

Health Care Services in Low-Income Countries

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Evaluations of health projects in real-life settings

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Outline of presentation

- Evidence in public health
- Probability designs
- Adequacy designs
- Plausibility designs
- What do we need?



Of mice, men and populations

- Laboratory (animal) sciences
 - *“A rat is a rat”*
- Clinical sciences
 - *“A patient is a patient”*
- Public health
 - *“Not all populations are the same”*
 - Effect modification is the rule
 - Particularly relevant for international health



Efficacy research

- Does the intervention work when delivered under optimal circumstances?
- Usual characteristics:
 - Fully implemented intervention
 - High-quality delivery
 - High population coverage
 - Including the poorest
 - Setting usually has great need for the intervention
 - Contextual factors seldom described



Effectiveness research

- Will this intervention work in my setting?
- Usual characteristics:
 - Imperfect implementation
 - Average quality
 - Partial population coverage
 - Most likely to leave out the poorest
 - Need for the intervention may be lower than in the efficacy test sites
 - Essential contextual factors may be absent



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Randomised controlled trials

- Prioritise internal validity
 - random allocation reduces selection bias and confounding
 - blinding reduces information bias
- Gained popularity through clinical trials of new drugs
- Essential for determining efficacy of new biological agents
- Adequate for short causal chains

drug → pharmacological reaction → disease cure or alleviation



What does a RCT show?


- The probability that the observed result is due to the intervention
- But additional evidence is required to make this result conceptually plausible
 - Biological plausibility
 - Operational plausibility





CONSORT

Strength in science, sound ethics 

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- Allocation
 - Rationale
 - Eligibility
 - Interventions
 - Objectives
 - Outcomes
 - Sample size
 - Randomization
 - Sequence generation
 - Concealment
 - Implementation
 - Blinding (masking)
 - Statistical methods
 - Participant flow
 - Recruitment
 - Baseline data
 - Numbers analyzed
 - Outcomes and estimation
 - Ancillary analyses
 - Adverse events
 - Interpretation
 - Generalizability 
 - Overall evidence

