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

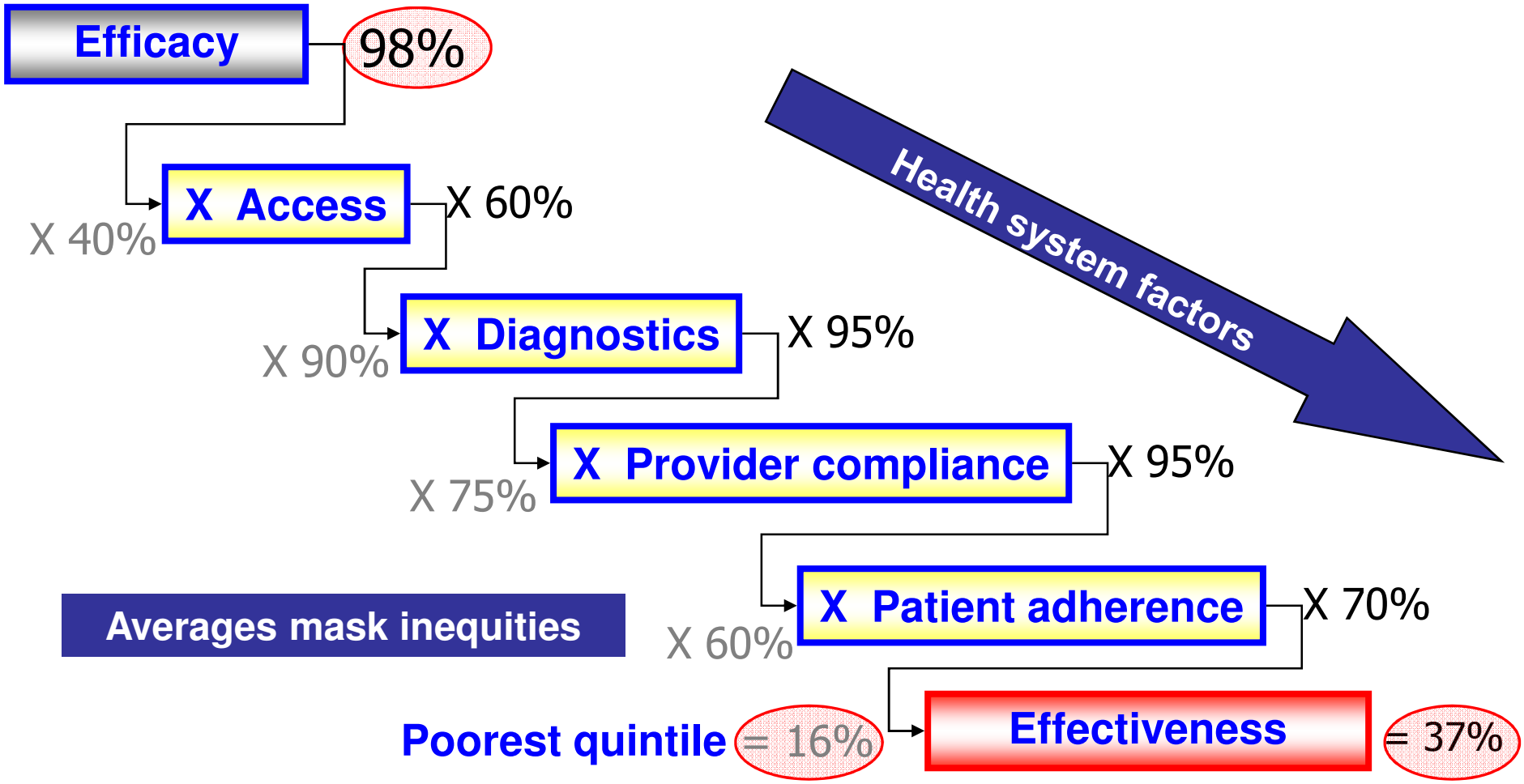
Challenge for INDEPTH HDSS

→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



Data source: IMPACT Tanzania. Effectiveness data are actual. Poorest quintile estimates are hypothetical

What does this mean?

- 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:

	Module	Task team facilitator	Level
1	Access	STI	HH
2	Diagnostic targeting	CDC	HF
3	Provider compliance	CDC	HF
4	Patient Adherence	STI	HH
5	Community acceptability	CDC	Community & HF
6	Contexts and other effects	STI	District & HH
7	Costs and cost effectiveness	SPH	District, HF & HH

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