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Piloting the global subsidy: the impact of subsidised artemisinin-based combination therapies distributed through private drug shops in rural Tanzania

Submission date
31/05/2009

Recruitment status
No longer recruiting

Registration date
07/08/2009

Overall study status
Completed

Last Edited
07/06/2012

Condition category
Infections and Infestations

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Study information

Scientific Title

The impact of subsidised artemisinin-based combination therapies distributed through private drug shops on consumer uptake and retail price in rural Tanzania: a non-clinical district-randomised controlled trial

Study objectives
The introduction of subsidised artemisinin-based combination therapies (ACTs) at the top of the private sector supply chain will lead to a significant increase in consumer purchase and use of these recommended first-line therapies and a corresponding significant decrease in purchase and use of sub-optimal therapies such as amodiaquine and sulphadoxine-pyramethamine.

The lower price for ACTs offered at the top of the supply chain as a result of the subsidy will result in significantly lower retail prices for these drugs, with consumers paying an equivalent amount as for the most commonly purchased suboptimal therapies.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Tanzania Ministry of Health and Social Welfare approved on the 20th July 2007

Primary study design
Interventional

Study design
Non-clinical district-randomised controlled trial

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Malaria

Interventions
A total of four interventions are applied during the project:
1. Provision of ACTs at a price 95% below standard market level to a pharmaceutical wholesaler with agreement to distributed to drug shops
2. Training of drug shop owners and shopkeepers on recognition of malaria symptoms, the importance of use of ACTs as first-line malaria treatment, and proper storage and dispensing practices for ACTs
3. Comprehensive behaviour change communication activities through a variety of media to promote prompt treatment seeking for malaria, demand for and acceptance of ACTs as first-line malaria treatment, and to generate awareness of low-priced ACT in private shops
4. Placement of a suggested retail price on subsidised ACTs distributed through private shops to provide consumers with a clear indication of the appropriate amount to pay for the product

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Proportion of consumers purchasing anti-malarials at private drug shops that buy ACTs. Measured through exit interviews at all shops in target districts at baseline and four surveys during intervention.
2. Price paid for subsidised ACTs and most common alternative anti-malarials by consumers at private drug shops. Measured through exit interviews and the mystery shopper technique at baseline and four times during intervention.
3. The total volume of ACTs distributed by private drug shops in the previous month. Measured through retail audits conducted twice during each survey period (once to establish baseline stock level and follow-up to measure change due to sales), including baseline.

Key secondary outcome(s)
1. Socioeconomic status of consumers purchasing ACT and other anti-malarials at private drug shops as determined through principal component analysis of household assets. Measured through exit interviews of consumers at baseline and four times during intervention.
2. Volume of ACTs dispensed by all public and nongovernmental health facilities in target districts during preceding month. Measured through audits of public facilities and NGO health facilities at baseline and four times during intervention.
3. Proportion of private drug shops stocking ACTs and alternative anti-malarials. Measured through retail audits at baseline and four times during intervention.
4. Geographic location of drug shops and public/NGO health facilities distributing anti-malarials. Measured through recording of GPS coordinates of all drug shops and facilities during each audit using Garmin Etrex hand units.

Completion date
31/12/2009

Eligibility

Key inclusion criteria
All consumers purchasing anti-malarials from a private drug shop (duka la dawa baridi) in target districts (no age or gender restrictions).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Other

Sex
All

Key exclusion criteria
1. Consumers purchasing medicines other than anti-malarials from private drug shops
2. Patients obtaining anti-malarials from other sources, including public health facilities, in the target districts

Date of first enrolment
01/11/2007

Date of final enrolment
31/12/2009

Locations

Countries of recruitment
Tanzania

United States of America

Study participating centre
383 Dorchester Avenue
Boston
United States of America
02127

Sponsor information

Organisation
Tanzanian Ministry of Health and Social Welfare (Tanzania)

ROR
https://ror.org/03vt2s541

Funder(s)

Funder type
Charity

Funder Name
Bill and Melinda Gates Foundation (USA)

Alternative Name(s)
Bill & Melinda Gates Foundation, Gates Foundation, Gates Learning Foundation, William H. Gates Foundation, BMGF, B&MGF, GF

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	02/09/2009		Yes	No
Results article	results	02/07/2010		Yes	No