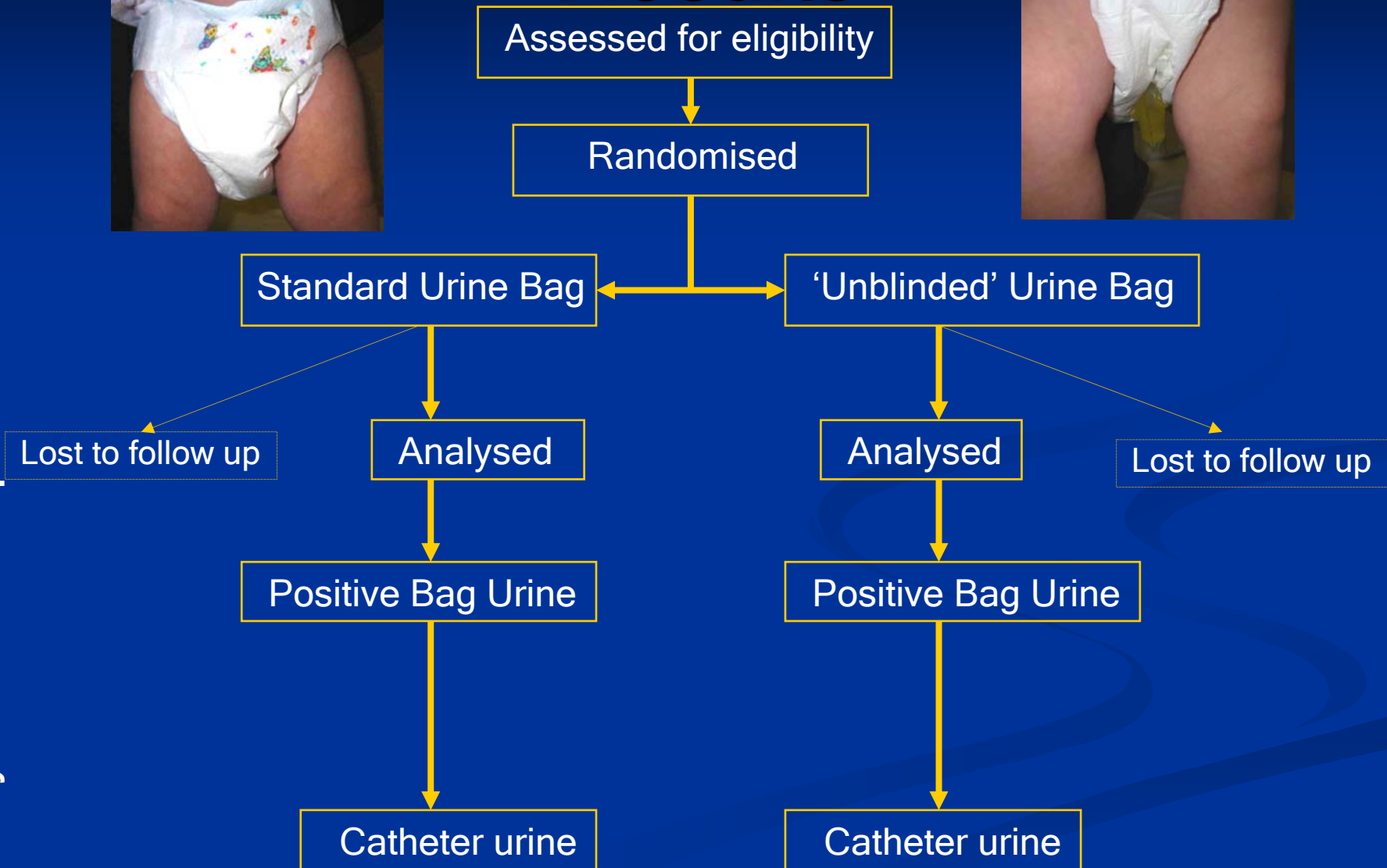
Catheter urine



Results



Enrolment
Allocation
Follow-up
Analysis



Results



Enrolment
Allocation
Follow-up
Analysis

Assessed for eligibility n= 73

