ISRCTN86533387 https://doi.org/10.1186/ISRCTN86533387

Improving supply chain for essential drugs in low income countries: a large scale cluster randomized experiment in Zambia

Submission date
05/02/2019

Recruitment status
No longer recruiting

Registration date
07/02/2019

Overall study status
Completed

Last Edited
19/04/2021

Condition category
Other

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

Plain English summary of protocol

Background and study aims
The availability of essential medicines is a persistent challenge in developing countries. A third of the world's population, including almost half of the population on the African continent, lacks systematic access to essential drugs. Access to essential drugs is contingent upon well-functioning supply chain systems that move drugs from the manufacturer through to end use. Supply chain management in public sector health systems has received increasing attention in recent years—as both a priority and a challenge for many countries—as governments struggle to deliver an increasing number of products. Many developing county health systems, including Zambia, typically have three levels in their public-sector distribution system, where the central warehouse supplies to the district or provincial warehouses which in turn send supplies to the health facilities. Knowing how many levels are best for a public-sector run medicines distribution system in a developing country requires understanding not only the cost and technical variables but also some complex incentives issues. As health systems decentralize it also raises questions about which decisions related to ordering, stocking and inventory control should be centralized and which decisions should be decentralized. The aim of this study is to examine the relative effectiveness of two alternative supply chain structures, including cross-docking, a supply chain structure where warehouses function as inventory coordination points rather than inventory storage points. As either alternative is relatively low cost to implement, a successful trial may point towards effective national policy reforms for the government to consider.

Who can participate?
All primary health care centers and district hospitals in participating districts

What does the study involve?
The study involves adopting, at the district level, one of two drug supply chain reforms and then contrasting the relative effectiveness of each reform against each other and against the existing distribution system of essential drugs. A successful reform may be considered for national scale-up so that all health centers in the country may benefit.

What are the possible benefits and risks of participating?
Possible benefits for participating districts involve reduced rates of essential drug stock-outs and hence increased effective drug coverage at all health facilities in the district. Risks of participation include decreased drug availability if either pilot intervention is less effective than the status quo.

Where is the study run from?
416 health centers, 23 hospitals and 18 District Health Offices (Zambia)

When is the study starting and how long is it expected to run for?
March 2008 to January 2010

Who is funding the study?
Ministry of Health, Government of Zambia

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Improving supply chain for essential drugs in low income countries: a large scale cluster randomized experiment in Zambia

Study objectives
A more direct distribution system will outperform a traditional three-level drug distribution system due to improved information flow and increased managerial accountability.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study analyzes routinely collected data by the Ministry of Health (MoH), Government of Zambia, or a contractor of the government. The pilot interventions evaluated were supply chain reforms decided and implemented by the MoH. As the evaluation involved the analysis of secondary data, and evaluated policy reforms decided and implemented by the government, no IRB approval was sought.or deemed necessary.

Study design
Prospective cluster randomized trial with randomization at the district level

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Essential drug availability at front-line primary health centers and hospitals

Interventions
Districts were first grouped into strata based on geography and risk factors for drug stockouts. Then districts were allocated to study arms within each of 8 strata on the basis of a computer generated random number sequence. The two interventions were assessed against the current essential drug distribution system.

Model A: the health facilities order drugs from the district and the district store maintains the stock of drugs i.e. the district store remains a stock holding point, hence Model A remains a three-tier system. A new role called the Commodity Planner (CP) is introduced at the district to enhance stock planning capacity. This CP is responsible for coordinating orders from the health facilities and stock management at the district.

Model B: eliminates the intermediate storage of drugs at the district level. The district store is converted into a “cross-dock”, i.e. point of transit, wherein it receives shipments from MSL that

are pre-packed for individual health facilities. As in Model A, a commodity planner (CP) is added to the district store under this option but her role is limited to ensuring the delivery of the packages to the health facilities as well as facilitating the order information from the health facilities to MSL.

The intervention itself lasted for 13 months from December 2008 to January 2010, and follow-up data collection was collected in January 2010.

Intervention Type
Other

Primary outcome measure
1. The likelihood of stockout of key tracer drugs at the time of data collection team visit (both baseline and endline)
2. The total days of stockout experienced by the facility in the final quarter of 2009

Contemporaneous stockout was assessed by the trained observation of the data collection teams. Days of stockout were determined by the data collection team review of facility drug stocking cards. Tracer drugs are listed here:
AL 1x6 (strip of 6 tabs)
AL 2x6 (strip of 12 tabs)
AL 3x6 (strip of 18 tabs)
AL 4x6 (strip of 24 tabs)
Amoxicillin Suspension (bottle of 100ml)
Benzyl Penicillin Inj. (5ML 10ml vials)
CTX 480mg (bottle of 1000 tabs)
DepoProvera (vial)
Malaria RDTs (box of 25 tests)
Male Condoms (box of 100/144)
Metronidazole 200mg tabs (bottle of 1000)
OralconF (Levonorgestre/Ethinylestradio)
Quinine Injection (2ml ampoules)
Quinine Tabs (bottle of 1000 tabs)
SP (bottle of 1000 tabs)

Secondary outcome measures
Pharmaceutical storage conditions at primary health care centers as observed by trained data collection teams at endline. The conditions recorded derive from an original observation tool developed by the study team.

Overall study start date
01/03/2008

Completion date
31/01/2010

Eligibility

Key inclusion criteria
All primary health care centers and district hospitals in participating districts

Participant type(s)
Other

Age group
Other

Sex
Both

Target number of participants
416 health centers, 23 hospitals and 18 District Health Offices covered in the baseline data

Total final enrolment
463

Key exclusion criteria
All facilities in participating districts are included

Date of first enrolment
01/12/2008

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
Zambia

Study participating centre
416 health centers, 23 hospitals and 18 District Health Offices
Zambia
-

Sponsor information

Organisation
Development Research Group, The World Bank

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Sponsor type
Research organisation

ROR
https://ror.org/00ae7jd04

Funder(s)

Funder type
Government

Funder Name
Ministry of Health, Government of Zambia

Results and Publications

Publication and dissemination plan
A working paper summarizing the results to be submitted to a peer-reviewed journal.

Intention to publish date
01/06/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository. The data will be made available through the World Bank's Development Data platform: https://data.worldbank.org/, available to all interested parties, and will remain in the public domain for the foreseeable future. Anonymization will ensure that individual districts and facilities cannot be identified. Facility management had to consent to data collection for any collection activities to ensue. The data will be available by June 2019.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Preprint results	results	28/03/2015		No	No
Results article		01/01/2019	19/04/2021	Yes	No