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Randomised Exposure Study of Pollution Indoors and Respiratory Effects (RESPIRE): the effect of reducing exposure to smoke from traditional woodstoves on child pneumonia in rural Guatemala

Submission date
22/09/2009

Recruitment status
No longer recruiting

Registration date
14/10/2009

Overall study status
Completed

Last Edited
16/11/2011

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
http://ehs.sph.berkeley.edu/guat/page.asp?id=02

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NIEHS #R01ES010178

Study information

Scientific Title
Woodsmoke exposure and childhood acute lower respiratory infections in Guatemala: a randomised intervention

Acronym
RESPIRE

Study objectives
Acute lower respiratory infection (ALRI) incidence in children and pollution exposure will be reduced in the intervention group (children who reside in a household with a chimney woodstove) versus the control group (children who reside in a household that uses an open woodfire for cooking and heating).

Acute lower respiratory infections (ALRI) are the chief killer of children. Most cases are pneumonia and the majority occur among poor children under five years in developing countries. Poverty might be said to be the primary cause, which manifests as malnutrition, including micro-nutrient deficiencies, and lack of access to medical care. Another attribute of poverty is household indoor air pollution (HAP) from use of unprocessed solid fuels such as biomass (wood, animal dung and crop wastes) and coal in simple stoves. A meta-analysis of published observational studies found that young children exposed to smoke from household solid fuel use had a rate of ALRI twice that of children not exposed or where clean fuels were used. Recent studies have shown similar ALRI risks associated with short-term air pollution measurements and other indicators of exposure.

The substantial indoor concentrations of important health-damaging pollutants which result from the use of these fuels are thought to explain the relationship with ALRI. As with tobacco smoke, there are thousands of compounds in gaseous and aerosol forms found in biomass fuel smoke, including dozens with effects that include immune system suppression, severe irritation, inflammation, cilia toxicity, and carcinogenicity. Small particles are typically used as an indicator of the health risk for these mixtures, and in households using biomass fuels without effective chimneys are typically found in concentrations 10 to 100 times higher than health-based guidelines.

Viral agents play an important role in ALRI, although it is thought that most deaths occur through bacterial infection, which may occur with or without initial viral infection. Of the viral agents, respiratory syncytial virus (RSV) is the most common, although its importance varies by season. Evidence to date about the relationship between solid fuel smoke pollution and risk of RSV illness, is conflicting. One study from the Gambia reported reduced risk of severe RSV illness with higher exposure to cooking smoke, raising the possibility of a differential effect on viral and bacterial ALRI.

The evidence from existing studies of ALRI risk associated with solid fuel use is limited by a range of methodological issues. All used observational designs which carry the inherent difficulty of residual confounding from the association between solid fuels and other poverty-related ALRI risk factors, particularly nutrition. Studies used a mix of hospital and community-based case-finding: those using the latter will have had particular difficulty distinguishing lower respiratory tract infections from acute upper respiratory tract infections (AURI). This is important as the more common AURI may have a quite different relationship with air pollution, and is not responsible for significant morbidity or mortality. Since few studies have assessed indicators of ALRI severity (e.g. hypoxaemia), and none has attempted to differentiate all ALRI by aetiologic agent (viral versus bacterial), it has not been possible to assess the impact of HAP on factors known to increase case fatality. Almost none of the studies carried out pollution assessment, relying instead on indirect exposure indicators such as fuel or stove type, or whether a child is carried on the mother's back during cooking - methods which are inevitably associated with substantial exposure misclassification. Finally, lack of blinding may have led to bias.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Committee for the Protection of Human Subjects, University of California Berkeley, approved in October 2002 and renewed anuually (ref: 2003-8-165)
2. Institutional Review Board, Centers for Disease Control and Prevention, US Government, approved in August 2002 (ref: 3452)
3. Ethics Committee Review Board, Universidad del Valle de Guatemala, approved on the 11th October 2002 and renewed annually
4. Research Ethics Committee, Liverpool School of Tropical Medicine, approved on the 10th October 2001 and renewed annually (ref: 01.68)

Study design
Single centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Screening

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Acute respiratory tract infection (ARI) in children under 18 months

Interventions
The intervention group was offered a chimney stove (plancha) at the beginning of the study. The improved chimney stove was locally made, well-liked by people in the community, and the stove of choice for both independent buyers and community stove programmes. Pilot work confirmed that the plancha met all cooking and space-heating needs, achieved a 8 - 10 fold reduction in kitchen pollution levels and (depending on design, condition and how it was used) a modest saving in wood fuel in everyday use.

The control group continued to use the traditional open fire, in effect with no change to usual practice. All control households were offered an improved stove to be installed on completion of household surveillance (when child reached 18 months).

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Physician-diagnosed pneumonia in children through 18 months of age. Pneumonia case finding and management were based on the Integrated Management of Childhood Illness (IMCI) Strategy, developed by World Health Organization (WHO)/United Nations Children's Fund (UNICEF). This approach was selected because:
1. Experience has demonstrated that locally recruited field staff can be trained to assess ALRI and other common conditions using this method
2. In terms of case definition, it is sufficiently valid and consistent with most other recent population-based field studies of ALRI
3. There are well developed training materials and procedures for both case finding and management
4. It integrates case finding with clinically effective management of sick children

Child health outcomes were assessed through weekly home visits by trained field workers, with referral to study physicians working in local community centres to maintain blindness to interventions status for clinical examination. Follow-up of children were from age at initial recruitment (birth to 4 months) until they reached 18 months of age. The fieldworkers, trained in IMCI, assessed and identified all children with rapid breathing, in addition to other signs of ALRI and the WHO-defined general danger signs. The rationale for carrying out the home visits at weekly intervals was based on the duration of pneumonia, in particular the duration of visible signs (principally fast breathing and chest indrawing). Estimates of this vary and depend on definitions of when an episode finishes. Weekly visits allowed almost all cases of ALRI to be identified through direct observation of the sick child, with a minority by mother's recall of the most relevant signs. Maternal recall of these signs does not have a high sensitivity and specificity, and was kept to a minimum.

