Protocol Training

- Presenter -

- Institution -

Date:

PediCAP is part of the EDCTP2 programme supported by the European Union under Grant Agreement RIA2017MC - 2023.

Trial Overview

PediCAP (Paediatric Community Acquired Pneumonia)

Impact of oral step-down to amoxicillin or co-amoxiclav and of duration of antibiotic therapy on effectiveness, safety and selection of antibiotic resistance in severe childhood community-acquired pneumonia (CAP): a randomised controlled trial

Learning Objectives for PediCAP Protocol Training

- **Background**
  - Research Question
  - Outcomes
  - Trial Design
- **Participants**
  - Sites and participants
  - Inclusion and Exclusion Criteria
- **Trial**
  - Screening and Recruitment
  - Consent and Randomisation
  - Treatments
  - Trial assessments and substudies
  - Early stopping and lost to follow up

Background

Learning Objectives

In this section:

- Research Question
- Outcomes
- Trial Design

Research Questions

For hospitalised children with severe CAP, the specific objectives of the PediCAP trial are to answer the following questions:

- Is the rate of clinical cure superior with co-amoxiclav 7:1 versus amoxicillin oral step-down therapy?

- What is the optimal antibiotic treatment duration that achieves good rates of clinical cure whilst minimising length of hospital stay, toxicity and acquisition of multidrug antimicrobial resistance?

(Co-Primary Objectives)

PediCAP

Research Questions

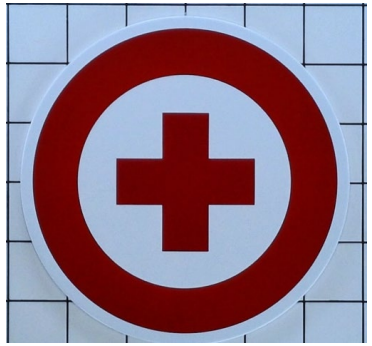
For hospitalised children with severe CAP, the specific objectives of the PediCAP trial are to answer the following questions:

- Does the optimal duration vary by key characteristics, such as age, underlying conditions or risk factors such as HIV exposure, malnutrition or severity, suggesting that antibiotic selection or duration should be personalised to specific subgroups?

- What plasma exposures of amoxicillin and clavulanate are achieved with standardised allometric-based dosing of co-amoxiclav in 4:1, 7:1 and 14:1 dispersible tablets, and do any have significant advantages in terms of PK or toxicity?

(Secondary Objectives)

Outcome Measures



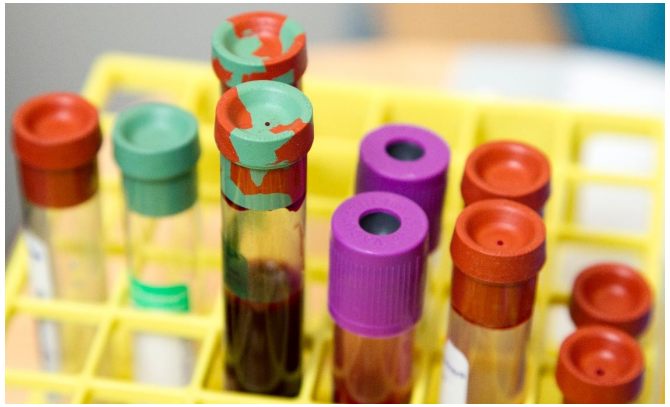
Primary Outcomes

For the main trial (PediCAP-A):

- Hospital readmission or death within 28 days of randomisation (all-cause)

For the Phase II PK trial (PediCAP-B):

- Plasma exposure to amoxicillin and clavulanate



Secondary Outcomes

For the main trial (PediCAP-A), within 28 days of randomisation:

Clinical

- CAP-related readmission or CAP-related mortality
- Length of stay required during the index hospitalisation, and overall through 28 days
- Mortality (all-cause)
- Duration of supplemental oxygen during the index hospitalisation
- Total days of antibiotic exposure through 28 days
- Modification of randomised antibiotics for any reason except early stopping or receipt of subsequent course of antibiotics for any reason
- Modification of randomised antibiotics for inadequate response or additional courses for CAP relapse

Secondary Outcomes

For the main trial (PediCAP-A), within 28 days of randomisation:

Safety

- Serious adverse events
- Grade 3 or 4 adverse events
- Adverse events of any grade related to antibiotics
- Key solicited events, specifically diarrhoea, vomiting and gastrointestinal disorders, skin rash, thrush/candida
- Modification of antibiotics for adverse reactions
- Specific clinical complications, including sepsis, lung abscess, empyema
- Line complications

Substudies

- Antimicrobial resistance (see Substudies below)
- Cost and cost-effectiveness (see Substudies below)

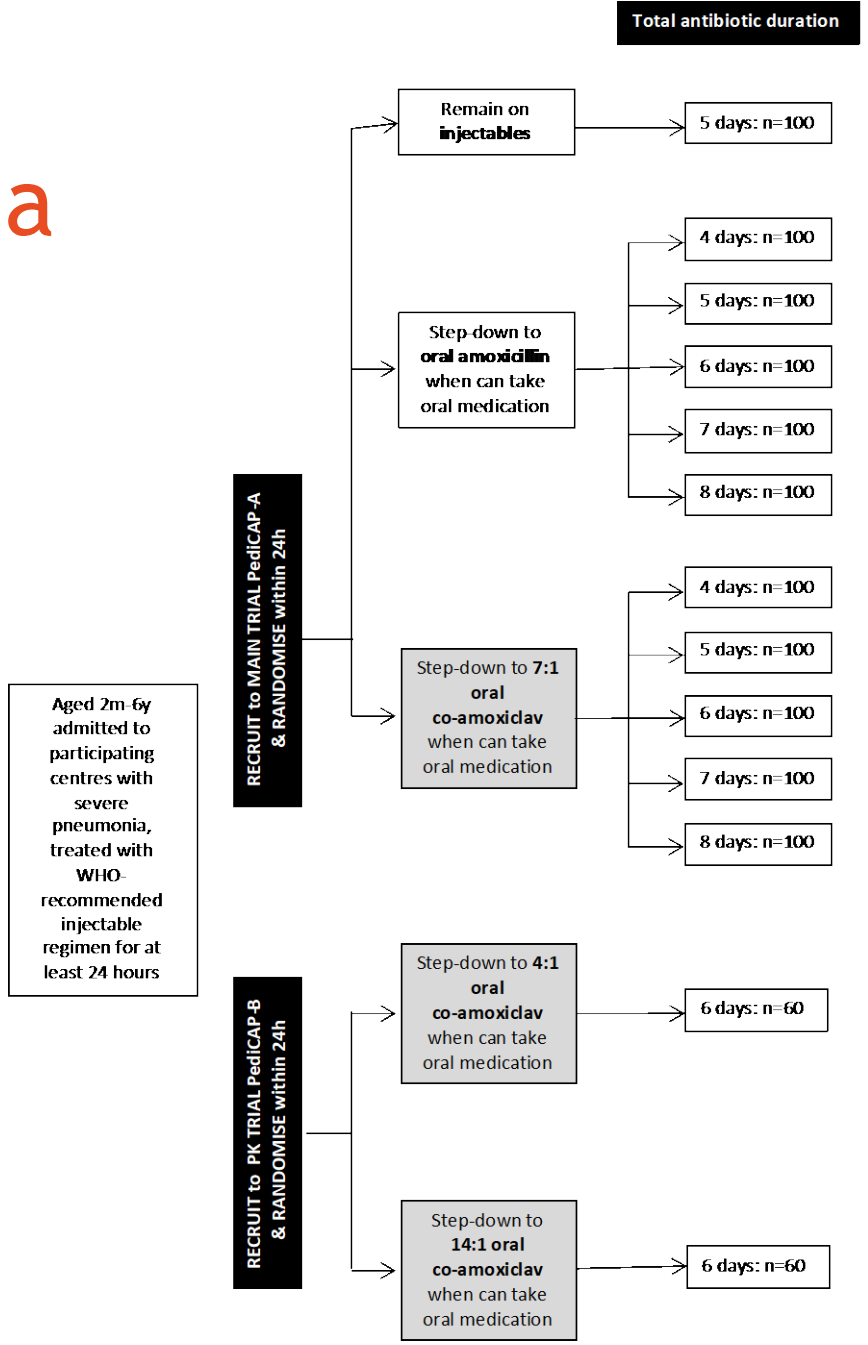
PediCAP

Trial Design

- An open-label, parallel group, 2x5 factorial randomised trial assessing 2 different oral step-down antibiotics (amoxicillin and co-amoxiclav given after intravenous antibiotics for a total of 5 different durations (factorial design) with an additional continued intravenous control group, using a novel design to optimise duration of treatment (main trial, PediCAP-A)