Randomised n= 70

Standard Urine Bag

'Unblinded' Urine Bag

Lost to follow up

Analysed

Analysed

Lost to follow up

Positive Bag Urine

Positive Bag Urine

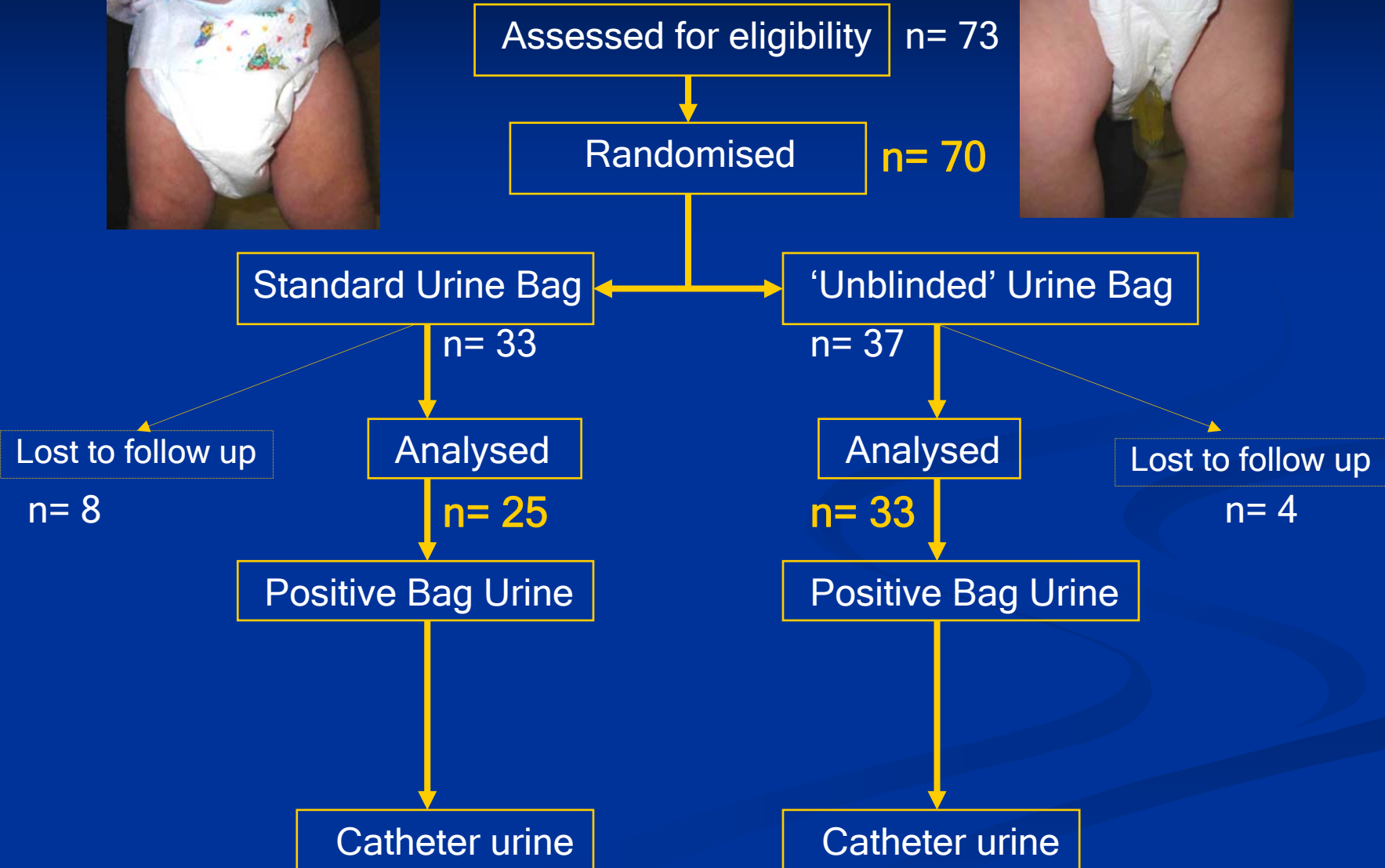