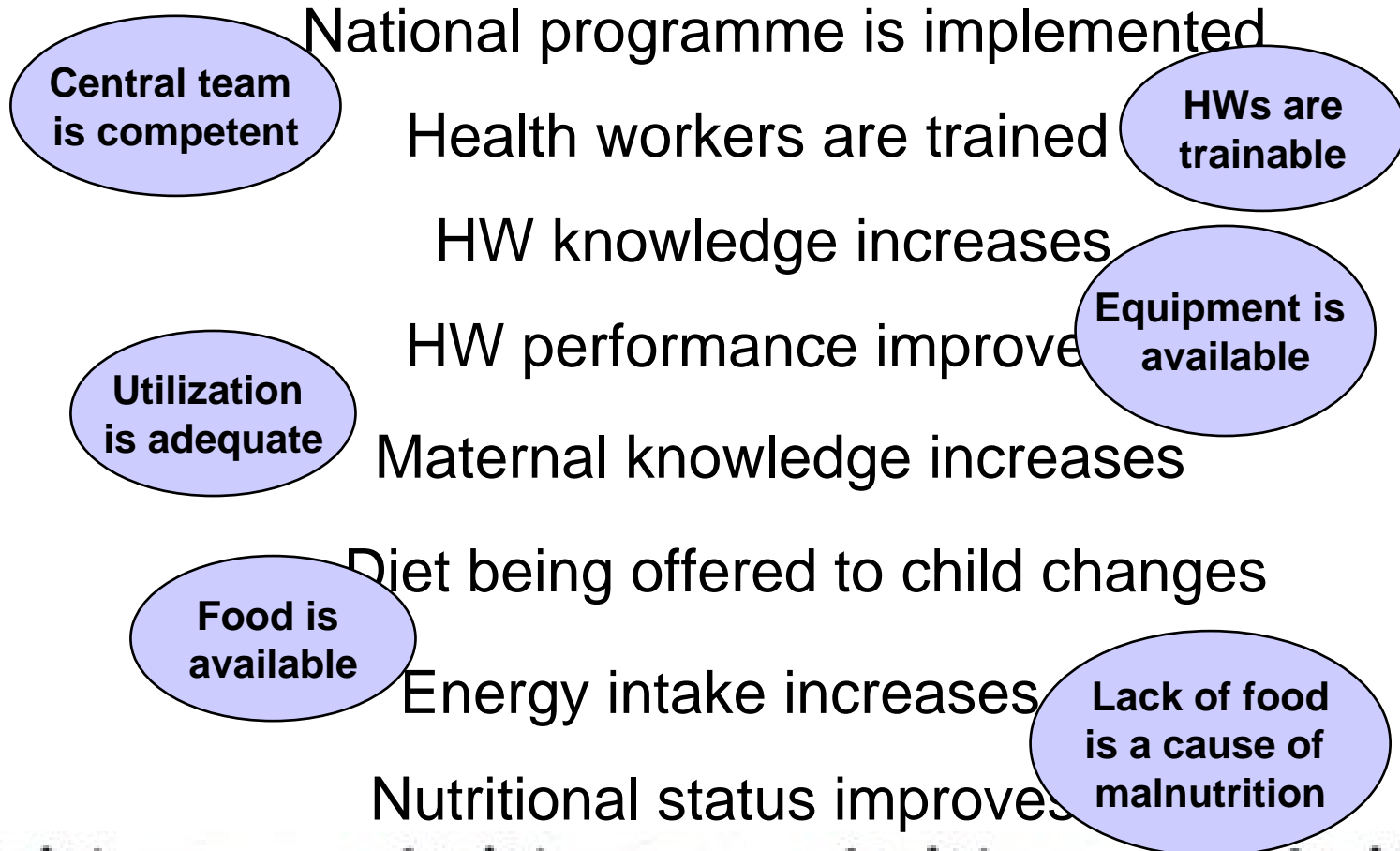


Major steps in Public Health trials

- Central-level provision of intervention to local outlets (e.g. health facilities)
- Local providers' compliance with delivery of intervention
- Recipient compliance with intervention
- Biological effect of intervention

Causal chains in Public Health evaluations are much longer than in clinical studies

Example of Public Health Intervention: Nutrition Counselling RCT



Example of Public Health Intervention: Nutrition Counselling Trial

National programme is implemented

Health workers are trained

HW knowledge increases

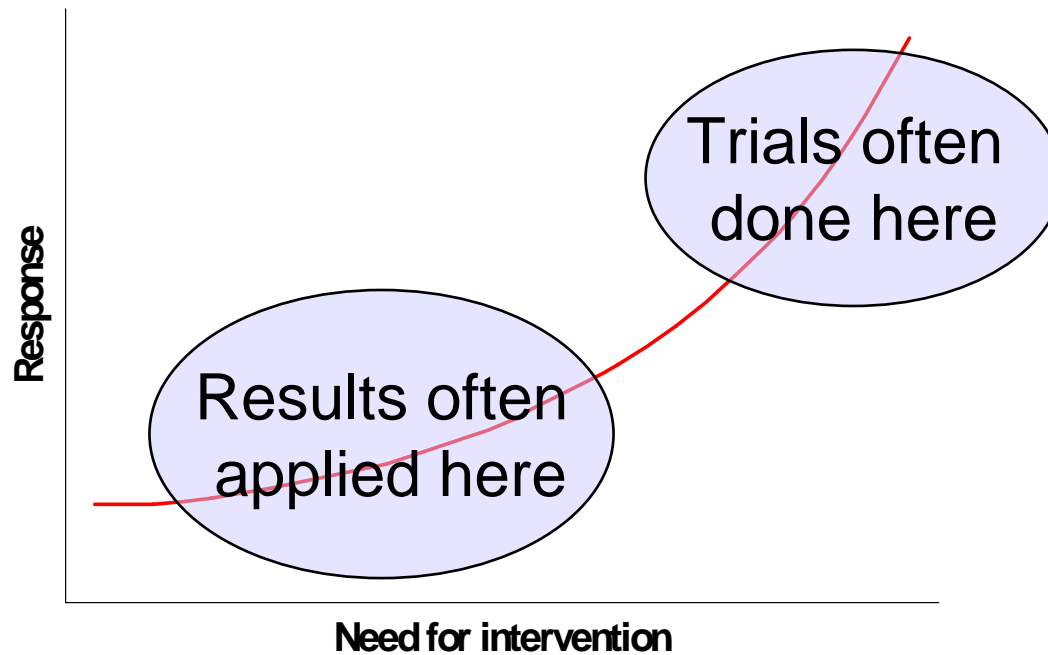
HW 80% success in each step
Mat 21% overall effectiveness

Child diets change

Energy intake increases

Nutritional status improves

Curvilinear associations



RCTs have a limited role in large-scale effectiveness evaluations

- Often impossible to randomize
 - unethical, politically unacceptable, rapid scaling up
- Evaluation team affects service delivery
 - service delivery is at least “best-practice”
- Effect modification is the rule
 - implementation may vary
- Need for supplementary approaches for evaluations in Public Health



Types of inference in impact evaluations

- Adequacy (descriptive studies)
 - the expected changes are taking place
- Plausibility (observational studies)
 - observed changes seem to be due to the programme
- Probability (RCTs)
 - randomised trial shows that the programme has a statistically significant impact