- Plus a parallel Phase II pharmacokinetic (PK) trial comparing two additional different ratios for one of the oral step-down options, co-amoxiclav (14:1 and 4:1) (PediCAP-B), to enable the PK of all three ratios to be compared across the main trial (PediCAP-A) and the PK trial (PediCAP-B)

Trial Schema



Follow-up to 28 days post randomisation for

Primary outcome:

- Hospital readmission or death

Secondary outcomes:

- CAP-related readmission /death
- Length of stay
- Mortality
- Duration of supplemental oxygen
- Total antibiotic exposure
- Modification of trial antibiotics
- Serious adverse events
- Grade 3 or 4 adverse events
- Adverse events related to antibiotics
- Diarrhoea/vomiting and gastrointestinal disorders/skin rash/thrush/candida
- Modification of antibiotics for adverse reactions
- Specific clinical complications
- Line complications
- Antimicrobial resistance
- Costs and cost-effectiveness

PK substudy primary outcome:

- Plasma exposure to amoxicillin and clavulanate acid

Note: shaded boxes indicate PK comparisons (60 children per formulation)

PediCAP Substudies

Pharmacokinetics (PK) – this includes PediCAP - B:

What is the PK of amoxicillin and clavulanic acid when administered as step-down in severe childhood CAP in three different ratios (7:1, 4:1 and 14:1)?

- 60 of 500 children randomised to co-amoxiclav 7:1 in PediCAP-A

- 120 children randomised to co-amoxiclav 4:1 vs 14:1 in PediCAP-B

Microbial sampling:

Are there any changes in nasopharyngeal and faecal prevalence of antimicrobial resistance in relation to randomisation to amoxicillin/co-amoxiclav, duration of antibiotic exposure and inpatient stay?

- 330 children from across PediCAP-A

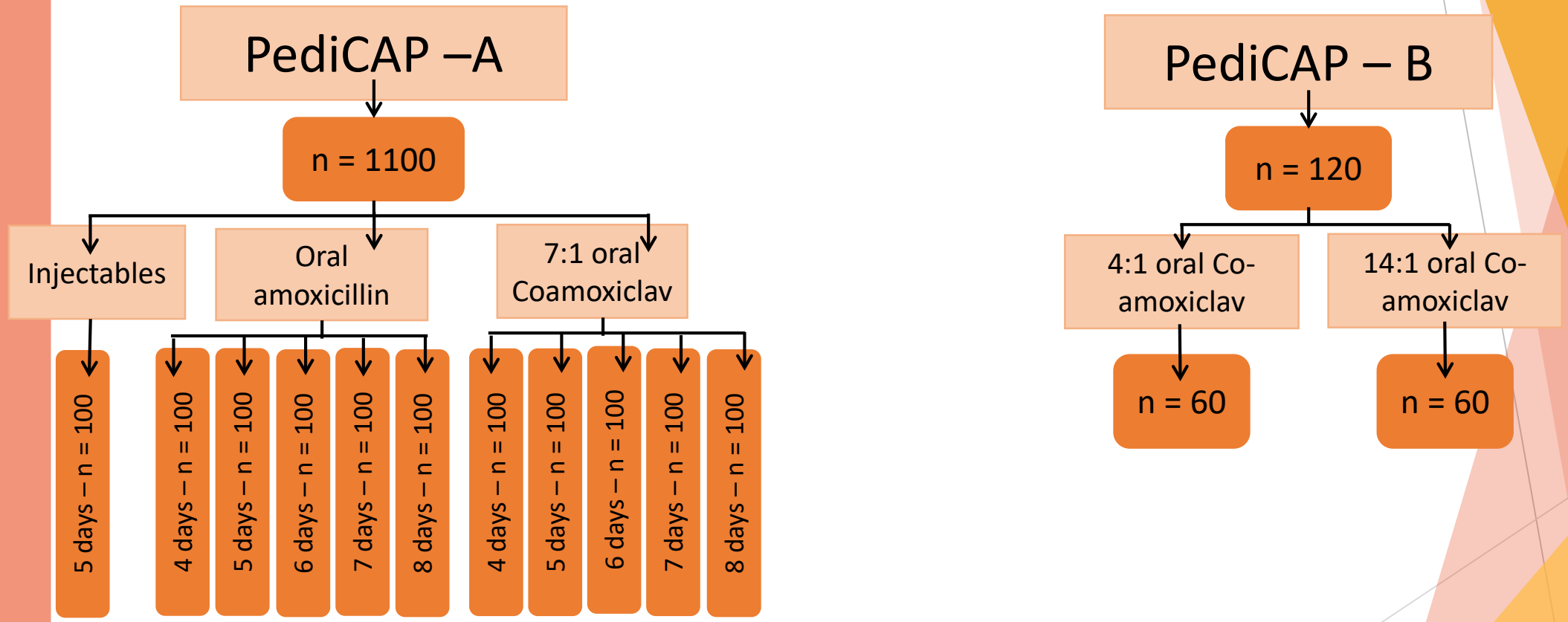
Health economics and equity:

What are the costs and cost-effectiveness of different treatment strategies in the randomised trial as well as their equity impacts at household level ?

Duration

Recruitment for **23 months** (2 years in total)

Recruitment



Microbiology Sub-Study

n = 330

PK Sub-Study

n = 180

PediCAP Protocol
Background Summary Questions

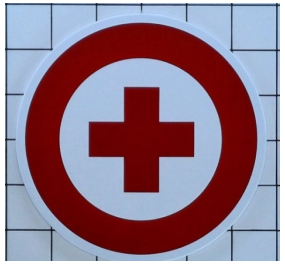
What is the primary outcome for the main trial (PediCAP-A)?

What are the three PediCAP substudies?

PediCAP Protocol
Background Summary Questions

What is the primary outcome for the main trial (PediCAP-A)?

Hospital readmission or death within 28 days of randomisation (all-cause)



What are the three PediCAP substudies?

