# STRAP -Study to Reduce Antibiotic prescription in childhood Pneumonia: implementation of a validated decision rule to target antibiotic prescription in children with suspected community acquired pneumonia

*A Data Management Plan created using dmponline*

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**Project abstract:**

Achtergrond: Het onnodig voorschrijven van antibiotica draagt bij aan de ontwikkeling van antibioticaresistentie, een actuele bedreiging voor de behandeling van infecties wereldwijd. Longontsteking (pneumonie) is de meest voorkomende doodsoorzaak bij kinderen wereldwijd, en een van de meest frequente bacteriële infecties waar antibiotica voor wordt voorgeschreven. Daarentegen wordt een groot deel van pneumonieën op de kinderleeftijd veroorzaakt door virussen, waar geen antibiotica voor nodig zijn. Bij kinderen verdacht van een pneumonie is een beter onderscheid nodig tussen kinderen die wel en geen antibiotica nodig hebben. Doel: Veilige reductie van antibioticagebruik met een beslisregel (Feverkidstool) in kinderen met koorts, verdacht van longontsteking. Design: Stepped-wedge design met sequentiële implementatie van de Feverkidstool die de indicatie stelt voor antibiotica bij kinderen verdacht van longontsteking in 7 kindergeneeskundige spoedeisende hulp afdelingen. Populatie: Kinderen met koorts (1 maand – 5 jaar) die de kindergeneeskunde spoedeisende hulp bezoeken met verdenking longontsteking in 7 ziekenhuizen in Zuid-West en Centraal Nederland. Uitkomsten: Primair: Aantal antibioticavoorschriften en falen van de strategie. Secundair: compliantie aan het advies van de Feverkidstool, duur en dosis van antibiotica, aantal complicaties van pneumonie, kosten van uitkomstmaten. Interventie: Feverkidstool (beslisregel) die de kans op pneumonie schat voor de individuele patient en de indicatie stelt voor antibiotische behandeling. Analyse: Met een ‘general linear mixed model’ worden verschillen in primaire en secundaire uitkomsten vergeleken en gecorrigeerd voor ziekenhuis, leeftijd, urgentie en seizoen. Kostenanalyse wordt verricht vanuit gezondheidszorgperspectief, en vergelijkt kosten en effecten voor- en na implementatie. Power analyse: een steekproef van 1100 kinderen is gevoelig voor het vaststellen van een 10% (laagrisico) tot 15% reductie (matig risico) van antibiotica voorschrift bij kinderen verdacht van pneumonie. Tijdsschema M 0-3: Voorbereiding; M 4-15: Basis dataverzameling; M 13-15: Implementatie; M16-27: postimplementatie dataverzameling; M 28-30: Datanalyse, verslaglegging. Impact: De Feverkidstool bevordert toepassing van huidige inzichten in beperking van antibioticavoorschrift bij kinderen met pneumonie in de routine zorg.

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## 1. General features of the project and data collection

**1.1 Project leader contact details**

R Oostenbrink
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**1.2 I have composed my DMP with the assistance of a data stewardship (or management) expert. List his or her name, function, organisation/department, phone number and email address.**

- The expert is connected to my department or institution (please explain his/hr expertise related to data stewardship)

BWD de Jong (DMO erasmusMC)

**1.3 In collecting data for my project, I will do the following:**

- Generate new data

we will collect new data from 8 participating hospitals

**1.4 In my research, I will use:**

- Exclusively quantitative data

**1.5 I will be reusing or combining existing data, and I have the owner's permission for that.**

- No, I will not be reusing or combining existing data

**1.6 In collecting new data, I will be collaborating with other parties.**

- Yes, the new data will be (partly) provided by a project partner or supplier

project partners of the other 7 participating hospitals will provide additional data

**1.7 I am a member of a consortium of 2 or more partners. Clear arrangements have been made regarding data management and intellectual property. (also consider the possible effect of changes within the consortium on issues of data management and intellectual property)**

- Yes, clear arrangements have been made regarding data management and intellectual property through a consortium agreement

**1.8 I can give an estimate of the size of the data collection; specifically, the number of participants or subjects (“n=”) in the collection and its size in GB/TB**

- Yes (please specify)

1000 participants
<10GB

**1.9 The following end products I will make available for further research and verification (please elaborate briefly)**

- Biobank
- Syntaxes

- Data documentation
- (Several versions of) processed data

Data will be collected through Open clinica and processed and analysed by SPSS
Syntaxes are limited to processing datasyntaxes
Biobank samplesare stored at the department MMIZ of ErasmusMC, freezers and fridges are monitored and back up equipment is available.

**1.10 During the project, I will have access to sufficient storage capacity and sites, and a backup of my data will be available. (please elaborate briefly)**

- Yes, I will make use of my institution's standard facilities for storage and backup of my data

## 2. Legislation (including privacy)

**2.1 I will be doing research involving human subjects, and I am aware of and compliant with laws and regulations concerning privacy sensitive data.**

- Yes, I will involve human subjects in my research. I will comply with the Algemene Verordening Gegevensbescherming (AVG)
- Gedragscode Goed gebruik van lichaamsmateriaal (Code of Conduct for Responsible Use of Human Tissue)
- The Wet Medisch-Wetenschappelijk Onderzoek met Mensen (WMO, or Medical Research (Human Subjects) Act) applies to my project; I will have it reviewed by a Medical Research Ethics Committee. In addition I will comply with the Kwaliteitsborging Mensgebonden Onderzoek (Quality Assurance for Research Involving Human Subjects)