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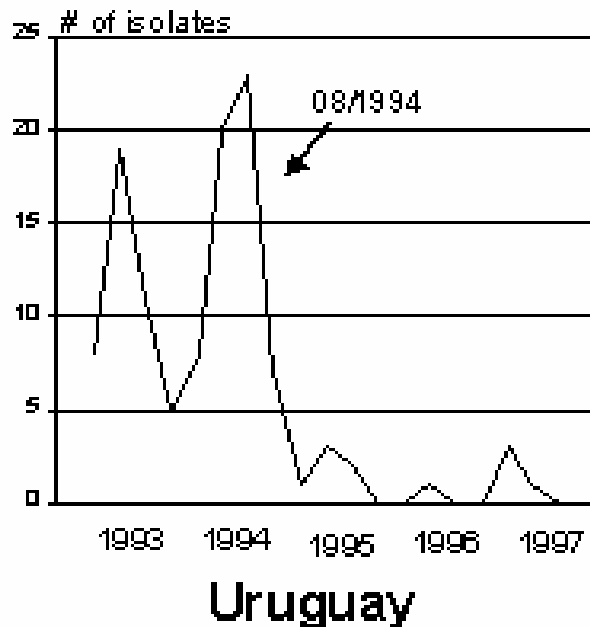


Adequacy evaluations

- Questions:
 - Were the initial goals achieved?
 - E.g.: reduce underfive mortality by 20%
 - Were the observed trends in impact indicators
 - in the expected direction?
 - of adequate magnitude?

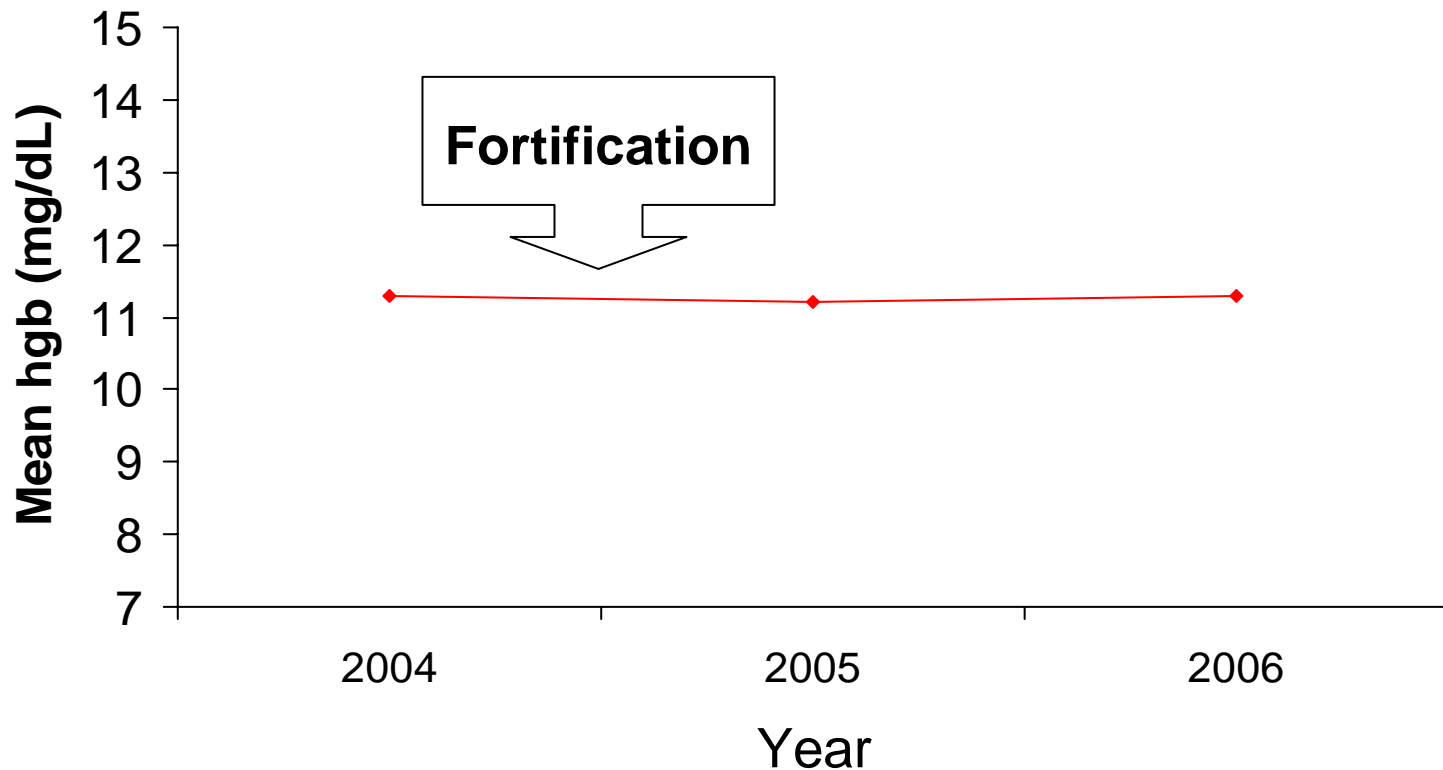


Hib vaccine in Uruguay, 1990's



In Uruguay, reported Hib cases declined by over 95 percent after the introduction of routine infant Hib immunisation in 1994.

