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Evaluating the impact of a training and social franchising program in addressing the prevention and treatment of diarrhea and pneumonia in Children Under 5 (CU5) among the poor in rural areas of Myanmar

Submission date	Recruitment status	[_] Prospectively registered
26/04/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
24/05/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
27/04/2015	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
10-02140

Study information

Scientific Title
A randomized controlled trial evaluating the impact of a training and social franchising program in addressing the prevention and treatment of diarrhea and pneumonia in Children Under 5 (CU5) among the poor in rural areas of Myanmar

Study objectives
The primary hypothesis (and basis of the sample size) is that households in village tracts receiving the intervention will have a different level of appropriate treatment of diarrhea in children under 5 (CU5) compared to those in control village tracts. Other hypotheses to be tested include differences in intervention versus control villages in terms of knowledge of diarrhea and pneumonia danger signs, awareness of treatment in the area, and access to treatment. The study will also test the hypothesis that the intervention serves the poorer part of society through comparing household socio-economic status (SES) among users and non-users of appropriate treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of California, San Francisco, Human Research Protection Program, The Committee on Human Research, 08/06/2010, Reference: 003942, IRB: 10-02140

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Prevention

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
Pediatric diarrhea and pneumonia

Interventions
The scale up of a social franchising program seeking to improve health in rural Myanmar through training and supplying of partners known as 'Sun Primary Health' (SPH) providers (e.g., rural health educators, midwives, pharmacists, traditional healers, educators, and others).

It is the introduction of a trained provider who is part of the franchise into the community. SPH providers are trained and supported to provide health communications, services, and commodities related to RH, diarrheal diseases, pneumonia, and malaria, and provide referrals for TB and other acute illnesses to SQH clinics. SPH members are not salaried, but receive financial incentives from PSI/M based on performance. It is a two-three day training course.

The SPH providers will impart the knowledge by delivering healthcare as needed. There will not be specific sessions dedicated to educating the community but the information will flow to community members via interactions with the SPH when they deliver health services.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. The difference in use of appropriate treatment for diarrhea within the last two weeks by mothers/primary care givers for CU5 in intervention versus control village tracts
2. The difference in recognition of danger signs of pneumonia among mothers/primary care givers of CU5 in intervention versus control village tracts
3. The differences in socio-economic status (SES) of households of users of appropriate treatment for diarrhea in CU5 versus non-users in intervention village tracts
4. The differences in SES of households aware versus unaware of the danger signs of pneumonia in CU5 in intervention village tracts

The survey to measure outcomes will be drawn at baseline (pre-SPH program), 12 months, and 24 months for repeated representative surveys

Secondary outcome measures
The study will also address secondary aims related to a behavior change model encompassing opportunity, ability, and motivation (OAM model) to improve health status.

Additional data collection will include exposures to the social franchising products and providers, perceived quality of care and services at the social franchising outlets, additional history of child health outcomes and treatments sought and used, and additional demographic information. The population-basis of the surveys allows for extrapolation of findings over similar areas of rural Myanmar that are poised to implement the Sun Primary Health (SPH) program.

Overall study start date
01/09/2010

Completion date
31/05/2012

Eligibility

Key inclusion criteria
1. The mother (first choice) and/or other primary caregiver (if mother not available or able to participate) of at least one CU5
2. Resident of the sampled household, defined as sleeping in the house the previous night and having no other usual residence
3. Age 18 years or older. Of note, PSI Myanmar ethical review recommends not including minors in research. In typical surveys of mothers of CU5, another caregiving adult (e.g., grandmother, father, aunt) can provide the relevant information for the children of mothers under the age of 18 years. Moreover, someone other than the mother is interviewed in < 5% of such surveys
4. Able to speak and provide informed consent in the majority language of Myanmar (Burmese). Of note, the our townships constituting the target area are located within the majority Burmese ethnic area

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
10,714, assuming a 70% participation rate of eligible households

Key exclusion criteria
Absent on two attempts to contact. In this case, the next nearest eligible household is substituted.

Date of first enrolment
01/09/2010

Date of final enrolment
31/05/2012

Locations

Countries of recruitment
Myanmar

United States of America

Study participating centre

UCSF Global Health Sciences, Global Health Group
San Francisco
United States of America
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Sponsor information

Organisation
Population Services International (USA)

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Sponsor type
Research organisation

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Funder(s)

Funder type
Research organisation

Funder Name
Population Services International (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?
Results article	results	01/06/2014		Yes	No