



Drug Safety and Quality

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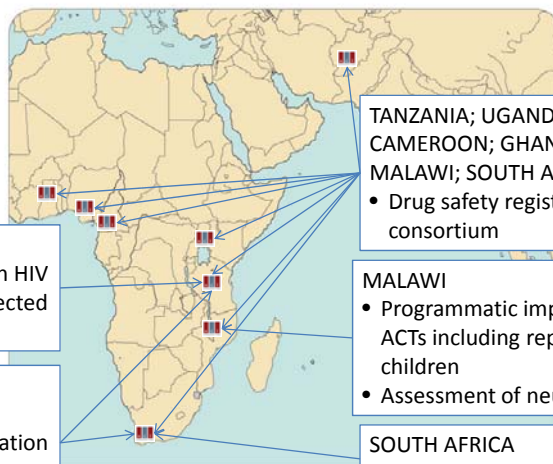
Rationale



- Drug safety
 - In clinical trials, ACTs appear to be safe and well-tolerated
 - Unanswered questions about drug safety remain:
 - Repeated dosing, drug interactions
 - Use in high-risk populations
 - Safety in unregulated settings
 - Mass roll-out of ACTs: monitoring for drug safety is high priority
 - Wide-scale pharmacovigilance is challenging
- Fake and substandard drugs
 - Poor quality drugs can lead to negative health outcomes
 - Scale of fake and substandard antimalarial drugs unknown



Drug safety questions



TANZANIA

- Safety of ACTs in HIV and malaria infected participants

SOUTH AFRICA; TANZANIA

- Improving elicitation of drug safety patient reports

TANZANIA; UGANDA; NIGERIA; CAMEROON; GHANA; AFGHANISTAN; MALAWI; SOUTH AFRICA

- Drug safety register for the ACT consortium

MALAWI

- Programmatic implementation of ACTs including repeat doses in children
- Assessment of neurotoxicity

SOUTH AFRICA

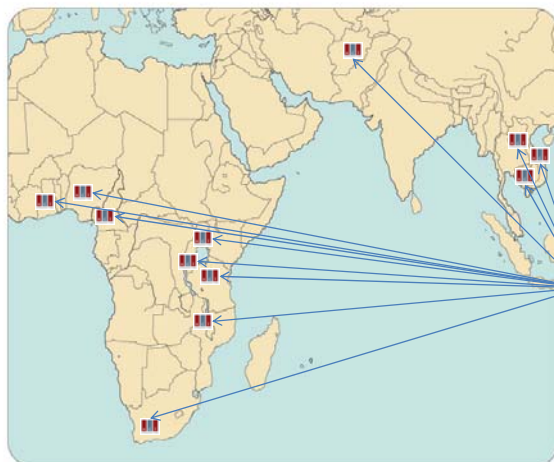
- Safety of ACTs in HIV infected adults

How are we addressing these questions?



- Developing adverse event monitoring tools to actively and passively collect drug safety data across ACT Consortium studies
- In South Africa and Tanzania, barriers and approaches to optimise accuracy of patient-reported drug-safety data
- In Malawi, cohort study of young children will assess the effectiveness and safety of ACTs with repeated treatments in real-world conditions
- In South Africa and Tanzania, observational studies will evaluate clinical safety, therapeutic efficacy and pharmacokinetic interactions
- Establishing a ACT drug safety register involving 8 countries in Africa and Asia

Drug quality questions



RWANDA; TANZANIA; UGANDA;
MALAWI; SOUTH AFRICA;
NIGERIA, CAMEROON; GHANA;
AFGHANISTAN; LAOS; CAMBODIA;
VIETNAM

- Systematic surveillance system to monitor prevalence of sub-standard and counterfeit ACTs
- Deterioration of genuine and good quality drugs during transport and storage
- Origins of counterfeit ACTs. Interfacing and supporting IMPACT/Interpol enforcement operations

How are we addressing these questions?



- Setting up a surveillance system to collect a systematic sample of ACTs from various countries



- Testing sampled ACTs for quality at LSHTM, CDC and Georgia Tech
- Establishing a counterfeit drug forensic network (CODFIN) to investigate origins of suspect drugs at Georgia Tech
- Identifying the minimum acceptable storage conditions necessary to retain quality of ACTs in peripheral health centres and shops