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**MEETING OF TECHNICAL PARTNERS
ON THE EVALUATION OF IMCI IMPACT
GENEVA, SWITZERLAND
APRIL 15-16, 1998**

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ACRONYMS

BASICS	Basic Support for Institutionalizing Child Survival
DALY	Disability-Adjusted Life Year
DHS	Demographic and Health Survey
IMCI	Integrated Management of Childhood Illness
JHU	Johns Hopkins University, School of Hygiene and Public Health
MOF	Ministry of Finance
MOH	Ministry of Health
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
WHO	World Health Organization

EXECUTIVE SUMMARY

The purpose of this trip was to attend and participate in the Meeting of Technical Partners in the Evaluation of IMCI Impact. The objectives of the meeting were 1) to define and, if possible, resolve questions about the design of evaluations of IMCI impact and 2) to develop a work plan among technical partners for the further development of the design and methods for evaluations of IMCI impact.

Day 1 of the meeting was devoted to a review of IMCI core indicators, presentation of a framework for IMCI evaluation including four design scenarios, a presentation of cost issues in IMCI evaluation, and in-depth discussions of three evaluation scenarios. Within this context, this reporter presented the JHU proposal for a scenario IV (probability longitudinal experimental-comparison) design for evaluating the effectiveness of the IMCI approach to health care delivery. This proposal was developed under an existing BASICS-JHU subcontract.

On Day 2 the participants were divided into two smaller working groups. Each group was asked to identify and assess important design issues further with regard to evaluation Scenarios I (longitudinal without a comparison group) and II (cross sectional with geographic comparison). WHO will produce an official report of the meeting that will focus on the Day 2 outcomes.

Wrap-up of the meeting included 1) a delineation of important criteria in site selection for IMCI impact evaluation and a discussion of possible sites meeting the criteria and 2) identification of next steps. The next steps include 1) production of the meeting report (within one month), 2) drafting of guidelines (within two to three months) for Scenarios I and II evaluations of IMCI impact, 3) WHO is to work closely with groups, including JHU, that are designing Scenario III and IV studies, and 4) WHO is to develop a draft advocacy document for mobilizing donor support and partners for the further conduct of IMCI impact evaluation studies.

BACKGROUND

The IMCI approach of delivering health care to young children was developed by WHO and UNICEF to build on and increase the successes of its vertical disease control programs for pneumonia, diarrhea, malaria, vaccine preventable diseases and malnutrition. This development was in response to recognition of the deficiencies in patient care and the inefficiencies in the health system inherent in a vertical approach to disease control. The full IMCI approach includes three components: 1) improving health worker skills through the development and use of guidelines in the integrated management of childhood illness at first-level health facilities, 2) improving the health system to support IMCI, and 3) improving child care at family and community levels. In 1995, guidelines were finalized for the integrated management of childhood illness at first-level health facilities. In 1996, WHO and UNICEF issued a course for health workers to be trained in the use of these guidelines and training was begun in several countries. As of December 1997, IMCI had been introduced in 12 countries, completed early.

implementation in 23 other countries and undergone expanded implementation in a further six countries

Technical partners have supported WHO and UNICEF in implementing the IMCI strategy in individual countries and in evaluating and improving the IMCI guidelines. The guidelines were developed based on scientific evidence and evaluations of their effectiveness. A recent supplement (Volume 75 Number 1, 1997) of the *Bulletin of the WHO* contributed to the continuing scientific dialogue regarding IMCI. A meeting entitled "Operations Research on Integrated Management of Childhood Illness" was held at BASICS in February 1997 and helped to define priority areas for operations research needed to advance the IMCI strategy, including studies of the impact of IMCI. The current meeting was held to advance the development of studies of IMCI's impact further.

PURPOSE AND OBJECTIVES OF THE MEETING

The purpose of the meeting was to bring together technical partners to advance the development of study designs for evaluating the impact of the IMCI approach on health outcomes.

The objectives were:

- 1) To define and, if possible, resolve questions about the design of evaluations of IMCI impact, and
- 2) To develop a work plan among technical partners for the further development of the design and methods for evaluations of IMCI impact.

PROCEEDINGS OF THE MEETING

Summary of Presentations and Highlights

Day 1 consisted of nine presentations.

- 1) Introductions and meeting objectives

The meeting objectives were presented.

- 2) An overview of IMCI implementation strategies affecting evaluation design.

IMCI implementation to date was reviewed. The three IMCI components (improve health worker skills, improve health systems, improve family and community practices) were

reviewed. The family and community practices component is the least well-developed. Possible areas for intervention and an implementation strategy were discussed.

3) A review of IMCI core indicators and their strategic development

The core indicators (Appendix C) and the principles behind their development were presented. A working group consisting of members from WHO, UNICEF, BASICS and USAID selected a limited set of core indicators which emphasize routine monitoring at the district level. Collection and use of these indicators will be supplemented by periodic surveys and operations research. The emphasis on district management acknowledges the increasing responsibilities of districts for planning and budgeting for health activities, the role of districts in IMCI implementation, and the need for a rapid alert system that supports local action. As such, the indicators address the full range of IMCI issues, yet are of low cost to collect and are meant to flag problems for further investigation rather than provide detailed information on their own.

Discussion following the presentation focused on whether evaluations of IMCI impact should attempt to analyze the impact of each implementation phase or component separately. One strategy might evaluate IMCI's impact at different sites, each of which was in a different implementation stage. Some felt that perhaps it is premature to attempt an effectiveness study prior to full implementation of IMCI, including the community component.