- **Pharmacokinetics (PK)**
- **Microbial sampling**
- **Health economics and equity**

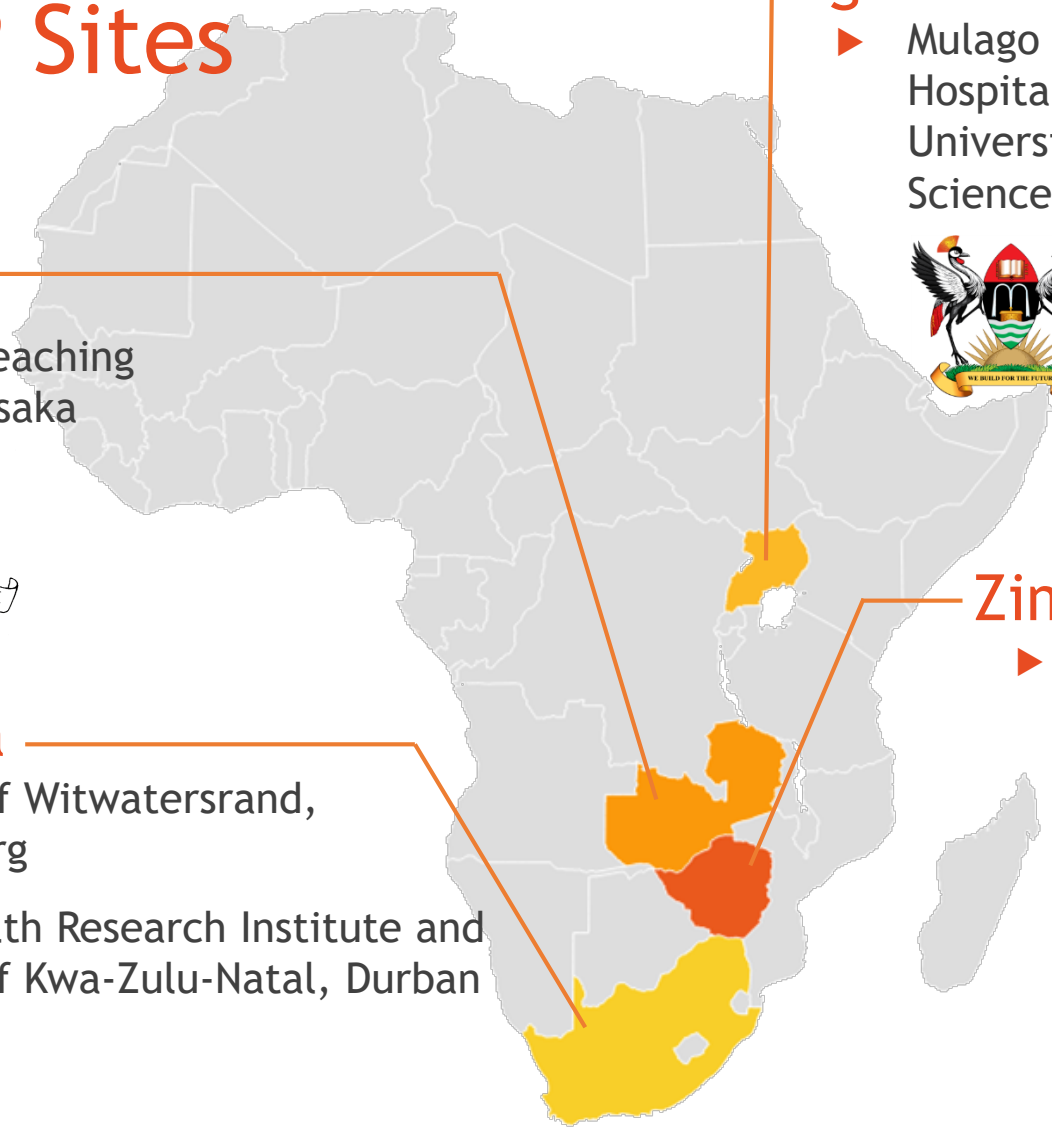
Participants

Learning Objectives

In this section:

- Sites and participants
- Inclusion and Exclusion Criteria

PediCAP Sites



Uganda

- Mulago National Referral Hospital and Makerere University College of Health Sciences, Kampala

Zambia

- University Teaching Hospital, Lusaka

South Africa

- University of Witwatersrand, Johannesburg
- African Health Research Institute and University of Kwa-Zulu-Natal, Durban

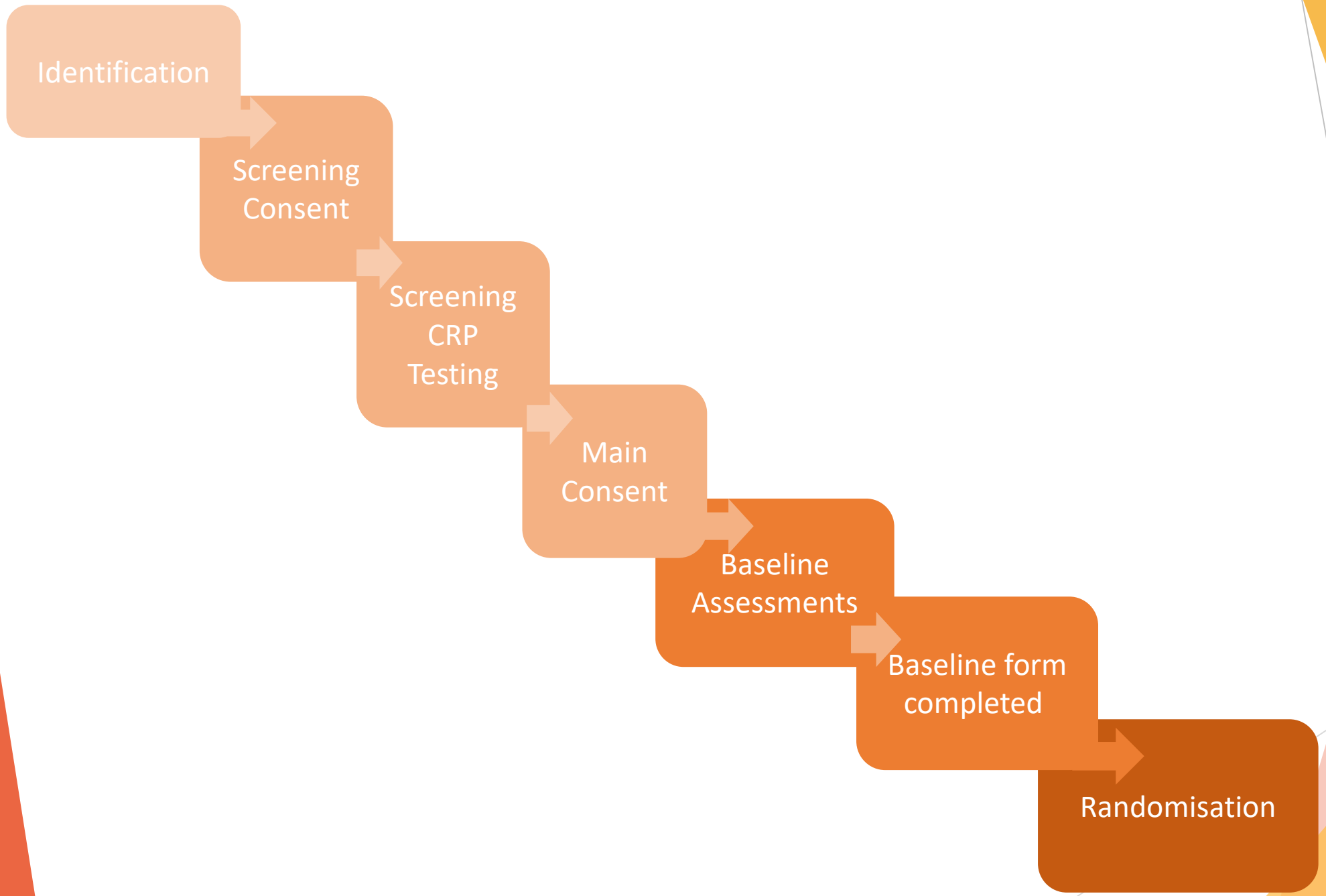
Zimbabwe

- Parirenyatwa and Harare Central Hospitals and the University of Zimbabwe Clinical Research Centre, Harare