Flour fortification with iron and haemoglobin in children 6-59 months, Pelotas, Brazil



Adequacy evaluations

- Are always necessary
 - even in more complex designs
- May be sufficient for decision-making when:
 - there is no improvement in the outcome
 - there is improvement and
 - the effect is large
 - the causal chain between the intervention and the outcome is relatively simple
 - confounding is unlikely

Adequacy evaluations

- Examples of interventions for which adequacy evaluations are the only option
 - changes in legislation
 - motorcycle helmet use
 - change in Cannabis status
 - tobacco taxation
 - large-scale implementation
 - universal vaccination
 - food fortification
 - etc



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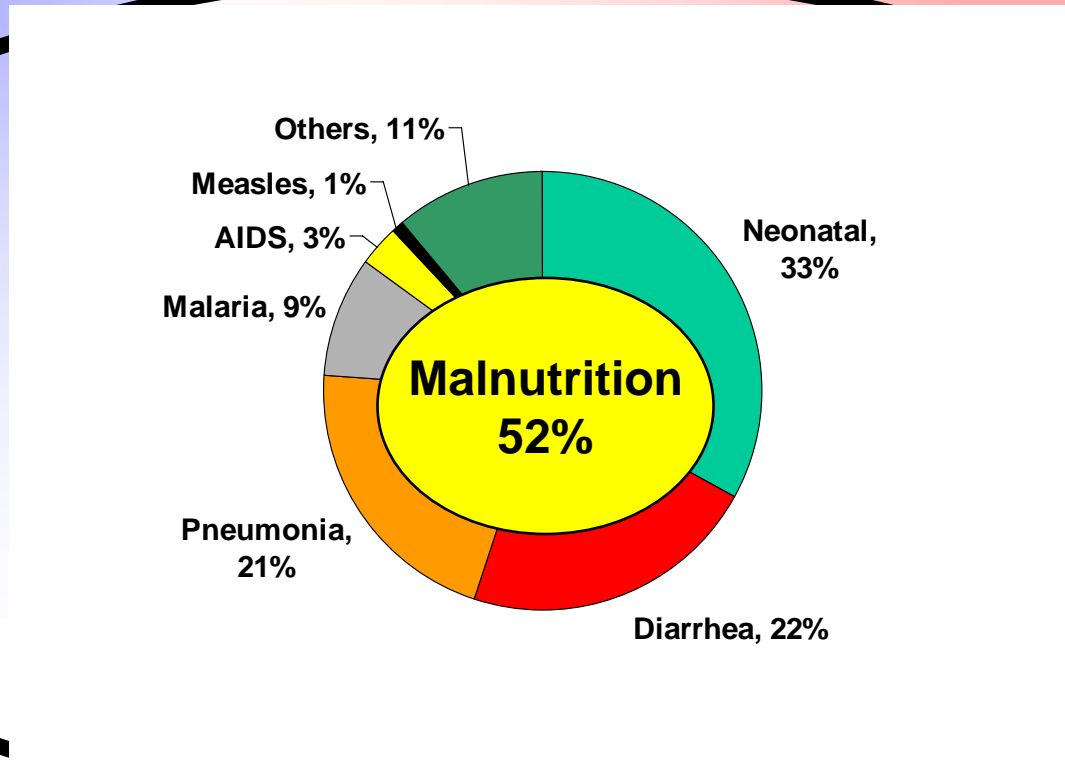
Plausibility evaluations

- Question:
 - Is the observed impact likely due to the intervention?
- Require ruling out influence of external factors:
 - need for comparison group
 - adjustment for confounders
- Also known as quasi-experiments