**2.2 I will be doing research involving human subjects, and I have (a form of) informed consent from the participants for collecting their data.**

- Yes (please describe the form this consent takes)

standardized METC form of EMC, containing....., evt weblink

**2.3 I will be doing research involving human subjects, and I will protect my data against misuse.**

- Yes, the data will be pseudonymised. (please explain how this will be done, and by which organisation) and

data contain age, gender, symptoms and signs, therefor pseudonymised
Subjects are characterised by research number, this key-
list that links resaerch number to patient identification number of the hospital will be stored separately at the institutions standars facilities for storage and back

**2.4 I will stick to the privacy regulations of my organisation**

- Yes

Yes, we will comply to the ErasmusMC research code

## 3. Making data findable

**3.1 The data collection of my project will be findable for subsequent research. E.g., on a catalogue, a web portal, or through the search enginge of the repository (note: this is key item 3, which you should report to ZonMw at the end of your project).**

- Yes, it can be found through an online (metadata) catalogue or web portal (please specify)

We have been advised to use DANS as both archive and repository facility. This will be organised in due time.

**3.2 I will use a metadata scheme for the description of my data collection (note: this is key item 7, which you should report to ZonMw at the end of your project).**

- Yes, I will use a generic metadata scheme (please specify)

We will use 'dataCITE' complying with use of DANS

**3.3 I will be using a persistent identifier as a permanent link to my data collection (note: this is key item 1, which you should report to ZonMw at the end of your project).**

- Yes, I will be using the DOI code

This will be available in due time, after completing uploading the data to DANS (see 3.1)

## 4. Making data accessible

**4.1 Once the project has ended, my data will be accessible for further research and verification.**

- Yes, after an embargo period (please explain)

after publication of main article

**4.2 Once the project has ended, my data collection will be publicly accessible, without any restrictions (open access).**

- No, there will be access restrictions to my data collection (please explain)

a request need to be submitted to principle investigator or to the head of the subdepartment General Pediatrics of ErasmusMC (Prof. Dr. HA Moll).

**4.3 I have a set of terms of use available to me, which I will use to define the requirements of access to my data collection once the project has ended (please provide a link or persistent identifier; also note that this is a key item 4, which you should report to ZonMw at the conclusion of your project).**

- Not yet, my institution will draft a set of terms of use with the help of a legal advisor

**4.4 In the terms of use restricting access to my data, I have included at least the following:**

- The sharing of data for commercial purposes, taking into account the provisions of state aid law
- A steering committee, programme committee or project leader will be charged with approving data requests
- Whether or not the data set may be linked with another data set (for reasons of privacy)
- The permitted period of use of the data set
- Collaboration in using the data set, including agreements on publication and authorship
- The manner in which the data set can be accessed
- Conditions related to data security

we donot have a defined set of restricting terms of use. However, on request of datasharing, we will consider the terms of use as stated above

## 5. Making data interoperable

**5.1 I will select a data format, which will allow other researchers and their computers (machine actionable) to read my data collection (note: this is key item 5, which you should report to ZonMw at the end of your project).**

- Yes (please specify)

datasets can be converted to csv files (data) and text files (syntaxes)
We have available SPSS (.sav and .sps file), and R workspaces

**5.2 I will select a terminology for recording my data (e.g., code, classification, ontology) that allows my dataset to be linked or integrated with other datasets (note: this is key item 6, which you should report to ZonMw at the conclusion of your project).**

- Yes, metadata standard (please specify)

Standardized questionaire templates
datadictionary is available as text file and SPSS (.sav) file

**5.3 I will be doing research involving human subjects, and I have taken into account the reuse of data and the potential combination with other data sets when taking privacy protection measurements.**

- Yes, the participants have given their permission for reuse of the data, and the data have been pseudonymised

we have included this item in the informed consent, subjects could opt for reuse of data yes/no

## 6. Making data reusable

**6.1 I will ensure that the data and their documentation will be of sufficient quality to allow other researchers to interpret and reuse them (in a replication package).**

- I will perform quality checks on the data to ensure that they are complete, correct and consistent (please explain)
- I will document the research process (please explain)

We have a protocol and  SAP

**6.2 I have a number of selection criteria, which will allow me to determine which part of the data should be preserved once the project has ended. (see also question 1.9 and 6.1)**

- No

all data preserved

**6.3 Once the project has ended and the data have been selected, I can make an estimate of the size of the data collection (in GB/TB) to be preserved for long-term storage or archival.**

- Not yet (please explain)

estimated <10GB

**6.4 I will select an archive or repository for (certified) long-term archiving of my data collection once the project has ended. (note: this is a key item, which you should report to ZonMw at the conclusion of your project)**

- Yes, and this archive has a data seal of approval (please specify the archive)

data will be stored for archive and repository through DANS

**6.5 Once the project has ended, I will ensure that all data, software codes and research materials, published or unpublished, are managed and securely stored. Please specify the period of storage.**

- Yes, in accordance with VNSU guidelines (please specify the number of years)

15 years for data, 10 years for biobank material

**6.6 Data management costs during the project and preparations for archival can be included in the project budget. These costs are:**

- Unknown (please explain)

no budget preserved as not foreseen during start of the project

**6.7 The costs of archiving the data set once the project has ended are covered.**

- Not yet (please explain)

no budget preserved as not foreseen during start of the project
storage in DANS is free of charge