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

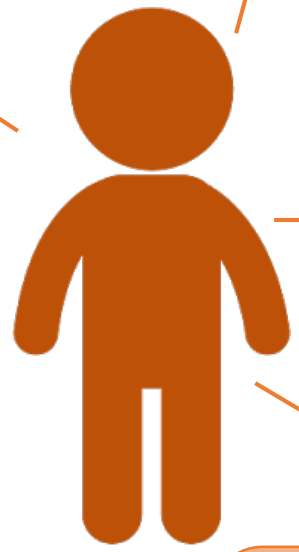
AHRI AFRICA HEALTH RESEARCH INSTITUTE

PediCAP


Identification
Screening Consent
Screening CRP Testing
Main Consent
Baseline Assessments
Baseline form completed
Randomisation

Participants

- Children aged 2 months to 6 years inclusive
- Weighing >=3kg and <30kg
- Hospitalised with severe community acquired pneumonia
- Who are about to start or who have started intravenous antibiotics for severe CAP
- With C-reactive protein >10 mg/l on a semi-quantitative point-of-care test at screening



PediCAP

Inclusion and Exclusion Criteria

Inclusion Criteria

- Aged 2 months to 6 years inclusive
- Weighing >= 3kg and <30kg (to align with weight-banded dosing schedule for the oral trial medications)
- Admitted to hospital with severe pneumonia judged to require at least 24h of intravenous antibiotics by the treating physician

Inclusion Criteria

About to initiate or already initiated

- **intravenous benzylpenicillin plus gentamicin**,
- **ampicillin plus gentamicin**,
- **benzylpenicillin or ampicillin alone**,
- **ceftriaxone alone** or **cefotaxime alone**

Received at most 24h of these intravenous antibiotics at the point of randomisation

(that is, first dose of any intravenous antibiotics must have been administered no more than 24h previously at randomisation)

Parent/carer willing to accept and adhere to all possible randomised allocations for their child, including 5 days of intravenous antibiotics, and signed written informed consent available from parent/carer

Available for follow-up for the entire study period; specifically, parent/carer willing to return with their child to clinic at 4 weeks, and be contacted at minimum by telephone at weeks 1, 2 and 3

PediCAP

Inclusion Criteria

Difficulty breathing
(with or without cough reported by parent/carer)

+

one or more the following occurring at any time from admission up to randomisation:

- Central cyanosis or hypoxaemia (room air pulse oximetry <90%) **indicating severe pneumonia**
- Any sign of severe respiratory distress: severe chest indrawing, grunting, nasal flaring, head nodding **indicating severe pneumonia**
- Signs of pneumonia
  - fast breathing (defined as respiratory rate ≥50 breaths per minute at age 2-11 months and ≥40 breaths per minute at age 1 years or older or chest indrawing)
  - PLUS a general danger sign **indicating severe pneumonia**

Inclusion Criteria
Pneumonia with general danger signs

- Tachydyspnoea, i.e. age-adapted fast-breathing or chest-indrawing
- General danger signs (WHO) relevant for PediCAP

❑ Audible stridor in a calm child

❑ Central cyanosis
❑ Severe respiratory distress or apnoea

❑ Unable to drink or breastfeed --> Severe dehydration/Shock
❑ Persistent vomiting --> Severe dehydration/Shock

❑ Lethargy (unusally sleepy) or unconciousness
❑ Convulsions

❑ Red on MUAC strap or other sign of severe malnutrition
❑ Swelling of both feed

Substudies – Additional Inclusion Criteria

- **If undergoing additional PK sampling:**

willing to provide samples and potentially to stay in hospital for up to an additional 12h (separate consent will be obtained for PK sampling which may be refused and the child still join the main trial; specific consent for PK sampling is required for inclusion in the Phase II PK trial)

- **If undergoing additional microbiological sampling:**

willing to provide samples at enrolment, discharge and week 4 (separate consent will be obtained for microbiological sampling which may be refused and the child still join the main trial)

Exclusion Criteria

- Point-of-care semi-quantitative C-reactive protein (CRP) test < 10mg/l at screening (very unlikely to represent severe pneumonia requiring antibiotics)
- Likely nosocomial pneumonia (onset >48h post-admission)
- Admitted to hospital overnight in the last 28 days (possibility of nosocomially acquired pneumonia)
- Known or anticipated need for invasive ventilation or admission to intensive care
- Clinician considers this episode to be predominantly due to reactive airways disease (e.g. asthma)

Exclusion Criteria

- Clinician considers this episode to be due to viral bronchiolitis alone in a child under 1 year
- Documented allergy to any drug from the penicillin class or contra-indications to penicillin/amoxicillin/co-amoxiclav
- Anticipated need for systemic treatment with an antibiotic other than trial regimens during hospital admission or in the following 28 days (e.g. for *Pneumocystis jiroveci*)
- On long-term antibiotics for prophylaxis or treatment (e.g. for tuberculosis treatment or cotrimoxazole prophylaxis for HIV infection)
- Previously enrolled in PediCAP

PediCAP Protocol
Participant Summary Questions

What four African countries are participating in this study?

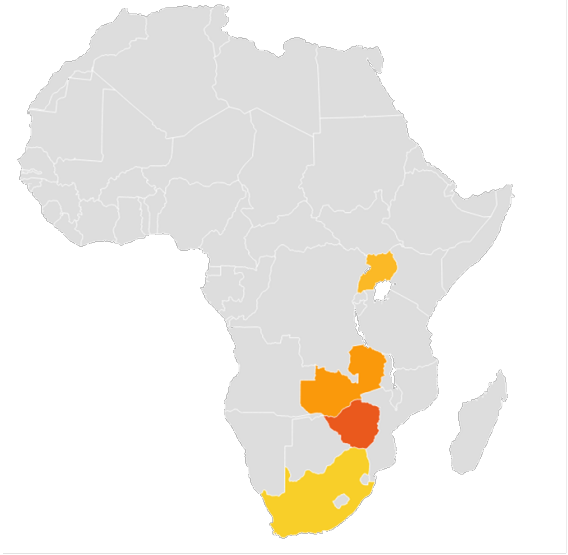
What is the age range we are recruiting for in this study?

PediCAP Protocol
Participant Summary Questions

What four African countries are participating in this study?

Zambia

Uganda



South Africa

Zimbabwe

What is the age range we are recruiting for in this study?