Health systems

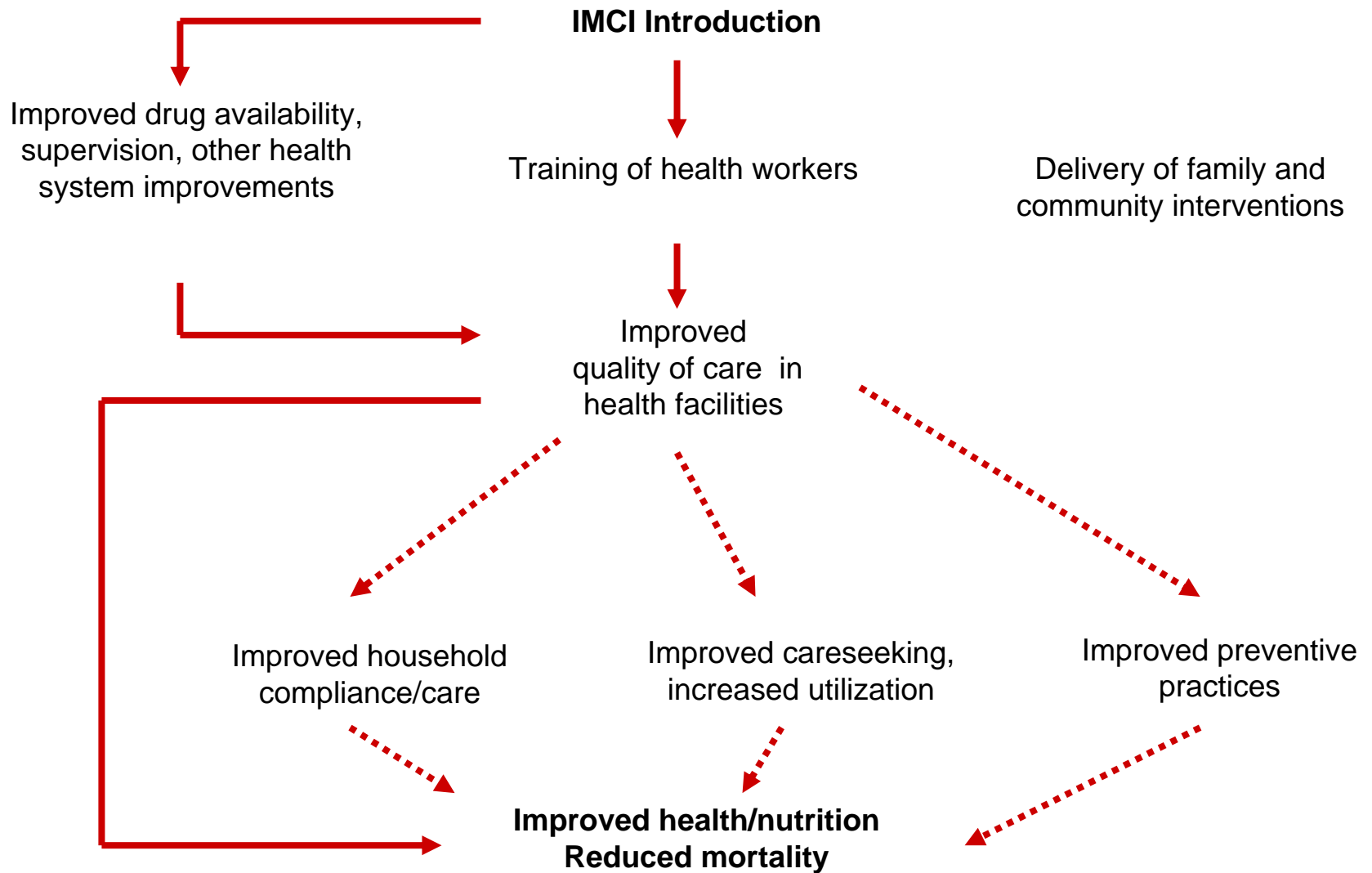
Health worker performance



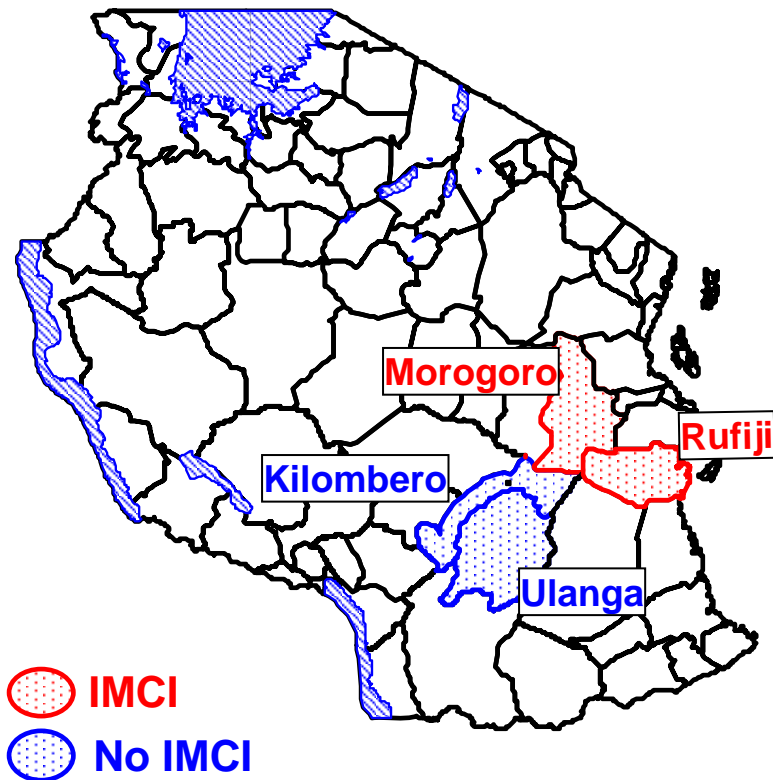
Families and communities

*Integrated Management of Childhood Illness

