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Controlling antibiotic resistance through education of mothers and healthcare providers to reduce the unnecessary use of antibiotics in pregnancy, childbirth and for young children

Submission date
04/06/2020

Recruitment status
No longer recruiting

Registration date
24/06/2020

Overall study status
Completed

Last Edited
12/01/2021

Condition category
Infections and Infestations

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Antibiotics are life-saving medicines. They are essential to treat common infections during pregnancy, and to reduce both maternal and infant deaths. Overall use of antibiotics in general, but especially non-indicated use and misuse are key drivers of antibiotic resistance (ABR). The consequences of ABR, and therefore being unable to treat infections, are severe and include increased levels of disease and death, and increased healthcare costs.

Nonetheless, studies show alarmingly high non-indicated use of antibiotics for normal vaginal deliveries in many parts of the world. Similarly, the irrational use of antibiotics is reported for children. Little is known regarding antibiotic use and ABR in Lao PDR (Laos).

This study aims to fill the identified knowledge gaps regarding antibiotic use in relation to pregnancy, childbirth and early childhood in Laos with the long-term aim to contain ABR by reducing unnecessary use of antibiotics.

Who can participate?
Pregnant women and mothers whose infants are born during the study period who will live within the study area for the following 24 months. Healthcare providers (HCPs) such as medical doctors, assistant doctors, midwives, nurses, pharmacists, assistant pharmacists at the Vientiane provincial hospital or district hospitals and health centres in the study area.

What does the study involve?
The planned educational measures comprises training workshops, educational materials and social media campaign over 12 months directed at both mothers and HCPs. For 12 months before and after the education period there will be assessment on the change to how antibiotics are being used using patient notes. Additionally, focus group interviews with pregnant women will be used to collect information on knowledge and attitudes on antibiotic use in pregnancy, during delivery and for their children during antenatal care visits and at home after birth.

Interviews with healthcare providers will also be used to assess their knowledge and attitudes, and their use of antibiotics for pregnant women, during delivery and for children.

What are the possible benefits and risks of participating?
Risk and benefits for the study participants have been carefully considered. During the data collection process, pregnant women and mothers of young children will be interviewed about their knowledge, attitudes, and practices regarding antibiotic use and ABR. There is a risk that some questions may be perceived as intimidating and cause stress, since women may be afraid that investigators are questioning their knowledge and practices. For HCPs, participation in the study may cause additional workload related to answering interview questions and filling in additional forms. However, it is believed that the short and long- term outcomes of the study overcome the possible risks attributable to this study. All researchers involved in the study will work together to minimize potential risks and stress factors for the study participants at the same time assuring them of the benefits.

Where is the study run from?
Feuang district hospital and Vangvieng District Hospital (lead centers) and 6 further health centres in each of Feuang and Vangvieng (Laos)

When is the study starting and how long is it expected to run for?
From October 2018 to December 2021

Who is funding the study?
Southeast Asia - Europe Joint Funding Scheme for Research and Innovation, via Swedish Research Council (Sweden)

Who is the main contact
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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2018-01027_3

Study information

Scientific Title
Containment of Antibiotic REsistance - measures to improve antibiotic use in pregnancy, childbirth and young children (CAREChild): a protocol of a prospective, quasi-experimental interventional study in Lao PDR

Acronym
CAREChild

Study objectives
An educational intervention will reduce the antibiotics administered for uncomplicated vaginal deliveries and lead to an improvement in knowledge regarding antibiotic use and resistance of both community and HCPs

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/03/2019, the National Ethics Committee for Health Research, Ministry of Health of Laos (Ban Kaognod, Sisattanack district, Vientiane, Laos; +85631250670 Ext 208; khampheng.phongluxa@gmail.com), ref:031/NECHR

Study design
Multi-centre prospective quasi-experimental interventional study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Community

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a patient information sheet which is available in Lao language.

Health condition(s) or problem(s) studied
Antibiotic use and antibiotic resistance among pregnant women and children under 2 years of age

Interventions
This study plans for 1-month intervention preparation in September 2020, followed by 3-month long intervention between October and December 2020. After completion of the intervention the research team aims to sustain some of the intervention activities e.g. posters display until the end of the study period.