Catheter urine

Catheter urine

Results



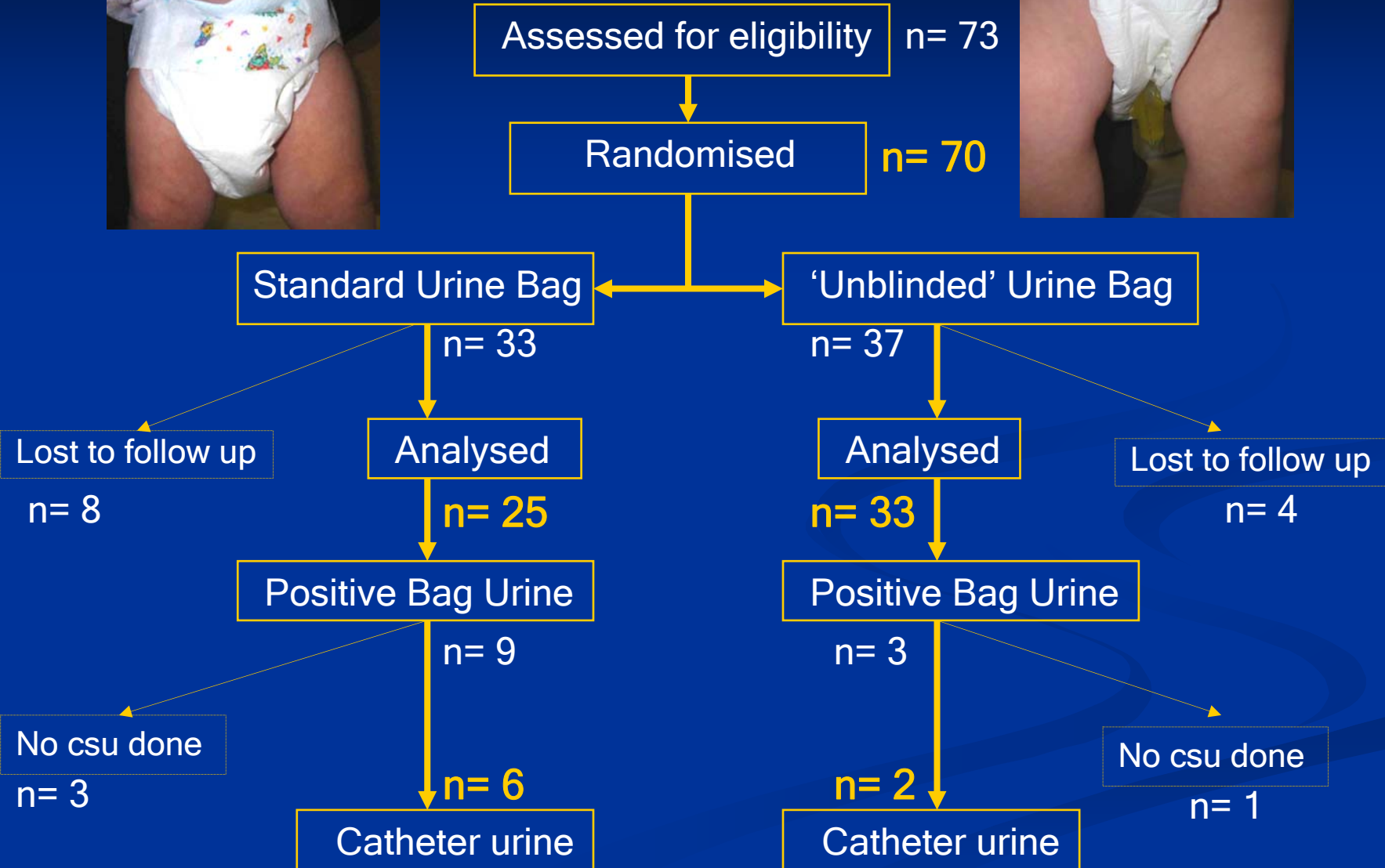
Enrolment
Allocation
Follow-up
Analysis



Results



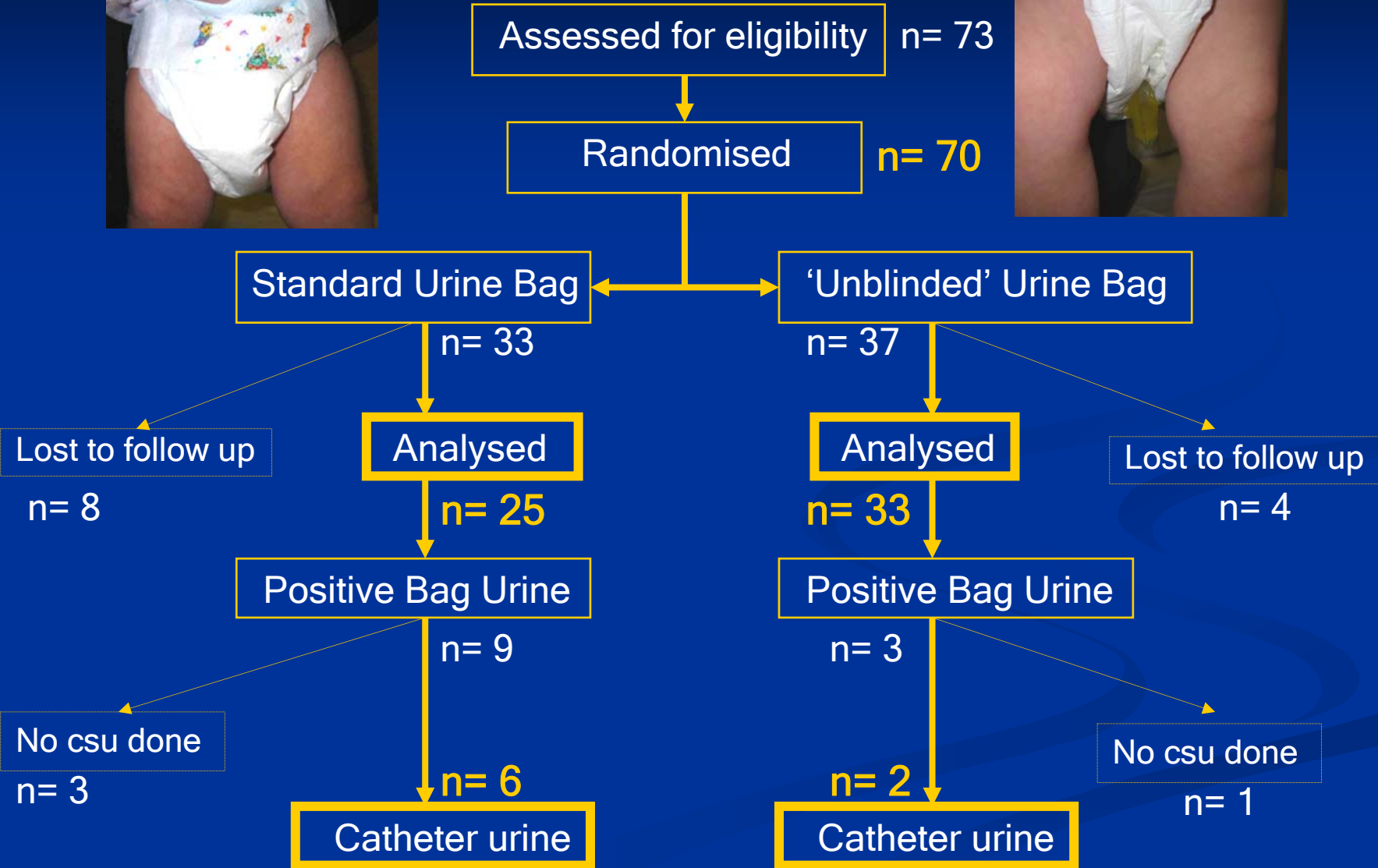