- Children aged 2 months to 6 years inclusive

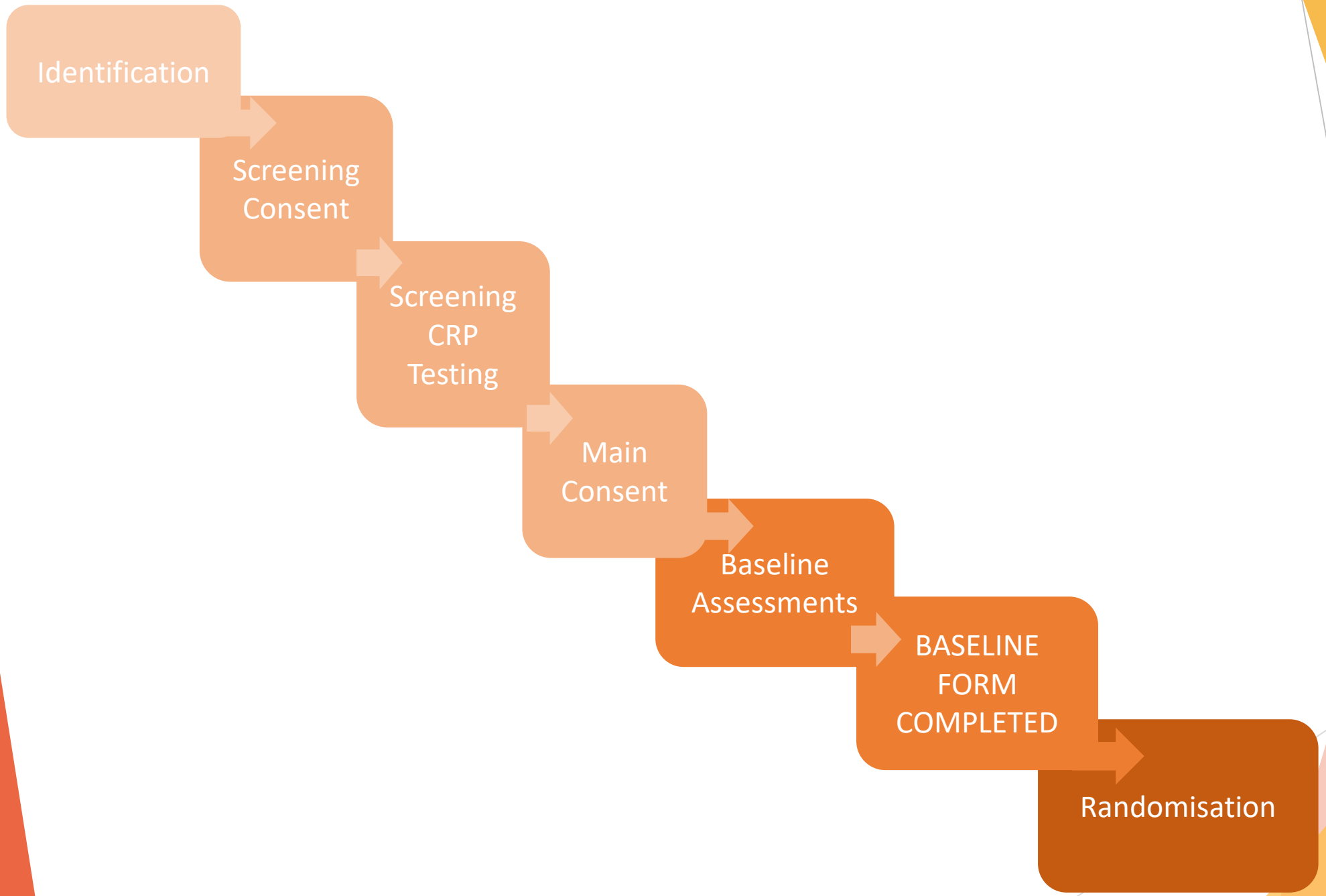
The Trial

Learning Objectives

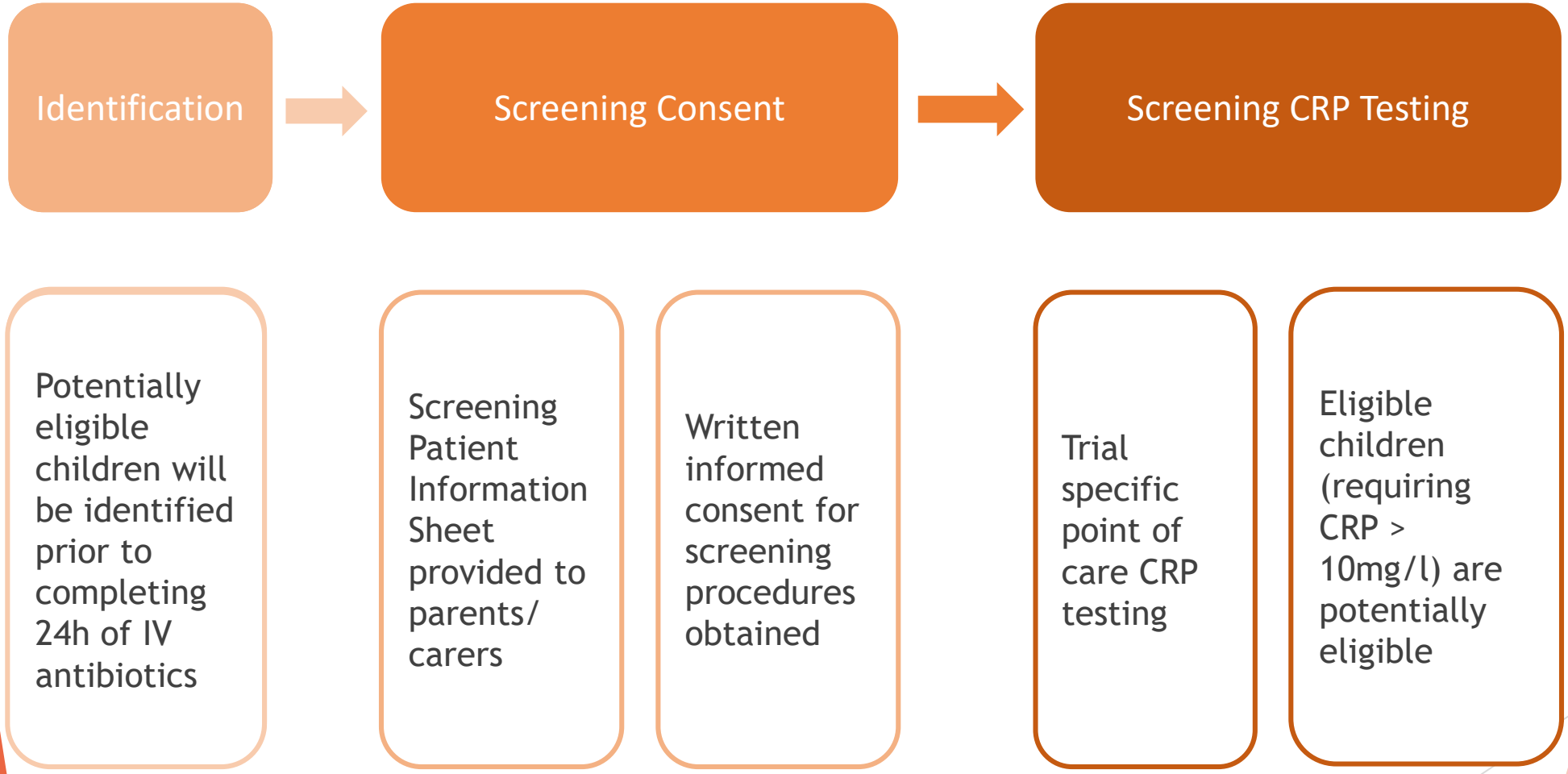
In this section:

- Screening and Recruitment
- Consent and Randomisation
- Treatments
- Trial assessments and substudies
- Early stopping and lost to follow up

Screening and Recruitment


Identification
Screening Consent
Screening CRP Testing
Main Consent
Baseline Assessments
BASELINE FORM COMPLETED
Randomisation

Screening Procedures



Consent Procedure

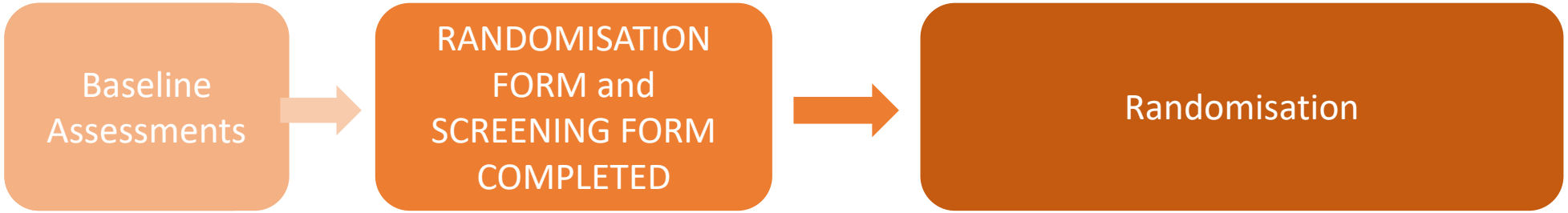
Main Consent obtained

For potentially eligible children, an information sheet for the full trial will be provided to parents/ carers