4) A framework for IMCI evaluation, including four evaluation design scenarios

A framework for evaluating the impact of IMCI (Appendix D) was presented. The point was made that IMCI bundles together several interventions, each of which has been shown to be efficacious against a particular health problem. Evaluations of IMCI should determine the efficacy of the bundled health intervention package, and whether the IMCI approach is effective in reducing population-based child mortality in real-life settings.

Discussion participants asked how IMCI is different from current health programs that include workers who are well-trained in ARI, EPI, CDD and nutrition management. This is relevant to the selection of an appropriate comparison group for an evaluation of IMCI impact, and points to the choice of a comparison area with a well-functioning standard health program.

5) Cost issues in IMCI evaluation

Important cost issues to be included in an evaluation of IMCI impact include health program finances, efficiency (the link between cost and impact) and equity. While costs include provider costs, utilization costs and behavior costs, the evaluation should emphasize incremental provider costs (by activity, source, operational level and timing,

i.e. start-up or recurrent) Possible data sources include routine information systems, health facility surveys and in-depth interviews. The circumstances in the study setting must be well documented to support a statement of generalizability. The MOF should be involved as well as the MOH.

Discussion emphasized that costs should be documented at the health facility level, rather than focusing on donor inputs. It was clarified that, while a single indicator such as mortality or DALYs is needed for presentation to donors, these need to be translated into appropriate language for presentation to different audiences, including the community.

6) Evaluation Scenario I

The Scenario I study site and design (Appendix F, longitudinal before-after without a comparison group) were described. Discussion pointed out that this may be a good site to focus on cost effectiveness since mortality is relatively low and other indicators are also at good levels. Generalizability may be limited due to the lack of malaria and measles.

7) Evaluation Scenario II

The Scenario II study site and design (Appendix G, cross sectional with a geographic comparison group) were described. Highlighted points included that mortality can be assessed in sites where the demographic surveillance system is in operation, morbidity impact should avoid facility data and could focus on proxy indicators of behavior change, process impact should focus on trends in indicators of service provision, quality, utilization and coverage, the effectiveness of IMCI in this setting will be driven by high utilization and quality of services and by the efficacy of IMCI anti-malarial interventions, and using this study design to determine the plausibility of IMCI's impact on mortality requires analyzing the process indicators and confounding factors.

8) Evaluation Scenario IV

The Scenario IV study design (probability longitudinal experimental-geographic comparison) was described. Discussion focused on when post-intervention data collection should begin and on the sample size requirements for both the baseline-final household surveys and the intermediate six-monthly surveys. It was felt that the intervention should be well underway prior to beginning post-intervention data collection, and that sample size should be sufficient to accommodate both within and between group comparisons.

9) A discussion of information needed for IMCI evaluation efforts to provide useful information to the global health community

This summary presentation highlighted that experience with the IMCI strategy is too limited at this point to measure its impact on mortality. A step-by-step evaluation is

needed until we better understand what IMCI is and what should be evaluated. However, we should take advantage of our current position at the early stages of IMCI implementation to gather baseline data on mortality. Impact evaluations should use the best experimental design whenever possible and this should include randomization of study areas to experimental and comparison groups. No one study will be generalizable to all situations, therefore three to five studies are needed covering different sites and situations. Finally, too early or poorly conducted evaluations could harm the future of IMCI.

Summary of Group Discussions

Day 2 was devoted to smaller work group in-depth discussions of study design Scenarios I (longitudinal before-after without a comparison) and II (cross sectional with comparison, using retrospective longitudinal data for plausibility). Study Design I is useful in situations where there is available baseline information, where IMCI has already been started and when resources or the situation do not favor inclusion of a comparison group. Its advantages are that it is rapid and low cost to perform. Disadvantages are that program implementation may fail during the course of the study and the findings can provide only adequacy statements (e.g., malnutrition rates are decreasing in the IMCI service area).

Study Design II is of lower risk because the health program is known to be functional prior to study implementation. Stability in the study area, both political as well as in other ways (e.g., no recent epidemics, no refugees or urbanization and minimal migration) will also lower the risk incurred by the study. The main disadvantage of this design is the long delay before results are available. The study site should preferably have high mortality at baseline since this is the main indicator of interest. Comparison districts should be comparable to IMCI districts pre-IMCI with regard to the under-5 mortality level. Selection of the comparison area can be conducted in a staged process, with initial selection of possible areas based on regional data (including proxy data such as socio-economic status), and subsequent fine tuning of the selection based on district-level morbidity data. District-level mortality data would have to be obtained through special surveys, or perhaps by coordinating with and upgrading a planned DHS with additional resources. Some participants felt it was important to evaluate IMCI in a setting with other existing health interventions, especially the Bamako program. In this case, IMCI would be added to some districts and not others, to compare Bamako plus IMCI to Bamako without IMCI.

IMCI should have been in the maintenance stage for three or more years prior to study onset with, at minimum, adequate implementation of Component 1 (improving first-level health worker performance through use of the IMCI case management guidelines) and adequate implementation of at least some elements of Component 2 (improving health system performance, with emphasis on the provision of an adequate supply of essential antibiotics and antimalarials). It was felt that the study could proceed prior to implementation of Component 3. This point led to some controversy during the follow-up general discussion, but the opinion of Working Group II prevailed in the larger group. It was felt that adequate implementation of IMCI

Components 1 and 2 should lead to decreases in under-5 mortality given adequate access to and utilization of services. Also, the elements to be included in Component 3 have yet to be adequately defined, they will likely vary greatly across communities, and many communities will in any case have implemented some interventions that are compatible with IMCI.