Enrolment
Allocation
Follow-up
Analysis



Results



Enrolment
Allocation
Follow-up
Analysis



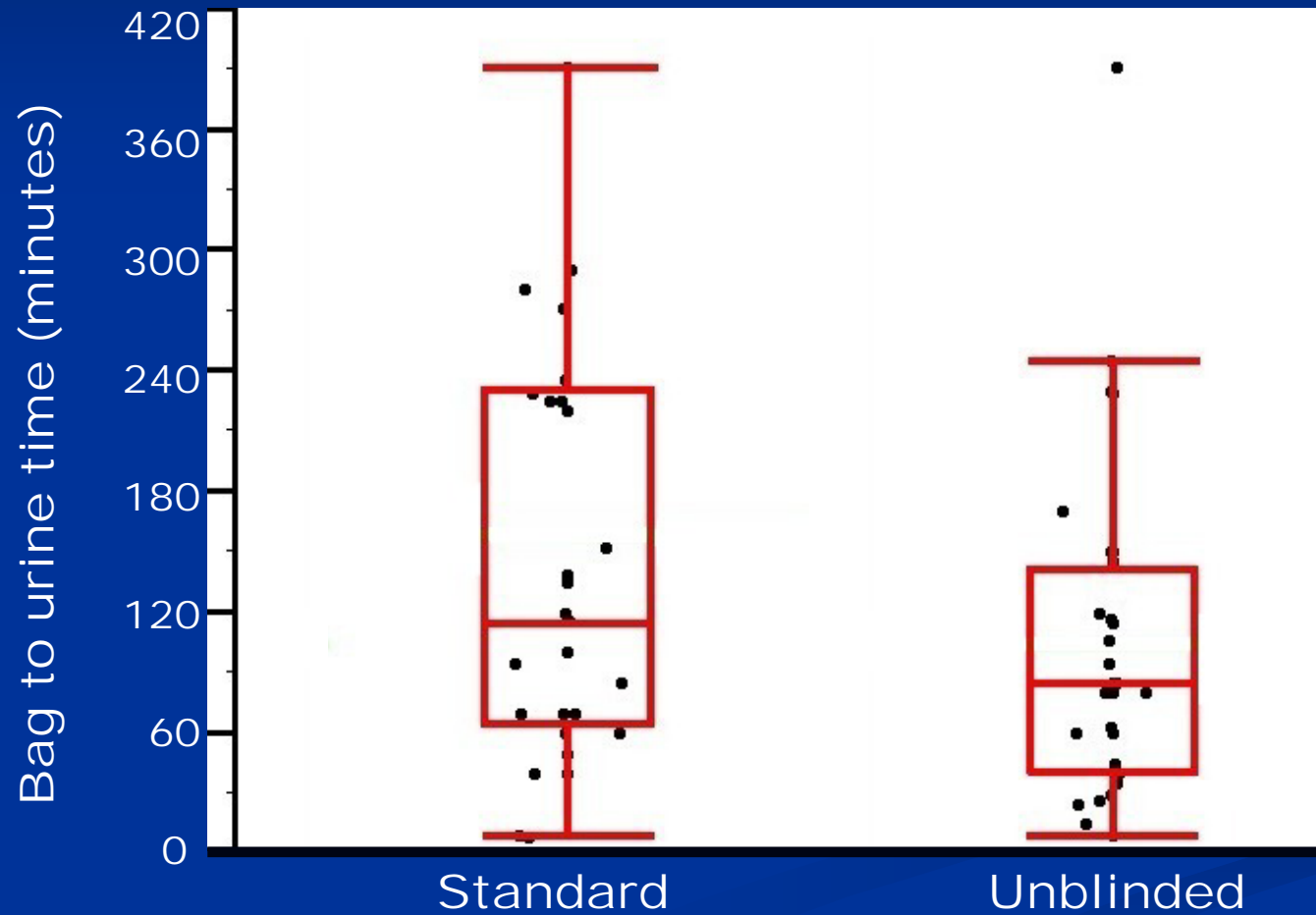
Results/ Analysis

Results/ Analysis

- Primary outcome: Urine collection time

Results/ Analysis

- Primary outcome: Urine collection time



Results/ Analysis

- Primary outcome: Urine collection time
 - Mean time saved=58 minutes (163 V 105)