Find the time to go through everything with families – fully informed consent

Randomisation

Baseline and Randomisation



- Medical and social history
- Weight
- Vital signs
- Clinical characteristics relevant to the episode

Forms sent directly onto secure web-based trial database

Details of child's treatment allocation generated and provided to study team

Randomisation

- Eligible children should be randomised as soon as possible, prior to completing 24h of IV antibiotics
- Confirmation of eligibility criteria and written informed consent must be obtained before randomisation

MICROBIOLOGY SUBSTUDY: Nasopharyngeal and peri-rectal swabs taken as soon as possible after consent

- Randomisation for PediCAP-A will be **stratified by site**
- Randomisation for PediCAP-B will be **stratified by weight band only**

Treatments

Intravenous Antibiotics (All Children)

- At point of randomisation, children should have received **no more than 24h** of IV antibiotics
- SOC IV treatment should be at **least 24 hours for all children** (i.e minimum of two IV doses)

- Dose should follow the local standard of care which generally follow WHO recommendations where given (local SOC may differ)
- Choice made by treating physician prior to randomisation
- Those randomised to IV antibiotics will be treated for **5 days in total**

Intravenous Antibiotics (All Children)

DRUG	SCHEDULE
Ampicillin	IV/IM: 50 mg/kg every 6 hours
Benzylpenicillin (penicillin G)	IV: 50’000-100’000 U/kg every 6 hours
Cefotaxime	IV: 50 mg/kg every 6 hours or 33.3 mg/kg every 8 hours
Ceftriaxone	IV: 80 mg/kg/d as a single dose once daily OR IV/IM: 50 mg/kg every 12 hours (max single dose 4g) OR IV/IM: 100mg/kg as a single dose once daily
Gentamicin	IV/IM: 5-7.5 mg/kg as a single dose once a daily
Procain benzylpenicillin (penicillin G for IM administration)	IM: 50’000 U/kg once a day

Dosing of standard intravenous antibiotics

Oral Step-Down Procedures

- Children who have received at most 24h of intravenous antibiotics will be randomised to step-down from intravenous antibiotics when they are clinically stable and able to take oral medication

- Child should have improved clinically, be currently clinically stable or continuing to improve
- To be well enough to take medication by mouth i.e. can ingest or keep down the dispersible tablets when made up in a small amount of liquid
- May move to oral medication whilst inpatients e.g. if they are still receiving supplemental oxygen

PediCAP-A

Oral amoxicillin or oral co-amoxiclav (7:1 amoxicillin:clauvulanate) or IV antibiotics

- Children randomised to oral amoxicillin or co-amoxiclav will step-down from intravenous antibiotics when they are clinically stable and able to take oral medication to:
  - either oral amoxicillin or oral co-amoxiclav (7:1) (1:1), both as dispersible tablets
  - for a total duration of 4, 5, 6, 7 or 8 days antibiotics (1:1:1:1:1) (from start of intravenous antibiotics);
- Children randomised to the iv arm will remain on intravenous antibiotics for a total of 5 days following current WHO recommendation

PediCAP-A

Oral amoxicillin or oral co-amoxiclav (7:1 amoxicillin:clauvulanate)

FORMULATION	WEIGHT BAND	# TABLETS AM	# TABLETS PM	# TABLETS DAILY	DAILY DOSE (MG)
Amoxicillin (250mg tablets)	3 - <6kg	1	1	2	500
	6 - <10kg	2	1	3	750
	10 - <14kg	2	2	4	1000
	14 - <20kg	3	3	6	1500
	20 - <25kg	4	4	8	2100
	25 - <35kg	5	5	10	2500
Co-amoxiclav 7:1 (200/28.5mg tablets)	3 - <6kg	1	1	2	400/57
	6 - <10kg	2	2	4	800/114
	10 - <14kg	3	2	5	1000/142.5
	14 - <20kg	4	4	8	1600/228
	20 - <25kg	5	5	10	2000/285
	25 - <35kg	6	6	12	2400/342

Dosing for oral amoxicillin and co-amoxiclav

PediCAP-B
Oral co-amoxiclav (4:1 or 14:1)

- In the parallel Phase II PK trial (PediCAP-B), children who have received at most 24h of intravenous antibiotics will be randomised to step-down from intravenous antibiotics when they are clinically stable and able to take oral medication to
  - either oral co-amoxiclav 4:1 or 14:1 (1:1) for a total duration of 6 days antibiotics (from start of intravenous antibiotics)
- All children will receive at least 24h of intravenous antibiotics before stepping down to oral medication.