CONCLUSIONS OF THE MEETING AND NEXT STEPS

It was concluded that no one study will answer all questions nor be generalizable to all sites or situations regarding the impact of IMCI. Three to five studies in different sites covering different situations are needed. Studies should be conducted in a staged fashion as IMCI is implemented and should examine the full range of intermediate and final outcome indicators. While a Scenario IV study design is needed to provide the most valid data regarding mortality impact, other designs can provide useful information in a more timely fashion and help document the experience with IMCI.

Studies should be conducted in diverse regions, including Africa, South Asia and the Americas, and in diverse disease settings, including those with and without malaria. The effects of existing services, such as the Bamako Initiative, and other effect modifiers should be examined. Essential site characteristics include the adequate and timely implementation of IMCI, a sufficient population size and the availability of partners to help conduct the study. Desirable site characteristics include high mortality areas with available costing data. Political and other types of stability are desirable, and are especially important for the conduct of large-scale randomized trials.

Next steps include

- 1) Production by WHO of an official report of the meeting within one month,
- 2) Drafting of generic guidelines for Study Scenarios 1 and 2 within two to three months,
- 3) WHO will work closely with groups designing Scenario 3 or 4 studies, and
- 4) WHO is to develop an advocacy document describing the set of desirable studies and the need for these to help mobilize donor support and technical partners

APPENDIXES

APPENDIX A
Participant List

PARTICIPANT LIST

Dr Cecilia Acuin, De La Salle University, Philippines

Dr Don de Savigny, Tanzania Essential Health Interventions Project, Tanzania

Dr Joseph Foubi, UNICEF, USA

Dr Jean-Pierre Habicht, Cornell University, Ithaca, USA

Dr Henry Kalter, Dept of International Health, The Johns Hopkins University, Baltimore, USA

Ms Margaret Phillips, Cambridge, USA

Dr Patrick Vaughan, International Center for Diarrheal Disease Research, Bangladesh

Dr Cesar Victora, Universidade Federal de Pelotas, Brazil

Dr John Walley, Nuffield Institute for Health, UK

WHO Secretariat

CHD

Dr Jennifer Bryce

Dr Jose Martines

Dr Thierry Lambrechts

Regional Offices

Ms Suzanne Verver, WHO Tanzania

APPENDIX B
Conference Agenda

CONFERENCE AGENDA

Day 1 (April 15, 1998)

Morning session

- 9 00-9 30 Welcome and introductions (J Bryce)
- 9 30-10 00 IMCI Implementation Strategies and Opportunities for Evaluation (J Bryce/J Martines)
- 10 00-10 15 IMCI core indicators (J Foubi)
- 10 15-10 30 Discussion
- 10 30-11 00 Coffee break
- 11 00-11 20 Framework for IMCI Evaluation and Country Scenarios (C Victora)
- 11 20-11 40 Discussion
- 11 40-12 00 Cost Issues in IMCI Evaluation (M Phillips)
- 12 00-12 30 Discussion
- 12 30-2 00 Lunch

Afternoon session

- 2 00-2 30 Scenario I (historical) (C Victora)
- 2 30-3 00 Discussion
- 3 00-3 30 Scenario II (geographical) (D de Savigny)
- 3 30-4 00 Coffee break
- 4 00-4 30 Scenario IV (stepped wedge) (H Kalter)
- 4 30-5 00 Discussion
- 5 00-5 30 Information needed for this evaluation to be useful globally (P Vaughan)

Day 2 (April 16, 1998)

Morning session

- 8 30-9 00 Review of expected outcomes and definition of small groups (C Victora)
- 9 00-12 30 Small Group Work
- 12 30-2 00 Lunch

Afternoon session

- 2 00-3 00 Small Group Work
- 3 00-3 40 Small Group Presentations (20 minutes each)
- 3 40-4 00 Coffee break
- 4 00-5 00 Discussion
- 5 00-5 30 Summary and Next Steps (J Bryce)

APPENDIX C
Core Indicators

TOPICAL LIST OF CORE INDICATORS FOR IMCI MONITORING AND EVALUATION (25 March 1998)

HEALTH WORKER SKILLS

Assessment

- 1 Child assessed for four general danger signs
- 2 Child assessed for the presence of cough, diarrhoea, and fever
- 3 Child's weight checked using a growth chart
- 4 Child's vaccination status checked
- 5 Caretaker of child under two years of age asked about breastfeeding and complementary foods

Correct treatment and counselling

- 6 Child needing referral is referred
- 7 Child needing oral antibiotic and/or antimalarial is prescribed drug(s) correctly
- 8 Caretaker of child with diarrhoea and no dehydration is advised to give extra fluids and continue feeding
- 9 Child leaves facility with all needed vaccinations
- 10 Caretaker of child who is prescribed ORS and/or oral antibiotic and/or an antimalarial knows how to give the treatment

HEALTH SYSTEM SUPPORTS FOR IMCI

Supervision

- 11 Health facility received at least one supervisory visit during the previous four months

Drugs, equipment and supplies

- 12 Health facility has all essential equipment and materials for IMCI
- 13 Health facility has all essential IMCI drugs available
- 14 Health facility has the equipment and supplies to provide full vaccination services

IMCI training coverage

- 15 Health facilities with at least 80% of health workers who manage children trained in IMCI

