INDEPTH Network Effectiveness and Safety Studies Platform (INESS)

Update-INDEPTH AGM 2010

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INESS objectives

- To develop and maintain a phase IV Effectiveness and safety studies platform.
- To assess the effectiveness, and determinants of effectiveness, of new malaria treatments in real world health systems. m in antimalarials in Africa
- To evaluate safety of new treatments through a comprehensive pharmacovigilance in a health system context
Challenge for INDEPTH HDSS

→ To move beyond population health observatories to include a health system observatory function.

→ To link population health and health behaviours to health services and to health system behaviours.
Driving with the brakes on: How interventions lose traction in health systems

Example of ACT anti-malarial treatment in Rufiji DSS in 2006

Efficacy X 98%
X Access X 60%
  X 40%
  X 90%
  X Diagnostics X 95%
  X 90%
  X Provider compliance X 95%
  X 75%
  X 75%
  X Patient adherence X 70%
  X 60%
  Effectiveness = 37%

Averages mask inequities

Poorest quintile = 16%

Health system factors

Data source: IMPACT Tanzania. Effectiveness data are actual. Poorest quintile estimates are hypothetical.
Presently more traction can be gained by removing health system bottlenecks than by improving the efficacy of new drugs.
INESS Technical approach for systems effectiveness

- So seven linked study modules for the effectiveness estimation:

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Other supportive modules of INESS

- Safety Monitoring
- Data Linkage
- Data analysis and synthesis
Module 1. Access

Main purpose:
- determine proportion of cases needing to seek care that actually gain physical access to a point of provision

Quick overview and update:
- Ongoing Household surveys of fevers in prior two weeks through HDSS rounds
- Will provide total annual fever burden
- Plans to analyze across time, space, socio-economic quintiles and provider characteristics
Module 2 & 3.
Diagnostic targeting & Provider compliance

Main purpose:
- determine the proportion of cases having access that are correctly diagnosed / classified
- determine the proportion of correctly diagnosed cases that are provided with the correct treatment

Quick overview and update:
- On going Health facility / provider surveys
- Sampled at peak and low seasons –all sites collected one season data
- Exit interviews with gold standard diagnostic
- Assesses stock-outs and quality of drugs on hand
Module 4. Patient adherence

→Main purpose:
  - Estimate proportion of patients who receive treatment who use it as intended; and the proportion who are satisfied with the treatment

Quick overview and update:

- Household survey ongoing
- Standard interviews for adherence and acceptability
- Further follow-up and filter paper blood at day 28 (and 42 depending on ACT)
- RDT taken
Module 5. Community acceptance

Main purpose:
- Examine the social, cultural and behavioural factors that facilitate or impede uptake and adherence to new ACTs when introduced

Quick overview and update:

- Community survey of three different populations
  - Persons having a recent malaria fever episode (45-50 interviews)
  - Adult men & women living in DSS area (15 FGDs per year)
  - ACT providers (15-20 interviews)
- Two communities <5km and two communities >5km from ACT
Module 6. Contexts and additional effects

Main purpose:
- Estimate the contribution to reduced morbidity & mortality.

Quick overview and update
- Training on the module has been concluded in August 2010
- HMIS document reviews for trends and patterns in:
- DSS database and VA review for trends in:
- Other contextual data (rainfall, EIR, molecular markers for resistance)
- Plans to repeat therapeutic efficacy (100 patients)
Module 7. Overall effectiveness and costs

→ Main purpose:
  - Determine the effectiveness, and the determinants of effectiveness

Quick overview and update:
  - Plan to put it all together
  - Determine overall population effectiveness by equity quintile
  - Determine the efficacy losses, and where the greatest losses occur
Safety Monitoring module

→ Main purpose:
  - To strengthen existing safety monitoring system and to collect longitudinal data on safety of ACTs

Quick overview and update
- Spontaneous adverse event reporting system strengthened
- Active cohort event monitoring ongoing
- Plans to link Health Information & Demographic Surveillance Systems
- INESS – a platform to generate data on safety in pregnancy
Policy analysis module

Main purpose: To learn and understand processes and dynamics involved with formulation and implementation of antimalarial policies at international, national and district level

Quick overview and update

- Module SOPS and tools developed
- Stakeholder analysis of all actors concerned with the policy change; national & sentinel DSS district
- Documentation of national procurement & supply chain (to sentinel district)
- Document analysis of Rx guidelines
Data linkage module

- **Main purpose**: Provide a mechanism to identify HDSS residents visiting HF and link their information

**Quick overview and update**

- INESS data linkage softwares developed and applied
- Biometric enrolment is ongoing in the HDSS
- Piloting of the system in health facilities is ongoing
- To fully operationalise the data linkage system to link data sets
Thank you