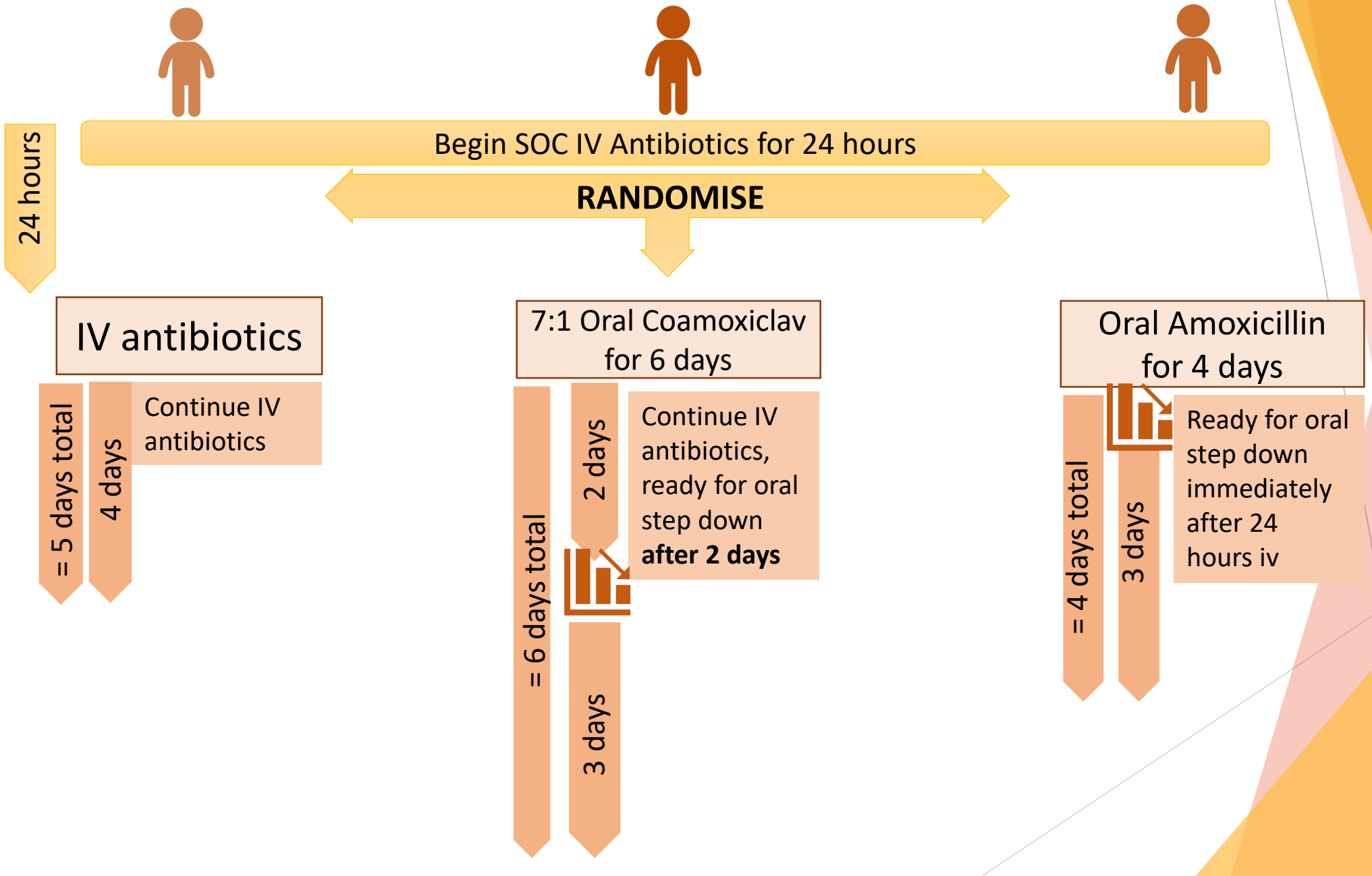
PediCAP-B

Oral co-amoxiclav (4:1 or 14:1)

FORMULATION	WEIGHT BAND	# TABLETS AM	# TABLETS PM	# TABLETS DAILY	DAILY DOSE (MG)
Co-amoxiclav 4:1 (250/62.5mg)	3 - <6kg	1	1	2	500/125
	6 - <10kg	2	1	3	750/187.5
	10 - <14kg	2	2	4	1000/250
	14 - <20kg	3	3	6	1500/375
	20 - <25kg	4	4	8	2000/500
	25 - <35kg	5	5	10	2500/625
Co-amoxiclav 14:1 (150/10.725mg)	3 - <6kg	2	1	3	450/32.175
	6 - <10kg	3	2	5	750/53.625
	10 - <14kg	4	3	7	1050/75.075
	14 - <20kg	5	5	10	1500/107.25
	20 - <25kg	6	7	13	1959/139.425
	25 - <35kg	8	8	16	2400/171.6

Dosing for oral co-amoxiclav

Total Duration of Antibiotics for PediCAP



Trial Assessments

Face to Face Assessments

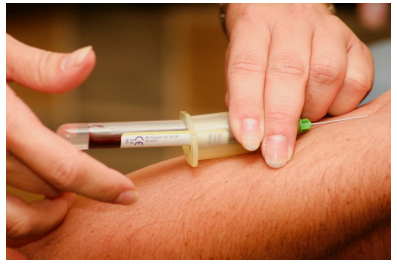
- A physical examination must be performed at each face-to-face assessment, including acute events if the child returns to the randomising site.

The following will be recorded for all face-to-face assessments:

- Vital signs (respiratory and heart rate, oxygen saturation) and temperature (during hospitalisation only)

- Symptoms and clinical signs, specific solicited side-effects and adverse events

- Concomitant care/ healthcare utilisation

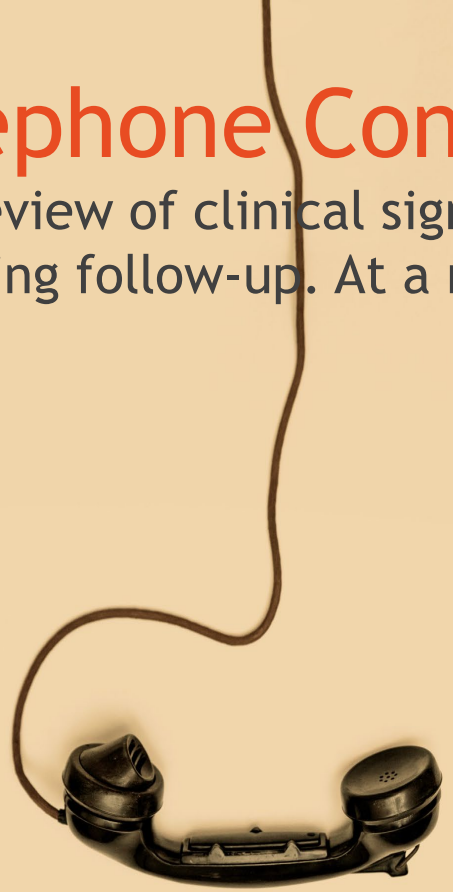


- Results of any haematology/ biochemistry/ microbiological investigations/ chest X-rays undertaken as part of the usual standard of care, but not required by the trial

- Children will be weighed on the day of step-down to oral antibiotics to ensure correct dosing and at the week 4 face to face visit.

Telephone Contacts

A review of clinical signs and symptoms must be performed at each telephone contact during follow-up. At a minimum, the following will be recorded:



- Standardised symptom checklist including review of cough, presence of rapid breathing, fever, general state and common known side effects of amoxicillin or co-amoxiclav.
- Solicited clinical adverse events since last protocol contact, including rashes, diarrhoea, vomiting, gastrointestinal events, and thrush/candida.
- Any acute illnesses requiring assessment by a healthcare provider (including traditional healers) since last protocol contact, including whether any antibiotic prescriptions were issued.
- Systemic antibiotic treatment since last protocol contact, including, as appropriate, adherence to PediCAP treatment and whether any additional/new antibiotic prescriptions were issued.
- Adherence and tolerability of PediCAP treatment, including any medication errors (week 1 only).
- Concomitant care/healthcare utilisation (including traditional healers).

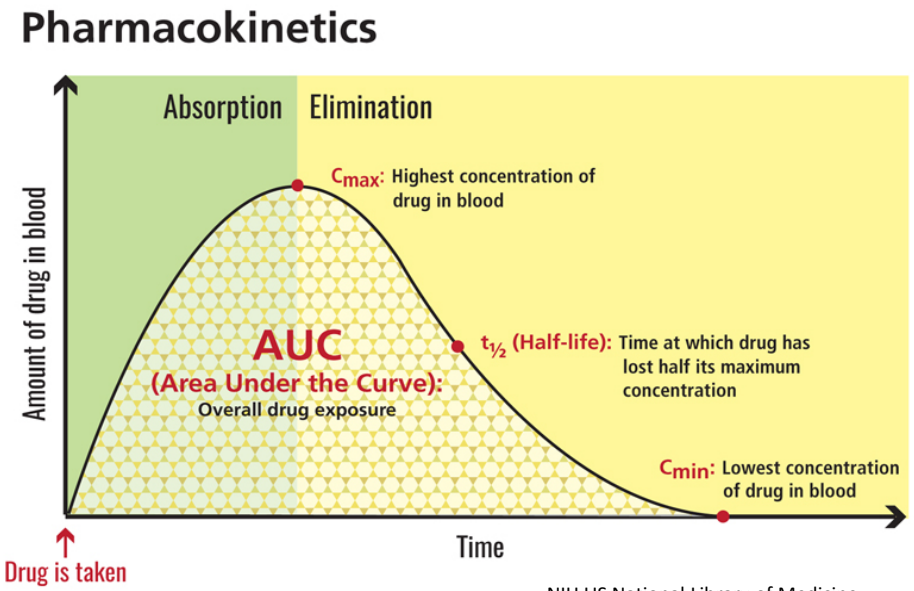
Substudies

PK Sampling Substudy

- Additional written informed consent will be obtained to take part in the PK substudy

- PK sampling will occur immediately before and then after the first morning dose

- Will consist of 5 samples per child weighing 6kg or more
  - before observed dosing (5-10 min pre-dose),
  - during early absorption (0.25-1h post dose),
  - around the expected Cmax (1-2h),
  - during early disposition (2-6h),
  - and in the terminal phase (6-12h).