Children meeting criteria for possible ALRI (or other significant illness) were referred to one of the study doctors who carried out a clinical examination including pulse oximetry. All children with a diagnosis of pneumonia were offered a direct antigen test for RSV, and a chest X-ray). Chest X-rays were carried out initially at San Marcos Hospital and subsequently at a private clinic to ensure quality control, normally within 24 - 48 hours of the initial assessment by the study doctor, subject to parental consent. All X-rays images were stored (scanned), and read by independent reviewers, blind to intervention status, using WHO training software and

procedures. Children meeting the criteria for referral to hospital were admitted (subject to parental consent) to San Marcos hospital. All children admitted with suspected pneumonia received a chest X-ray, as per usual practice at this hospital. All children diagnosed with ALRI or other severe conditions by study MDs were offered free treatment under normal medical protocols.

Definition of new episodes:
New episodes were defined, drawing on current practice for ALRI field studies, as follows:
1. A sick child meeting the criteria for ALRI less than 15 days after apparent recovery from an earlier episode is regarded as a relapse of the first episode
2. A sick child meeting the ALRI criteria 15 or more days after apparent recovery from an earlier episode is regarded as a new episode

Severity:
The severity of the illness as determined by field workers was categorised according to the symptoms and signs included in the IMCI algorithm. Severe FW-cases were those with chest indrawing and/or the most reliably described general danger sign, that is inability to breast-feed or drink. Severity of all physician-diagnosed outcomes was determined by the level of oxygen saturation measured by pulse oximetry. A cut off of 87% was taken, based on the established definition of this being 2 standard deviations below the mean level for a representative group of well children in the study sample. The relatively low level reflects the altitude of the study site (mean 2,600 metres).

Secondary outcome measures
Derived from the case finding methods described above:
1. ARI outcomes based on field worker assessments in the home:
1.1. Acute upper respiratory infections
1.2. All ALRI
1.3. Severe ALRI
2. ARI outcomes based on physician diagnosis and investigations:
2.1. Severe (hypoxaemic) physician-diagnosed pneumonia
2.2. All RSV positive physician-diagnosed pneumonia
2.3. Severe (hypoxaemic) RSV positive physician-diagnosed pneumonia
2.4. All RSV negative physician-diagnosed pneumonia
2.5. Severe (hypoxaemic) RSV negative physician-diagnosed pneumonia
2.6. All chest X-ray positive physician-diagnosed pneumonia
2.7. Severe (hypoxaemic) chest X-ray positive physician-diagnosed pneumonia
3. Outcomes based on verbal autopsies:
3.1. All deaths
3.2. Deaths due to pneumonia
4. Other child health outcomes:
4.1. Diarrhoea
4.2. Birth weight
4.3. Burns and scalds

Overall study start date
19/10/2002

Completion date
18/12/2004

Eligibility

Key inclusion criteria
1. Households used only an open fire for cooking and heating
2. Had a pregnant woman or child less than 4 months residing in the home
3. Identified as Mam (the regional ethnic group)
4. Minimal summer migration (less than 12 weeks per year)

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
500 children

Key exclusion criteria
1. The household is already using a chimney stove for cooking
2. There is no child less than 4 months of age or a pregnant woman residing in the home
3. Seasonal migration required the family to move to another region for more than 12 weeks of the year

Date of first enrolment
19/10/2002

Date of final enrolment
18/12/2004

Locations

Countries of recruitment
Guatemala

United States of America

Study participating centre
School of Public Health
Berkeley
United States of America
94720-7360

Sponsor information

Organisation
National Institutes of Health (NIH) (USA) - National Institute of Environmental Health Sciences (NIEHS)

Sponsor details
P.O. Box 12233, MD K3-16
Research Triangle Park, NC
United States of America
27709-2233

Sponsor type
Government

Website
http://www.niehs.nih.gov/index.cfm

ROR
https://ror.org/00j4k1h63

Funder(s)

Funder type
Government

Funder Name
National Institutes of Health (NIH) (USA) - National Institute of Environmental Health Sciences (NIEHS) (ref: R01ES010178)

Funder Name
World Health Organization (WHO) (Switzerland)

Alternative Name(s)
, , Всемирная организация здравоохранения, Organisation mondiale de la Santé, Organización Mundial de la Salud, WHO, , ВОЗ, OMS

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
Switzerland

Funder Name
The AC Griffin Family Trust (USA)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results		01/11/2006		No	No
Results article	results	01/01/2007		Yes	No
Results article	blood pressure results	01/07/2007		Yes	No
Results article	pneumonia case findings results	01/07/2007		Yes	No
Results article	mapping results	01/10/2007		Yes	No
Results article	lung function results	01/12/2007		Yes	No
Results article	self-rated health results	05/06/2008		Yes	No
Results article	exposure information results	01/01/2009		Yes	No
Results article	results	15/07/2009		Yes	No
Results article		13/10/2009		Yes	No
Results article	methods and results	01/07/2010		Yes	No
Results article	results	12/11/2011		Yes	No