CARETAKER SATISFACTION

- 16 To be determined at country level

CHILD CARE AT FAMILY AND COMMUNITY LEVELS*

Nutrition

- 17 Child under 4 months of age is exclusively breastfed
- 18 Child aged 6 - 9 months receives breastmilk and complementary foods

Immunization

- 19 Child 12 - 23 months of age who is vaccinated against measles before 12 months of age

*These proposed indicators may need to be adapted when more IMCI interventions to improve child care at family and community levels become available

DEFINITIONS OF CORE INDICATORS FOR IMCI MONITORING AND EVALUATION

25 March 1998

TITLE	DESCRIPTION OF INDICATOR	<p align="center"><u>NUMERATOR</u> <u>DENOMINATOR</u></p>
IMPROVED HEALTH WORKERS' SKILLS (for the management of children 2 - 59 months of age)		
ASSESSMENT	1 The proportion of children assessed for the four general danger signs	<p align="center">Number of children seen who are assessed for danger signs (is the child able to drink or breastfeed, <u>does the child vomit everything, has the child had convulsions, is the child lethargic</u>)</p> <p align="center">Number of children seen</p>
	2 The proportion of children assessed for the presence of cough, diarrhoea, and fever	<p align="center"><u>Number of children seen who are assessed for the presence of cough, diarrhoea, and fever</u></p> <p align="center">Number of children seen</p>
	3 The proportion of children who have their weight checked using a growth chart	<p align="center"><u>Number of children seen who have their weight checked using a growth chart</u></p> <p align="center">Number of children seen</p>
	4 The proportion of children who have their vaccination status checked	<p align="center"><u>Number of children seen who have their vaccination card checked or who are asked their vaccination history</u></p> <p align="center">Number of children seen</p>
	5 The proportion of children under two years of age whose caretakers are asked about breastfeeding and complementary foods	<p align="center">Number of children under two years of age whose caretakers are asked if they <u>breastfeed this child and whether the child takes any other food or fluids</u></p> <p align="center">Number of children under two years of age seen</p>
CORRECT TREATMENT AND COUNSELING	6 The proportion of children needing referral who are referred	<p align="center">Number of children with a validated classification of severe disease needing referral (severe pneumonia or very severe disease, and/or severe dehydration with any other severe classification, and/or severe persistent diarrhoea, and/or very severe febrile disease, and/or severe complicated measles, and/or <u>mastoiditis, and/or severe malnutrition or severe anaemia</u>) <u>who were referred</u></p> <p align="center">Number of children with a validated classification of severe disease needing referral</p>
	7 The proportion of children who do not need urgent referral, who need an oral antibiotic and/or an antimalarial who are prescribed the drug(s) correctly	<p align="center">Number of children with validated classifications, who do not need urgent referral, who need an oral antibiotic and/or an antimalarial (pneumonia, and/or dysentery, and/or malaria, and/or acute ear infection, and/or anaemia in high malaria risk areas) <u>who are correctly prescribed them, including dose, number of times per day, and number of days</u></p> <p align="center">Number of children with validated classifications who do not need urgent referral, who need an oral antibiotic and/or an antimalarial</p>
	8 The proportion of children with diarrhoea with no dehydration whose caretakers are advised to give extra fluid and continue feeding	<p align="center">Number of children with validated classifications of diarrhoea with no dehydration <u>whose caretakers are advised to give extra fluid and continue feeding</u></p> <p align="center">Number of children with validated classifications of diarrhoea with no dehydration</p>

TITLE	DESCRIPTION OF INDICATOR	<p style="text-align: center;"><u>NUMERATOR</u> <u>DENOMINATOR</u></p>
CORRECT TREATMENT AND COUNSELING (CONT)	9 The proportion of sick children who leave the HF with all needed vaccinations	<p style="text-align: center;"><u>Number of sick children who leave the HF with all needed vaccinations</u> Number of sick children seen</p>
	10 The proportion of children prescribed ORS, and/or an oral antibiotic and/or antimalarial whose caretakers (CTs) know how to give the treatment	<p style="text-align: center;">Number of children prescribed ORS, and/or an oral antibiotic and/or antimalarial whose CTs know how to give <u>the treatment, including the amount, number of times per day, and number of days</u> Number of children prescribed ORS and/or an antibiotic and/or antimalarial</p>
IMPROVED HEALTH SYSTEM SUPPORTS FOR IMCI		
SUPERVISION	11 The proportion of HFs with IMCI-trained health workers (HWs) that received at least one clinical supervisory visit during the previous 4 months	<p style="text-align: center;">Number of health facilities with IMCI-trained HWs that received <u>at least one clinical supervisory visit during the previous 4 months</u> Number of health facilities with IMCI-trained health workers</p>
DRUGS, EQUIPMENT AND SUPPLIES	12 The proportion of HFs that have all needed equipment and materials available on the day of contact	<p style="text-align: center;">Number of health facilities with all needed equipment and materials <u>(accessible weighing scale, timing device, mother's card, child health cards, IMCI chart booklet, patient recording form, stock cards or drug logbook, source of clean water, supplies to mix ORS) available on the day of contact</u> Number of health facilities contacted</p>
	13 The proportion of HFs that have ORS, and all first-line and pre-referral antibiotics and antimalarial available on the day of contact	<p style="text-align: center;">Number of health facilities with ORS, and all first line and pre-referral antibiotics and antimalarial (as recommended in the national adaptation of the IMCI clinical guidelines) <u>available on the day of contact</u> Number of health facilities contacted</p>
	14 The proportion of HFs that have the equipment and supplies to provide full vaccination services on the day of contact	<p style="text-align: center;">Number of health facilities that have the equipment and supplies to provide full vaccination services (functioning refrigerator, functioning sterilizer, needles/syringes, refrigerator temperature chart, <u>temperature chart up-to-date, and bcg, opv, dpt, TT, measles vaccines) available on the day of contact</u> Number of health facilities contacted</p>
MCI TRAINING COVERAGE	15 The proportion of first-level health facilities with at least 80% of health workers managing children trained in IMCI	<p style="text-align: center;">Number of health facilities with at least 80% of health workers managing children <u>who are trained in IMCI</u> Number of health facilities</p>