Results/ Analysis

- Primary outcome: Urine collection time
 - Mean time saved=58 minutes (163 V 105)
 - Students t oneway unpaired $p= 0.03$

Results/ Analysis

- Secondary outcome: number of invasive catheter specimens

Results/ Analysis

- Secondary outcome: number of invasive catheter specimens
 - Number of invasive catheter samples
 - Standard care: 7 / 28 *
 - 'Unblinded' group: 2 / 33

Results/ Analysis

- Secondary outcome: number of invasive catheter specimens
 - Number of invasive catheter samples
 - Standard care: 7 / 28 *
 - 'Unblinded' group: 2 / 33
- Pearson Chi- square $p= 0.038$

Results/ Analysis

- Secondary outcome: number of invasive catheter specimens
 - Number of invasive catheter samples
 - Standard care: 7 / 28 *
 - 'Unblinded' group: 2 / 33
- Pearson Chi- square $p= 0.038$
- NNT= 6

Weaknesses

Weaknesses

- Recruitment was suspected to be influenced by author presence in the emergency department

Weaknesses

- Recruitment was suspected to be influenced by author presence in the emergency department
- Losses to follow- up

Weaknesses

- Recruitment was suspected to be influenced by author presence in the emergency department
- Losses to follow- up
 - Those with long urine collection times and ward allocation
 - During busier ED periods

Weaknesses

- Recruitment was suspected to be influenced by author presence in the emergency department
- Losses to follow- up
 - Those with long urine collection times and ward allocation
 - During busier ED periods
- 4 children had positive bag urine screen but did not go on to 'definitive' sample

Weaknesses

- Recruitment was suspected to be influenced by author presence in the emergency department
- Losses to follow- up
 - Those with long urine collection times and ward allocation
 - During busier ED periods
- 4 children had positive bag urine screen but did not go on to 'definitive' sample
 - 2 bag urine samples grew contaminants with culturing
 - 1 alternative diagnosis found
 - 1 balanitis

Strengths

Strengths

- Cross over not suspected between the groups

Strengths

- Cross over not suspected between the groups
- Times were entered prospectively

Strengths

- Cross over not suspected between the groups
- Times were entered prospectively
- Demographic analysis showed similar characteristics between the two groups

Strengths

- Cross over not suspected between the groups
- Times were entered prospectively
- Demographic analysis showed similar characteristics between the two groups
- Overall incidence of UTI = 5.2%

Discussion

Discussion

- Unblinding the urine bag is quick, cheap and easy to initiate

Discussion

- Unblinding the urine bag is quick, cheap and easy to initiate
- Unblinding the urine bag significantly reduces urine collection time and may obviate the need for potential invasive urine collections

Discussion

- Unblinding the urine bag is quick, cheap and easy to initiate
- Unblinding the urine bag significantly reduces urine collection time and may obviate the need for potential invasive urine collections
- No reported cases of diarrhoea- illnesses causing problems with collection via the 'unblinded' nappy

Acknowledgements

Waikato Hospital ED staff

Dr Noel Manikkam

Dr David Herd (Supervisor)

Children and their caregivers

References

1. AAP. Practice parameter: the diagnosis, treatment and evaluation of the initial urinary tract infection in febrile infants and young children. American Academy of Pediatrics. Committee on Quality Improvement. Subcommittee on Urinary Tract Infection. Pediatrics April 1999; 103 : 843- 852
2. Van der Voort et al. The struggle to diagnose UTI in children under two in primary care. Family Practice. Feb 1997; 14 (1): 44- 48
3. Baumer. Urinary tract infection in children, National Institute for Health and Clinical Excellence. Archives of Disease in Childhood Education and Practice. Dec 2007; 92 (6) :189- 192
4. Isaacman et al. Comparative practice patterns of emergency medicine physicians and pediatric emergency physicians managing fever in young children. Pediatrics Aug 2001; 108 (2) : 354- 358
5. Coultard et al. Is reflux nephropathy preventable and will the NICE childhood UTI guidelines help? Archives of Disease in Childhood. Oct 4, 2007
6. Larcombe et al. Urinary tract infection in children. BMJ Oct 30 1999; 319 (7218): 1173- 1175