The intervention consists of several components tailored to healthcare practitioners (HCPs) and the community:
1. A participatory, iterative process-based model for improvement will be used as a conceptual framework for developing, testing, and implementing changes in the proposed intervention. The Plan-Do-Study-Act cycle allows the changes in the intervention to be tested on a small scale, building on the learning from these cycles in a structured way before the full-scale implementation. Results from this formative phase showed that almost all HCPs have access to a mobile phone and would accept an intervention provided via online platforms or social media. Although there are several treatment guidelines in place at the national level, there are no specific guidelines regarding intrapartum antibiotic use. Therefore, several interventional components will be targeted to HCPs:
1.1. Educational workshops with key content on the selection of antibiotics per indication, use of broad vs narrow-spectrum antibiotics, and feedback on qualitative and quantitative findings. Workshops will be delivered by a facilitator using powerpoint, case studies, presentation of support tools (e.g. alcohol-based hand rub), and role-playing. These workshops will take place on several occasions during 3 months intervention period and the facilitator will use Train the Trainers approach.
1.2. Educational tools (leaflets, handouts) regarding: antibiotic use during pregnancy, childbirth, and to treat children; antibiotic resistance (ABR); and infection prevention and control will be developed and provided by the study team to each HCP via both traditional (at health care facilities) and online channels.

1.3. Short, acceptable messages will be developed and send regularly from a trusted source (i.e. Lao Tropical and Public Health Institute) via WhatsApp to all HCPs who participated in the workshops.
1.4. A revision of existing curricula for HCPs educational tracks and, if needed, initiation of recurrent training regarding intrapartum antibiotic use will take place. A collaboration with the national Obstetrics and Gynaecology Association will be initiated to work on the development of local prescribing guidelines.
2. Women are usually the main caregivers of the children in the community and often the main decision-makers regarding health care seeking behavior, and so have a great impact on the use of antibiotics among pregnant women and children. Simple and inexpensive interventions using short text messages have been widely used in LMICs and some of them showed to be a potent tool for behavioral change. The results from the formative phase showed that initially planned mHealth intervention will not be feasible to target community members. Mobile phone ownership is as low as 30% among the rural population and the male, head of household, often is in charge of the phone. Therefore, the following intervention components will be used:
2.1. Educational workshops that will cover a broad range of topics e.g. antibiotic use during pregnancy, hygiene and self- care during pregnancy and delivery (in case of home deliveries) and after delivery, breastfeeding and other feeding practices, vaccinations, caring for a sick child, antibiotic use for children. The workshops will be organized in the villages on several occasions during the intervention period, delivered by a facilitator and supported by local health staff. The study will also aim to ask local Lao Women´s Union to support and endorse the activities.
2.2. Several well-accepted communication channels such as posters and radio campaigns to convey the key message on prudent antibiotic use during pregnancy and for children will be used. Posters will be displayed in villages e.g. around intersections or by residents' gathering places, such as the door of the supermarket or village clinic or pharmacy, or outer wall of a house located on the main road. Radio campaigns will be designed and delivered as short role-playing scenarios e.g. newly delivered women and HCPs talking about the need for antibiotics after delivery in decided broadcasting time.

In order to assess the impact of the 3 month intervention on pregnant women and mothers, and HCPs, data on antibiotic use will be collected from patient records at the included health facilities for 12 months before the interventions (from -12 months), during the 3 month intervention period, and 12 months after the intervention (total 27 months). The impact of the intervention will be evaluated through time series analysis.

In addition, focus group discussions will be organized with women and individual interviews with key stakeholders to explore their perceptions regarding antibiotic use. These will occur at 12 months before the intervention and immediately following the intervention.

Faecal samples for culturing Escherichia coli and Klebsiella spp. and antibiotic susceptibility testing will be taken before, during, and six months after delivery to determine colonization of resistant strains.

Intervention Type
Behavioural

Primary outcome measure
The proportion of uncomplicated normal deliveries for which antibiotics were used measured using data on antibiotic use for each delivery collected continuously from patient records for 27 months: from 12 months before the intervention, during the intervention (3 months), and 12 months after the intervention.

Secondary outcome measures
1. Pregnant women and mothers' knowledge, attitudes, and reported practices regarding antibiotic use during pregnancy and for children and antibiotic resistance (ABR) measured using repeated structured interviews performed at 3 time points: before the intervention (during pregnancy and within the 6 months after delivery) and within the 6 months after the intervention
2. Perceptions of pregnant women and mothers regarding antibiotic use and resistance during pregnancy, delivery, and for children under two explored using focus group discussions at 2 time points: 1 year before and within 3 months after the intervention
3. Healthcare practitioners (HCPs) knowledge, attitudes and reported practices regarding antibiotic use for pregnant women, during delivery and for children and antibiotic resistance (ABR) measured using repeated structured interviews performed at 2 time points: 1 year to 6 months before, and within 6 months after the intervention
4. Perceptions of HCPs towards antibiotic administration to pregnant women, during delivery and for children under two explored using individual interviews at 2 time points: 1 year before and within 3 months after the intervention
5. The proportion of children under 2 years of age where antibiotics have been used measured using data on antibiotic use for children under 2 years of age measured using repeated structured interviews on mothers' knowledge, attitudes, and reported practices regarding antibiotic use for children and antibiotic resistance performed at 2 time points: within the 6 months after delivery and within the 6 months after the intervention
6. The proportion of samples with ESBL or multidrug-resistant producing bacteria and other relevant resistances pattern to tested antibiotics (only pre-intervention phase) measured using fecal samples collected from all pregnant women before delivery, during delivery from women and their newborn children (meconium) and 6 months after delivery from mothers and their children
7. The proportion of caesarean section deliveries where antibiotics are given measured using data on antibiotic use in caesarean section deliveries collected continuously from patients' records for 27 months: 12 months before the intervention, during the intervention (3 months), and 12 months after the intervention