16

TITLE	DESCRIPTION OF INDICATOR	<u>NUMERATOR</u> <u>DENOMINATOR</u>
CARETAKER SATISFACTION	16 To be determined at country level	
IMPROVED CHILD CARE AT FAMILY AND COMMUNITY LEVELS (measured in the community)		
NUTRITION	17 The proportion of children less than 4 months of age exclusively breastfed	<u>Number of children less than 4 months of age whose caretakers report they are exclusively breastfed</u> Number of children less than 4 months of age
	18 The proportion of children aged 6-9 months who receive breastmilk and complimentary foods	Number of children 6-9 months of age whose caretakers report that they receive <u>both breastmilk and complementary food</u> Number of children 6-9 months of age
IMMUNIZATION	19 The proportion of children 12-23 months of age who were vaccinated against measles before 12 months of age	Number of children 12-23 months of age who have written documentation of measles vaccination or whose caretaker report <u>vaccination against measles between 9-12 months of age</u> Number of children 12-23 months of age

APPENDIX D
Design Issues

Evaluation of the Impact of Integrated Management of Childhood Illness

Design Issues

Introduction

- **Early stage of IMCI implementation**
- **Desire to assess the impact of IMCI on childhood morbidity and mortality**
- **Need to coordinate with ongoing work on monitoring indicators and on effectiveness evaluations**

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Characteristics of IMCI that will affect evaluation design

(J Bryce)

- **Broad overall strategy, encompassing multiple interventions**
- **Phased implementation introduction, early implementation, expansion**
- **District-by -district approach**
- **Staggered introduction of interventions**
- **Variable constellation of interventions across countries and districts**

Conceptual framework

- **Emphasis on summative, rather than formative evaluation**
- **Public Health Efficacy or Effectiveness?**
 - One efficacy study a limited area (population laboratory setting)
 - 3-4 large scale effectiveness evaluations
- **Stepwise approach to assessment of indicators**

INDICATOR	QUESTION	EXAMPLE OF INDICATORS
Provision	<p>Are the services available?</p> <p>Are they accessible?</p> <p>Is their quality satisfactory?</p>	<ul style="list-style-type: none"> • Number of health facilities offering IMCI activities per 100,000 population • Proportion of the population within 10 km of a health facility with IMCI activities • Proportion of health workers with appropriate case-management skills
Utilization	Are the services being used?	<ul style="list-style-type: none"> • Number of attendances of under fives per 1,000 children
Coverage	Is the target population being reached?	<ul style="list-style-type: none"> • Proportion of under-fives in population who were seen by a trained health worker
Impact	Were there improvements in disease patterns or health-related behaviors?	<ul style="list-style-type: none"> • Time trends in childhood deaths • Improvements in breastfeeding indicators or in health care seeking behaviors

Emphasis will be on impact, but it is essential to documentat changes in provision, utilization and coverage

IMCI Impact Evaluation - Main Issues

- Type of inference required (adequacy, plausibility, probability)

INFERENCE	QUESTIONS
Adequacy design	Have the programme goals been achieved? Are trends moving in the right direction?
Plausibility design ("likelihood")	Is it likely that the goals were achieved <u>due to</u> the programme?
Probability design	What is the statistical probability that the programme had an effect?

**Emphasis on evaluations with adequacy and plausibility designs,
but probability design may be possible for efficacy study**

- Close interaction with donors and other decision-makers in order to promote the instrumental use of evaluation results

Choosing a control group for plausibility analyses

- a) **Longitudinal (historical) design**
Hypothesis Implementation of IMCI led to improvements in impact indicators in relation to levels prior to implementation
- b) **Cross-sectional (geographical) design**
Hypothesis Impact indicators are better in areas where IMCI was implemented than in similar areas without IMCI
- c) **Longitudinal-control design**
Hypothesis Areas where IMCI was implemented show greater improvements in terms of impact indicators than similar areas without IMCI
- d) **Cross-sectional internal design**
Hypothesis Impact indicators are better among individuals who were reached by IMCI than among those who were not
 - **Useful only in conjunction with other control groups**

Questions influencing the choice of controls:

- **Does IMCI have an impact when compared with areas where there are few or no services?**
- **Does IMCI have an impact on top of “typical” health services?**
- **How does IMCI compare with “best practice” services?**

“Typical” and “best practice” services likely to be the most useful comparisons

Choice of countries: possible scenarios

- **Scenario I.**
 - IMCI is at the expansion stage
 - Good quality baseline data are available
 - Longitudinal, before-and-after comparison

- **Scenario II.**
 - IMCI is at the expansion stage
 - IMCI implemented in some districts or provinces, but not throughout the country
 - Cross-sectional geographical comparison

- **Scenario III.**
 - IMCI is at an early implementation stage
 - Some provinces will be reached earlier than others
 - Baseline data to be collected in a systematic way, and in a few years the data collection cycle would be repeated
 - A longitudinal-control design would be possible (final evaluation results available after a few years)