NIH US National Library of Medicine

Early Stopping & Lost to Follow up

Early Stopping of Follow Up

- **The parent/carers wishes regarding trial treatment and trial follow-up should be respected at all times.**

- If a parent/carer who chooses to discontinue trial treatment for their child remains happy to follow the other trial procedures and follow-up schedule, their child may remain in the trial **“on-study, off-study-treatment”**.
- If they do not wish to remain on trial follow-up, their decision must be respected and the child will be withdrawn from trial follow-up.
- If follow-up is stopped early, the anonymised medical data collected during their participation in the trial will be kept and used in the analysis
- Consent may be withdrawn at the discretion of the parent/carer for the future use of any stored samples.
- Children who stop trial follow-up early will not be replaced.

Lost to Follow Up

- **Follow up is for 28 days**

- Telephone contact after 1, 2- and 3-weeks post randomisation to ensure that contact is maintained before the face to face follow up at week 4.
- A child will be classified as **“lost-to-follow-up”** (meaning no further attempts at contact are made) only when three unsuccessful attempts have been made to contact the parent/carer following non-attendance at the face-to-face follow-up in week 4.

PediCAP Protocol
Trial Summary Questions

When should randomisation take place for all eligible children?

What six things should be recorded at face to face assessments ?

PediCAP Protocol
Participant Summary Questions

When should randomisation take place for all eligible children?

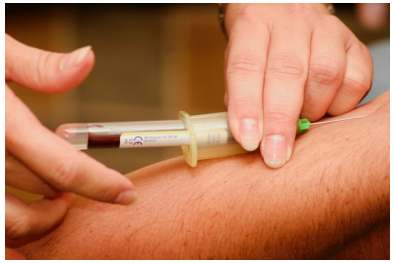
As soon as possible, prior to completing 24h of IV antibiotics

What six things should be recorded at face to face assessments ?

Vital signs

Symptoms and clinical signs,

Concomitant care/ healthcare utilisation



Results of any haematology/ biochemistry/ microbiological investigations/ chest X-rays

Weight

And Physical Examination

Questions?

Thank you for listening

PediCAP

Training Workshop
PediCAP Protocol Assessment

Please complete the following Assessment to test your learning and progress on the Pneumonia in Children workshop, covering pneumonia background, general aspects and clinical topics covered in this e-learning. There are 10 multiple choice questions (MCQs) to answer. To pass, you will need to achieve 80%.

Start the Assessment →

EDCTP

PediCAP is part of the EDCTP2 programme supported by the European Union under Grant Agreement RIA2017MC - 2023.

PediCAP Protocol Assessment

Question 1. Select the option that is NOT a trial arm that eligible children can be randomised to.

a. Oral Amoxicillin for 5 days

b. Oral 14:1 Co-amoxicillin for 6 days

c. Oral 7:1 Co-amoxicillin for 7 days

d. Oral 4:1 Co-amoxicillin for 3 days

PediCAP Protocol Assessment

That is the correct answer!

Continue to the next Question →

PediCAP Protocol Assessment

I am afraid that is incorrect……

← Try Again

Continue to the next Question →

PediCAP Protocol Assessment

Question 2. A 6 month old child weighing 8kg has been admitted with difficulty breathing and SpO2 of 89%, and is about to start on IV ampicillin plus gentamicin.

Can you approach this child and their parents to participate into the PediCAP study?

YES

NO

PediCAP Protocol Assessment

That is the correct answer!

Continue to the next Question →

PediCAP Protocol Assessment

I am afraid that is incorrect……

← Try Again

Continue to the next Question →

PediCAP Protocol Assessment

Question 3. A 5 year old child weighing 17kg was admitted 3 days ago and is presenting with difficulty breathing and signs of respiratory distress and is about to start on IV benzylpenicillin plus gentamicin.

Can you approach this child and their parents to participate into the PediCAP study?

YES

NO

PediCAP Protocol Assessment

That is the correct answer!

Continue to the next Question →

PediCAP Protocol Assessment

I am afraid that is incorrect……

← Try Again

Continue to the next Question →

PediCAP Protocol Assessment

Question 4. A 3 month old child is admitted and presenting with a cough, fast breathing and lethargy, and is has started IV ceftriaxone alone. Their parents have signed screening consent and their screening CRP results are 8mg/l.

Is this child eligible to participate into the PediCAP study?

YES

NO

PediCAP Protocol Assessment

That is the correct answer!

Continue to the next Question →

PediCAP Protocol Assessment

I am afraid that is incorrect……

← Try Again

Continue to the next Question →

PediCAP Protocol Assessment

Question 5. A 4 year old child is admitted with pneumonia. Their parents have signed screening consent and their screening CRP results are 11mg/l. They have been on IV cefotaxime alone for two days.

Is this child eligible to participate into the PediCAP study?

YES

NO

PediCAP Protocol Assessment

That is the correct answer!

Continue to the next Question →

PediCAP Protocol Assessment

I am afraid that is incorrect……

← Try Again

Continue to the next Question →

PediCAP Protocol Assessment

Question 6. A child is randomised onto the PediCAP study into the Oral amoxicillin arm for 8 days. They are ready to step down after 3 days of IV antibiotics.

What is the total duration that this child will receive antibiotics?

a. 12 days

b. 13 days

c. 14 days

d. 15 days

PediCAP Protocol Assessment

That is the correct answer!

Continue to the next Question →

PediCAP Protocol Assessment

I am afraid that is incorrect……

← Try Again

Continue to the next Question →

PediCAP Protocol Assessment

Question 7. A child is randomised onto the PediCAP study into the Oral 14:1 coamoxicillin arm for 6 days. They are ready to step down after 5 days of IV antibiotics.

What is the total duration that this child will receive antibiotics?

a. 10 days

b. 11 days

c. 12 days

d. 13 days

PediCAP Protocol Assessment

That is the correct answer!

Continue to the next Question →

PediCAP Protocol Assessment

I am afraid that is incorrect……

← Try Again

Continue to the next Question →

PediCAP Protocol Assessment

Question 8. When should a child NOT step down to oral antibiotics?

a. They are still an inpatient and on Oxygen

b. They are able to keep down dispersible tablets

c. They are unable to keep down dispersible tablets

d. They are clinically stable

PediCAP Protocol Assessment

That is the correct answer!

Continue to the next Question →

PediCAP Protocol Assessment

I am afraid that is incorrect……

← Try Again

Continue to the next Question →

PediCAP Protocol Assessment

Question 9. Which of the following statements is correct in regard to Early stopping and lost to follow up

a. Patients should be contacted unsuccessfully at least three times before deemed lost to follow up

b. Parents should be persuaded to stay on to the trial if they decide to withdraw

c. If Parents decide to discontinue treatment, they must withdraw from all study procedures

d. Children who have discontinued early must be replaced

PediCAP Protocol Assessment

That is the correct answer!

Continue to the next Question →

PediCAP Protocol Assessment

I am afraid that is incorrect……

← Try Again

Continue to the next Question →

PediCAP Protocol Assessment

Question 10. A child has been recruited for the microbiology substudy, when are the samples for the NOT collected during the study?

a. Trial Entry

b. First Dose of Step Down Antibiotics

c. Day of Discharge

d. Week 4 Follow up visit

PediCAP Protocol Assessment

That is the correct answer!

Continue →

PediCAP Protocol Assessment

I am afraid that is incorrect……

← Try Again

Continue →

Training Workshop
PediCAP Protocol Assessment

Congratulations for completing the assessment.

Your score is **XX%.**

Complete the Assessment Again →

EDCTP

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