Overall study start date
01/10/2018

Completion date
31/12/2021

Eligibility

Key inclusion criteria
Pregnant women/mothers:
1. 3rd trimester on enrolment and who, after the enrolment, plan to stay in the area for the next 24 months
2. Whose infants are born during the study period
3. Willing to participate in the study

Healthcare providers (HCPs):
1. All medical doctors, assistant doctors, midwives, nurses, pharmacists, assistant pharmacists at the Vientiane provincial hospital, district hospitals or health centres in Feuang or Vangvieng as well as pharmacists and assistant pharmacists at private pharmacies in these districts.
2. Some HCPs will be invited to participate in individual qualitative interviews:
2.1. Private providers (in private clinics and pharmacies) in the study area

2.2. Representatives from central level such as Ministry of Health, university and professional organizations
2.3. Providers from the public healthcare facilities involved
2.4. HCPs and policy makers from the Maternal and New-born Hospital (MNH) in Vientiane capital, where women from different parts of the country come for ANC and consultation

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
600 pregnant women, 200 healthcare providers

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
12/09/2019

Date of final enrolment
30/03/2020

Locations

Countries of recruitment
Lao People's Democratic Republic

Study participating centre
Feuang district hospital
Feuang district health office
Vientiane Provincial Health Department
Vientiane province
Feuang
Lao People's Democratic Republic
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Study participating centre
NaAng Health Centre
Feuang district health office
Vientiane Provincial Health Department
Vientiane province
Feuang

Lao People's Democratic Republic
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Study participating centre
Pakgua Health Centre
Feuang district health office
Vientiane Provincial Health Department
Vientiane province
Feuang
Lao People's Democratic Republic
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Study participating centre
Pholsavath Health Centre
Feuang district health office
Vientiane Provincial Health Department
Vientiane province
Feuang
Lao People's Democratic Republic
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Study participating centre
Pholyeng Health Centre
Feuang district health office
Vientiane Provincial Health Department
Vientiane province
Feuang
Lao People's Democratic Republic
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Study participating centre
Pholbeng Health Centre
Feuang district health office
Vientiane Provincial Health Department
Vientiane province
Feuang
Lao People's Democratic Republic
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Study participating centre

Phasang Health Centre
Feuang district health office
Vientiane Provincial Health Department
Vientiane province
Feuang
Lao People's Democratic Republic
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Study participating centre
Vangvieng District Hospital
Vangvieng district health office
Vientiane Provincial Health Department
Vientiane province
Vangvieng
Lao People's Democratic Republic
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Study participating centre
Somboun Health Centre
Vangvieng district health office
Vientiane Provincial Health Department
Vientiane province
Vangvieng
Lao People's Democratic Republic
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Study participating centre
Namone Health Centre
Vangvieng district health office
Vientiane Provincial Health Department
Vientiane province
Vangvieng
Lao People's Democratic Republic
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Study participating centre
Phatang Health Centre
Vangvieng district health office
Vientiane Provincial Health Department
Vientiane province
Vangvieng
Lao People's Democratic Republic
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Study participating centre
Namouang Health Centre
Vangvieng district health office
Vientiane Provincial Health Department
Vientiane province
Vangvieng
Lao People's Democratic Republic
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Study participating centre
Phonkha Health Centre
Vangvieng district health office, Vientiane Provincial Health Department
Vientiane province
Vangvieng
Lao People's Democratic Republic
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Study participating centre
Thin-on Health Centre
Vangvieng district health office
Vientiane Provincial Health Department
Vientiane province
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Sponsor information

Organisation
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Sponsor type

University/education

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ROR
https://ror.org/056d84691

Funder(s)

Funder type
Government

Funder Name
Southeast Asia - Europe Joint Funding Scheme for research and innovation

Results and Publications

Publication and dissemination plan
Findings from this project will be disseminated to a range of stakeholders, conference presentations (Lao National Health Research Forum), consortium meetings, symposia and networking events. As part of the project implementation process, we will feedback results to local stakeholders, authorities, policy makers and community members via various recognized communication channels. The local consortium partners will be responsible to assure the successful communication with relevant stakeholders. In addition, if feasible and appropriate dissemination through mass media will be done.

Several publications in peer-reviewed international or national journal such protocol, primary outcome, baseline characteristics of participants are planned.

Intention to publish date
30/07/2020

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	19/11/2020	07/01/2021	Yes	No