- **Scenario IV.**
 - IMCI is at an early implementation stage
 - Political will to randomize the order in which provinces would be enrolled
 - Baseline surveys in all provinces, to be repeated regularly
 - Provinces will remain in the control group until IMCI implementation, when they will change to the intervention group
 - A probability, longitudinal-control design would be possible (final evaluation results available after a few years)

**A combination of evaluations in scenarios I-III would be desirable
Scenario IV is less likely**

APPENDIX E
Working Group Scenario I

Scenario I

Sergipe State, Northeast Brazil

1 Background eligibility information

- 1.1 Brief description** Sergipe has a population of 1.6 million and is located in Northeast Brazil, the poorest region in the country. The capital is Aracaju (population 450,000) and two thirds of the state's population are urban.
- 1.2 Infant mortality rate** Indirect estimates put IMR at 53 per thousand for 1997, 21 municipalities are included in the national list of critical high-IMR municipalities¹.
- 1.3 IMCI implementation** Sergipe is one of the fastest moving states in Brazil regarding IMCI implementation. The training component is well under way. 66 health workers (doctors and nurses) from 11 municipalities have been trained so far and 16 more are being trained each month. The 8-day course is being used. Supervision activities are starting in April 1998. However, little has been achieved regarding the other two components of IMCI. The drug supply is still a problem.
- 1.4 Partners** The state government is highly motivated. IMCI is also supported by the federal government and by PAHO. No other international agencies are involved.
- 1.5 Probability of political stability over next 5 years** The State Governor is likely to be reelected for four years from November. Regardless of who wins, however, there is a strong core team in the State's Secretariat of Health who are willing to continue with IMCI implementation.

2 Availability of baseline information

- 2.1 Mortality data** Vital registration appears to be reasonably complete in the capital and in other urban areas, but coverage in rural areas is lower. Compared to indirect methods that give an estimated IMR of 53, the official figure for was 36, suggesting an overall under-registration rate of 32%.
- 2.2 Morbidity data** Two statewide representative surveys were carried out in 1989 (sample 1,043) and in 1994 (sample 1,329), using a methodology

¹ The actual mortality levels in these municipalities is not known but their inclusion in the list is based on socioeconomic indicators that are markers for high IMR.

developed by the University of Pelotas. Each survey covered the state's capital plus 14 other municipalities. The data collected included the prevalence of malnutrition, causes of health care seeking, hospital admissions, diarrhoea in the preceding two weeks. The main results of these surveys are shown in Table 1. A new survey is planned for late 1998, which will also include assessment of anemia.

2.3 Coverage data The statewide surveys also provided information on coverage of vaccinations, growth monitoring, and on breastfeeding prevalences (Table 1). The 1998 survey will also provide data on coverage of vitamin A supplementation and use of iodized salt.

2.4 Health services data The surveys provided population-based data on use of services in the last 3 months, and the Secretariat's information system produces utilization data. As mentioned, the IMCI supervision scheme will start soon.

3 Study design

Due to the existence of baseline information on malnutrition, breastfeeding and programme coverage, the proposed evaluation will employ a longitudinal design. The possibility of also using a parallel geographical design will be explored.

3.1 Longitudinal (historical)

3.1.1 Design This will consist of a before-and-after analysis, based on the hypothesis that IMCI implementation will lead to improvements in the indicators listed below.

3.1.2 Indicators The evaluation will cover indicators of services provision (availability and quality of training), utilization, coverage and impact on malnutrition, breastfeeding and mortality².

3.1.3 Type of inference The first level of inference will consist of adequacy statements. Indicators of provision, utilization, coverage and impact will be compared with pre-established goals³. If achievements in terms of adequacy criteria are satisfactory, a plausibility analysis will be carried out. This will entail attempting to rule out the effect of external factors that may have accounted for the observed improvements.

² For a preliminary list of indicators see Victora CG. Evaluation of the Impact of Integrated Management of Childhood Illness. Design Issues (WHO/CHD, unpublished paper 1998).

³ If goals have not been defined a priori, the evaluation team will work with the state Health Secretariat to define what would be realistic adequacy targets.

- 3 2 **Cross-sectional (geographical) design** The evaluation may also include a cross-sectional comparison of municipalities with IMCI with others without the programme. Since the highest-risk municipalities in the state were singled out for early implementation, the comparability between intervention and control municipalities may be affected. This design will not be further pursued in the present document but it may be developed in the future.

4 Data collection

The main sources of data for the evaluation will include Health Secretariat reports (on IMCI training and supervisory activities, on utilization of health services), vital statistics (mortality) and statewide surveys. As mentioned, statewide surveys were carried out in 1989, 1994 and one is planned for 1998. This survey should be repeated in 2-4 years, say in year 2001, to assess the changes in coverage and impact associated with IMCI implementation.

- 4 1 **Provision of services** Data on availability of IMCI (number of HW trained, geographical distribution) will be obtained from State Secretariat reports. Quality of care (use of integrated approach, correct treatment, missed opportunities for immunization avoided, effective counseling provided), the existence of supervision, and presence of drugs, equipment and supplies will be assessed from supervision records and, if required, through HF surveys.
- 4 2 **Services utilization** Utilization data will be derived from HF reports to the Secretariat, as well as from small scale surveys, if available. The statewide survey will also collect data on utilization.
- 4 3 **Coverage.** Data on programme coverage (vaccines, growth monitoring, ORT use, micronutrient supplementation) will be obtained through the statewide surveys.
- 4 4 **Impact.** Four main impact indicators will be used.
- 4 4 1 **Mortality** Information on mortality will be obtained from the State's vital registration system. As noted, about 70% of deaths are registered and information on time trends in proportionate mortality should be fairly reliable. Proportionate mortality rates for diarrhoea, pneumonia/ALRI and measles will be recorded (malaria is not prevalent in the state). If one assumes that under-registration is relatively constant over time, mortality rates may also be studied.