IMCI impact model



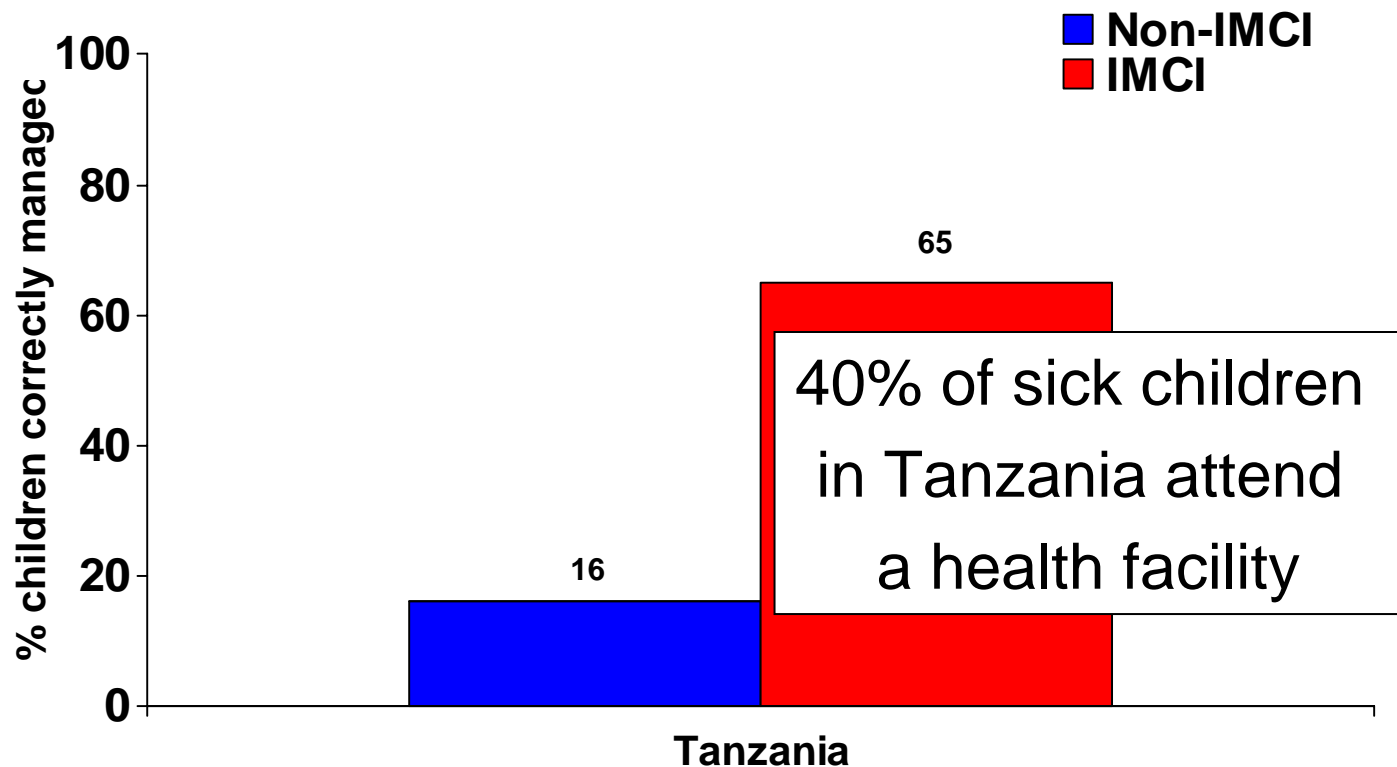
MCE Tanzania Design



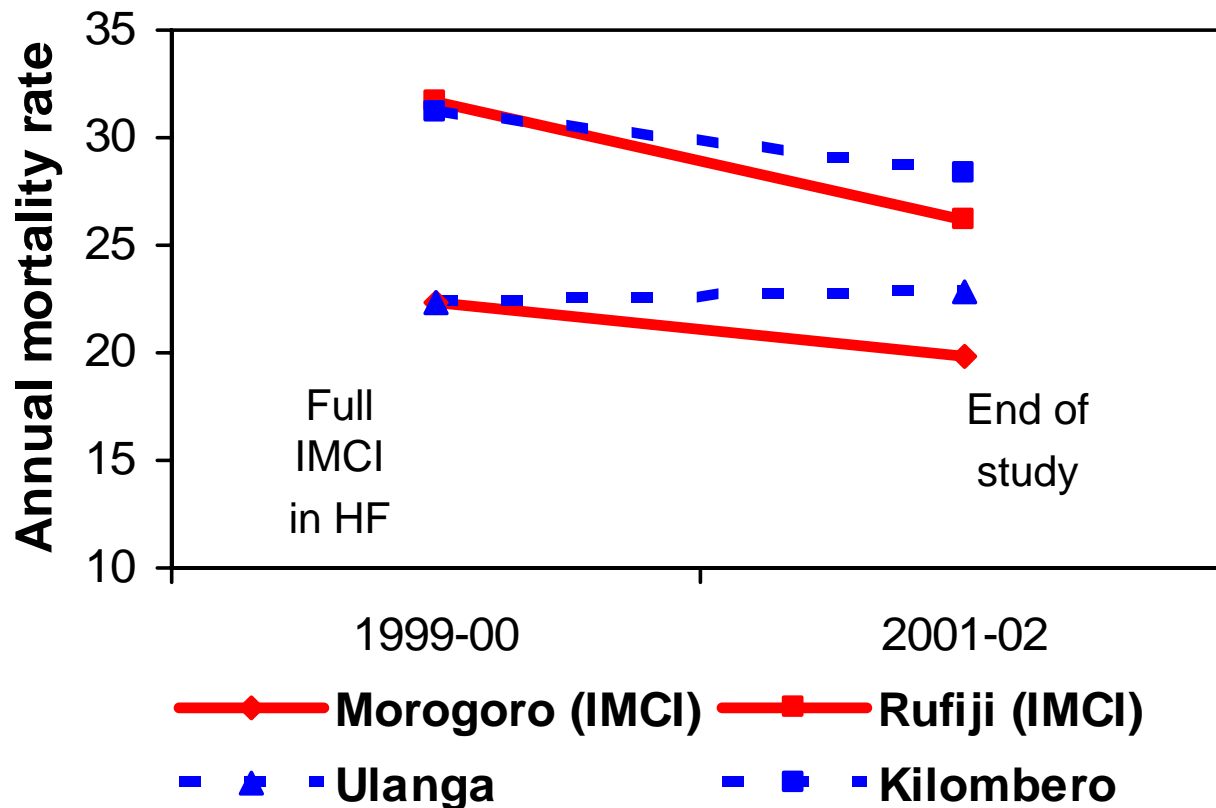
- Plausibility study in 4 districts
- IMCI implemented in 2 districts
 - high training coverage by 1999
 - district strengthening (TEHIP)
- Child mortality 1999-2002 (DSS)
- Household surveys 1999 & 2002
- Health facility survey 2000
- Costing study



