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

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

BWD de Jong (DMO erasmusMC)

- Generate new data

we will collect new data from 8 participating hospitals

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

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

1000 participants
<10GB

- Biobank
- (Several versions of) processed data
- Data documentation
- Syntaxes

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.

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

2. Legislation (including privacy)

- 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)
- Yes, I will involve human subjects in my research. I will comply with the Algemene Verordening Gegevensbescherming (AVG)

- Yes (please describe the form this consent takes)

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

- 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 backup of data

- Yes

Yes, we will comply to the ErasmusMC research code

3. Making data findable

- 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.

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

We will use 'dataCITE' complying with use of DANS

- 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

- Yes, after an embargo period (please explain)

after publication of main article

- 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).

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

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

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

- 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

- Yes, metadata standard (please specify)

Standardized questionaire templates

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

- 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

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

We have a protocol and SAP

- No

all data preserved

- Not yet (please explain)

estimated <10GB

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

data will be stored for archive and repository through DANS

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

15 years for data, 10 years for biobank material

- Unknown (please explain)

no budget preserved as not foreseen during start of the project

- Not yet (please explain)

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