Since no information on mortality was collected in the statewide surveys, and due to the large sample sizes required⁴, assessment of mortality impact will be restricted to

⁴ Under the sample size assumptions discussed in Section 5, a survey covering over 10 000 live births would be required for detecting a 20% reduction in IMR from a baseline level of 50 per thousand.

the use of vital statistics

- 4 4 2 **Hospital morbidity** In previous studies in the region⁵, hospital records were systematically reviewed to assess trends in hospitalizations. The same method will be used to investigate a possible impact on hospital admission rates due to diarrhoea, pneumonia/ALRI and measles

Hospital admissions (overall and cause-specific) were also measured in the statewide surveys, but since less than 10% of the children are admitted in a one-year period, the sample size requirements for precise estimates of cause-specific admission rates would be very large. Therefore, this method will not be used

- 4 4 3 **Malnutrition** Prevalences of malnutrition will be assessed through the statewide surveys

- 4 4 4 **Breastfeeding** The duration of exclusive and partial breastfeeding will also be measured through the statewide surveys

- 4 5 **External factors** Data on confounding factors that might account for changes in the indicators under study, including socioeconomic and demographic factors, water supply, sanitation, and other health initiatives, will be obtained through the statewide surveys, as well as from population censuses and from routine government statistics when applicable

5 Sample sizes

- 5 1 **Mortality** Data will be based on all registered deaths and will therefore not be subject to sampling error

- 5 2 **Hospital morbidity** A regional study in the Northeast³ in 1990 showed that 30% of infant admissions were due to diarrhoea, and 25% to ARI (these results are more credible than those reported in Table 1). To detect a 20% reduction in these proportions, it will be necessary to review 1,100 hospital records at the beginning of IMCI implementation and the same number again after a few years (assuming 5% significance and 80% power)

- 5 3 **Survey-based indicators** Table 2 shows the sample sizes, in numbers of children under five years, that would be required for detecting improvements of 10%, 20% and 30% in the indicators measured in the 1994 survey, using the baseline levels from that year. The shaded cells highlight samples larger than 1,330 children, which was the sample size for 1994 and is the planned sample size for the 1998 survey. Given the relatively high coverages for most interventions, and the relatively low prevalences of malnutrition, only improvements of 20% or even 30% would be detected. Changes in diarrhoea management would be the most difficult to detect, since the information is

⁵ Victora CG, Olinto MTA, Nobre LC, Barros FC. The recent fall in diarrhoea mortality in Northeastern Brazil: did ORT play a role? *Health Policy and Planning* 1996; 11: 132-41

based only on children with diarrhoea in the preceding fortnight

Table 3 shows the smallest improvement in each indicator that would be detected given two surveys with 1,330 children each. For six of the 11 indicators, only improvements greater than 25% would be detected.

There may be some alternatives for improving this pessimistic sample size scenario, that merit further discussion. For example, these may include

- more stringent definitions of vaccine coverage (child fully immunized with basic scheme for all vaccines, or all vaccines given within x months of recommended age),
- larger expected improvements in weight recording or in diarrhoea management,
- increasing the sample size of both surveys, or if this is not possible for the 1988 survey, increasing the size of the 2001 survey
 - *use same clusters in repeat survey, to ↓ sample size by ~ 30% (↓ intra-class variability)*

6 Data analysis

The data analysis will include the following components

- 6.1 **Analysis of mortality data.** Yearly data on the cause-specific numbers of deaths and the population of children will be entered in a spreadsheet. Proportionate mortality and population-based mortality rates will be calculated, and time trends will be analyzed.
- 6.2 **Analysis of hospital morbidity.** As above, year by year data will be entered on a spreadsheet and time trends in the proportions of admissions due to diarrhoea, pneumonia/ALRI and measles will be calculated.
- 6.3 **Survey analyses.** Coverage indicators will be calculated in a comparable way for both the 1998 and 2001 surveys. The results will be assessed through significance testing using standard statistics (comparison of two proportions or, for anthropometric indicators, of two means). If the data allows, breastfeeding duration will be analyzed through survival techniques.
- 6.4 **Plausibility analyses.** Changes in the above indicators will be further assessed through multivariate methods (such as logistic or multiple linear regression, as applicable) to allow control of confounding factors. For time trend data, simulations will be carried out to estimate the impact of changes in such external factors.

7 Time frame

IMCI is at an early implementation stage, and a statewide survey will be carried out later this year. Information on provision and utilization will be collected on a

continuous basis, and it is proposed that the statewide survey should be repeated in year 2001. Impact data should therefore be available at the end of that year.

8 Budget

Previous surveys of similar size in the region have been budgeted at US\$30,000-40,000. If both the 1998 and the 2001 surveys are covered by the present budget, and adding data analysis costs, the hospital survey and the review of secondary data, the complete IMCI evaluation should cost around US\$100,000. If the 1998 survey is financed separately (the State is currently applying for a federal government grant for this purpose), the total cost to WHO/CHD would be around US\$65,000. These are preliminary estimates and do not cover external costs (e.g., consultants, travel outside the state, etc).

9 Conclusions

This scenario provides a useful reflection on what may be some of the constraints and opportunities regarding IMCI evaluations.