Tanzania: IMCI improved health worker performance

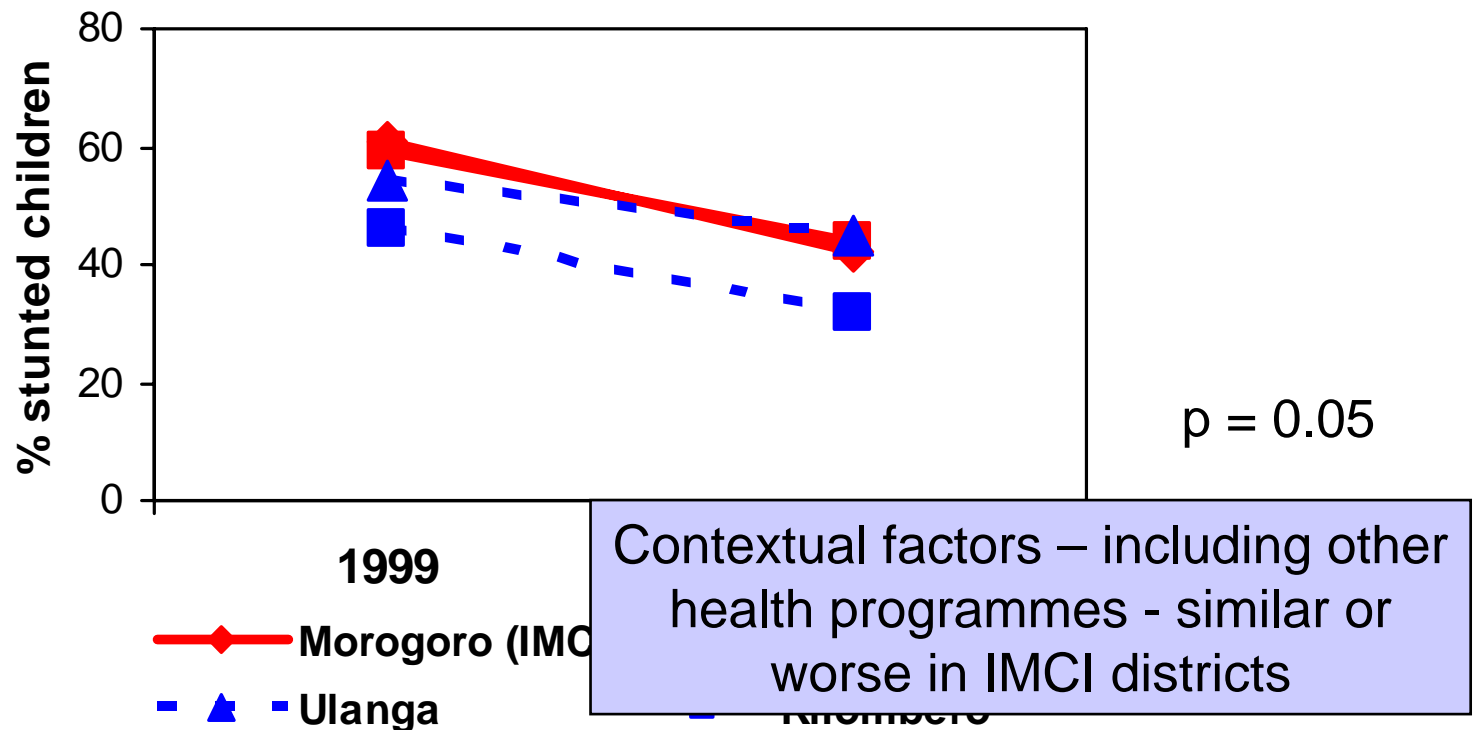


Tanzania: underfive mortality was 13% lower in the two IMCI districts



Tanzania: stunting prevalence dropped faster in the two IMCI districts

Stunting prevalence among children aged 24-59 months



Reasons for IMCI failure in some countries

- Poor quality of training
- Low training coverage
- Staff turnover
- Lack of drugs
- Poor supervision
- Low utilization of health services
- Low coverage of community interventions



Plausibility evaluations are particularly useful when:

- The artificiality of RCTs is inappropriate for the complexity of the intervention
- RCTs demonstrated efficacy but effectiveness is questionable
- Ethical or practical reasons preclude randomisation
- The intervention goes to scale rapidly
- Decision-makers require local data



Improving the Reporting Quality of Nonrandomized Evaluations of Behavioral and Public Health Interventions: The TREND Statement

Developing an evidence base for making public health decisions will require using data from evaluation studies with randomized and nonrandomized designs. Assessing individual studies and using studies in quantitative research syntheses require transparent reporting of the study, with sufficient detail and clarity to readily see differences and similarities among studies in the same area. The Consolidated Standards of Reporting Trials (CONSORT) statement provides guidelines for transparent reporting of randomized clinical trials.

We present the initial version of the Transparent Reporting for Evaluations With Nonrandomized Designs (TREND) statement. These guidelines emphasize the reporting of theories used and descriptions of intervention and comparison conditions, research design, and methods of adjusting for possible biases in evaluation studies that use nonrandomized designs. (*Am J Public Health*. 2004;94:XXX-XXX)

Don C. Des Jarlais, PhD, Cynthia Lyles, PhD, Nicole Crepaz, PhD, and the TREND Group

- OVER** decade ward e has em evidenc decisio: availab than or the per care pr parallel dence-l tices.^{4,5} tended availab the fou health- In th based r control consid tary vi cacy of the pre
- Transparent Reporting for Evaluations with Nonrandomised Designs (TREND)
 - Similar to CONSORT guidelines
 - Include
 - conceptual frameworks used
 - intervention and comparison conditions
 - research design
 - methods of adjusting for possible biases
 - AJPH, March 2004

sufficiently strong that when empirical evidence from RCTs is available, “weaker” designs are often considered to be of little or no evidentiary value. In this issue, Victoria et al.⁶ makes a

base toward interventions that are “easier” to evaluate but not necessarily more effective or cost-effective.

If nonrandomized designs are to be automatically used in

This statement has been adopted as a framework for the reporting of RCTs by a large number of medical, clinical, and psychological journals (153, according to <http://www.consort-statement.org>).



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What do we need?

- We need both efficacy and effectiveness studies
- We need both randomized and observational studies
- Internal and external validity are important
- Funders and journal editors must support and publish effectiveness studies

