



Assessing the scale of the problem: Sampling considerations for field surveys of drug quality

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Objectives of DQ studies

Potential questions of interest:

- Are poor quality drugs being imported into country X?
- Are poor quality drugs being manufactured in country X?
- Are poor quality drugs being sold in country X?
- What proportion of medicines are of poor quality ?
(estimating scale of the problem, precise estimate)
- What are the factors associated with increased risk of
poor quality medicines (risk factor analysis)?
- What proportion of the population are exposed to poor
quality medicines (public health burden)?

Fewer Sampling
Considerations



More Sampling
Considerations

MRA seizures / warnings



WARN

Antimalarial Quality Literature Surveyor



- Reports only published when a problem is found
- Where no data shown - No investigation or no problem detected?
- Useful for identifying a problem at point of import or manufacture
- Proportion of population exposed (scale of the problem) remains unknown

Filter studies by publication year range: 2005 to 2015

Outlet surveys – all methods



WARN

Antimalarial Quality Literature Surveyor

Medicine Quality Map

Report Table



Is variation due to:

- Geographical differences (types of drugs sold, source of drugs, regulatory practices – legislation, enforcement)?
- Temporal differences (changes in drug policy / regulation)?
- **Differences in method of sampling?**
- **Differences in precision of the estimates (random error due to sample size)?**

Convenience sampling



WARN

Antimalarial Quality Literature Surveyor



Filter studies by publication year range: 2005 to 2015

Random sampling



WARN

Antimalarial Quality Literature Surveyor

Medicine Quality Map

Report Table



- Failure rate seen in random samples tends to be lower than in convenience
- Small number of randomised studies



Filter studies by publication year range: 2005 to 2015

Convenience/purposive samples

ADVANTAGES	DISADVANTAGES
<ul style="list-style-type: none">• Does not require an up-to-date list of outlets (sampling frame)• Rapid• Low cost • Can be used purposively to investigate places of particular concern• Purposive – sampling for diversity	<ul style="list-style-type: none">• Small number of outlets surveyed• Small number of samples collected• Lack of defined sampling frame or standardised approach

Convenience
Less defined

Strength of evidence

Purposive
More defined

Random – Mystery clients

ADVANTAGES	DISADVANTAGES
<p><u>RANDOM SAMPLING OF OUTLETS</u></p> <ul style="list-style-type: none">• Use of defined sampling frame• Can yield representative sample from all types of outlets and/or brands	<ul style="list-style-type: none">• Sample will only be as comprehensive and/or representative as the sampling frame that was used• Need to authenticate and update sampling frame increases time and cost of survey
<p><u>USE OF MYSTERY CLIENTS</u></p> <ul style="list-style-type: none">• Low risk of sampling bias in samples collected, as outlets are unaware of survey	<ul style="list-style-type: none">• Information on sources of poor quality drugs is limited to brand, batch and country of manufacture as stated on packaging

Mystery client/simulated client visit (covert approach) - where the researcher poses as a malaria patient or relative and asks for a drug to treat malaria

Random – Mystery clients

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<ul style="list-style-type: none">• Reliability and generalizability of results should be strong• Results can be replicated	

Random – Overt sampling

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<p><u>OVERT SAMPLING OF DRUGS</u></p> <ul style="list-style-type: none">• Can collect additional information at minimal additional cost to mystery approach	<ul style="list-style-type: none">• Possible risk of sampling bias in samples collected, if some outlets refuse to be sampled or are aware of which samples might be poor quality and differentially withhold these

Overt approach - where the researcher informs drug outlet staff of the purpose of research, and obtains consent for collection of drugs for testing and interview

Random – Overt sampling

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ACTc DQ: Sampling methods used

COUNTRY	Method of sampling OUTLETS	Method of sampling DRUGS
Bioko Island, Equatorial Guinea	Random / National survey	<ul style="list-style-type: none"> • Mystery client • Overt
Cambodia	Random / National survey*	<ul style="list-style-type: none"> • Mystery client • Overt
Ghana	Random / 1 locality	<ul style="list-style-type: none"> • Mystery client
Nigeria	Random / 1 region	<ul style="list-style-type: none"> • Mystery client • Overt
Rwanda	Random / National survey	<ul style="list-style-type: none"> • Mystery client
Tanzania	Random / National survey	<ul style="list-style-type: none"> • Overt

* from malaria endemic areas only

Random – Overt sampling

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What proportion of the population are exposed to poor quality drugs (public health burden)?

ADDITIONAL INFORMATION REQUIRED:

- **Data on treatment-seeking behaviour**
 - Different sources of treatment - Public / Private; Regulated / Unregulated
- **Data on market share and volume**
 - Types of antimalarials purchased – Brands sold; Country of manufacturer; WHO pre-qualification; Quality marques (AMFm green leaf logo)
 - Consumer preferences – importance of price, branding, quality marque

SOURCES OF DATA

- **Household surveys**
DHS / MIC surveys
- **Outlet surveys**
Record reviews
Retail audits

WHO / HAI
ACTwatch
AMFm evaluation

ACT watch

www.actwatch.info

WHO / HAI medicine prices project

www.haiweb.org/medicineprices

Antimalarial markets

- Conteh & Hanson. Methods for studying private sector supply of public health products in developing countries: a conceptual framework and review. *Social Science & Medicine* 2003, 57: 1147-1161
- O'Connell *et al.* Got ACTs? Availability, price, market share and provider knowledge in public and private sector outlets in six malaria-endemic countries. *Malaria Journal* 2011, 10:326
- O'Connell *et al.* Methods for implementing a medicine outlet survey: lessons from the antimalarial market. *Malaria Journal* 2013, 12:52
- Patouillard *et al.* Comparative analysis of two methods for measuring sales volumes during malaria medicine outlet surveys. *Malaria Journal* 2013, 12:311

Surveys of drug quality

- Newton *et al.* Guidelines for field surveys of the quality of medicines: a proposal. *PLoS Medicine* 2009, 6(3):e1000052
- Kaur *et al.* Quality of artemisinin-based combination formulations for malaria treatment: Prevalence and risk factors for poor quality medicines in public facilities and private sector drug outlets in Enugu, Nigeria. *PLoS One* 2015

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Convenience
or Purposive
Sampling

Smaller
Lab-based
Studies



Population-based
Random

Larger
Multi-discipline

- ❑ **DESIGN:** Explicit link between study objectives => matching survey methodology
- ❑ **REPORTING GUIDELINES:** MEDQUARG , Newton *et al*, PLoS Medicine 2009
Include explicit description of sampling (scope; generalizability; sampling bias)
 - Selection of outlets - how outlets were identified, sampling frame used and date last updated, inclusion and exclusion criteria (if any)
 - Collection of drug samples - method of collection (overt/covert), number of samples/brands per outlet, inclusion and exclusion criteria
 - Risk of systematic bias in outlets surveyed and/or samples obtained
 - Sample size calculations, reporting of 95% CI – precision of estimates obtained
- ❑ **REVIEWS :** Explicit consideration of sampling methods when reviewing literature / pooling data on drug quality
- ❑ **IMPLICATIONS:** Develop multidisciplinary approaches to gain a fuller picture:
 - Chemical content analysis - supported by epidemiology, statistics, economics, anthropology, analysis of health policy and process



More information

www.actconsortium.org/drugquality