- 9.1 **Relatively low IMR and malnutrition prevalences** IMR is already 50 per thousand, although there are some high-risk municipalities with higher levels (yet to be defined). Except for stunting which affects 18% of the children, the other nutritional indicators have low prevalences. The likely impact of IMCI on mortality or malnutrition will be less than for less-developed scenarios. Mortality surveys are not feasible, and one must then rely on vital statistics.
- 9.2 **Reasonably good baseline coverages** As Table 1 shows, baseline indicators of coverage of vertical programmes are already quite good, except for weight recording, breastfeeding and diarrhoea management. Therefore, further increases in coverage would be limited. That would also restrict the possibility of IMCI impact.
- 9.3 **Low study power to detect small improvements** As a consequence of the above two statements, the study will have a relatively low statistical power to detect improvements below 20% of the baseline level.
- 9.4 **Rate of IMCI implementation** Only 66 HW's have been trained so far, and 16 are now being trained each month, or about 200 a year. The total number of HW's in the state is well over 1,000. At this rate, a few years will pass before a high training coverage is achieved. In addition, the 8-day training course is being used instead of the 2-week course, which might affect the quality of care.
- 9.5 **Positive points** On the positive side, the Secretariat staff appear to be highly motivated, the state is politically stable, vital statistics are reasonable and there will be 3 statewide representative surveys (1989, 1994 and 1998) by the time the evaluation starts.

9 6 **Conclusion** The Sergipe situation may be typical of a certain group of states or countries. Those with good baseline information and moving rapidly with IMCI are the same where the Health Ministry or Secretariat staff are highly motivated. For that very reason, they have already set up quite effective vertical programmes and achieved good health indicators, therefore restricting the possible impact of IMCI.

Nevertheless, a relatively inexpensive evaluation can be carried out since baseline information is available, thus making the evaluation exercise worthwhile. Further information is needed on the high-risk municipalities that have been prioritized for IMCI implementation, for an in-depth study in these municipalities may provide further information on IMCI impact.

Table 1 Baseline indicators from the two statewide surveys Sergipe, 1989-94

Indicator	Age group (months)	Survey	
		1989	1994
Percent of children breastfed	6 mos	35%	33%
Prevalence of underweight	< 5 yr	8%	5%
Prevalence of stunting	< 5 yr	16%	18%
Prevalence of wasting	< 5 yr	3%	1%
Growth card ownership ^(a)	< 5 yr	23%	71%
Recent weight registered in growth chart ^(b)	< 5 yr	5%	9%
DPT vaccine coverage	12-23 mos	58%	87%
Measles vaccine coverage	12-23 mos	84%	93%
Diarrhoea management ^(c)	< 5 yr		
Use of rehydration solution		28%	65%
Increased fluids		(d)	49%
Continued feeding		(d)	48%
Annual rate of hospital admissions	< 5 yr	8.7%	7.5%
Proportion of hospitalizations ARI	< 5 yr	32%	49% ^(e)
Diarrhoea		31%	40% ^(e)

- Notes
- a Growth card seen by the interviewer
 - b In the last 3 months
 - c Use of ORS, salt and sugar solution or rice water among children with diarrhoea in the preceding two weeks
 - d Information not collected in 1989
 - e These results are odd, since only 11% of admissions would be due to causes other than ARI or diarrhoea. A regional hospital-based study in the Northeast in 1990 showed 30% of admissions for diarrhoea and 25% for ARI

Table 2 Sample sizes (number of children under 5 years) required for detecting a significant improvement (5% significance, 80% power, design effect of 1.5)

Shaded cells represent samples of 1,330 or more

Indicator	Baseline level (1994)	Sample sizes required for detecting improvements ^(a) of		
		10%	20%	30%
Percent of children breastfed for ≥ 6 months	33%	4889	1247	563
Prevalence of underweight ^(b)	5%	9207	2100	843
Prevalence of stunting ^(b)	18%	4678	1086	444
Prevalence of wasting ^(b)	1%	15251	3450	1372
Growth chart ownership	71%	883	198	76
Recent weight registered in growth chart ^(c)	9%	24845	6473	2992
DPT vaccine coverage ^(d)	87%	1220	150	(e)
Measles vaccine coverage ^(d)	93%	1246 ^(e, f)	(e)	(e)
Increased fluids during diarrhoea ^(g)	49%	12225	3034	1330
Continued feeding during diarrhoea ^(g)	48%	12751	3171	1394
Annual rate of hospital admissions	7.5%	27668	6578	2771

- Notes
- a The estimates refer to reductions in the "negative" indicators (e.g., malnutrition, hospitalizations) and increases in the "positive" ones (e.g., breastfeeding, vaccinations, ORT)
 - b Estimates based on comparison of two mean z-scores, transformed into prevalences below -2 z-scores
 - c Given the low baseline level of weight charting, a more realistic sample size estimation would refer to a 100% increase, only 337 children would then be required
 - d Sample sizes corrected for the fact that indicator will be measured for children aged 12-23 months
 - e Coverage would exceed 100%
 - f Refers to an increase from 93% to 99%
 - g Sample sizes corrected for the fact that 20% (estimate) of the children will have presented diarrhoea in the preceding 2 weeks

Table 3 Smallest changes that would be detected with a sample survey of 1,330 children under five years

Indicator	Baseline level (1994)	Detectable change ^(a)
Percent of children breastfed for ≥ 6 months	33%	18%
Prevalence of underweight ^(b)	5%	26%
Prevalence of stunting ^(b)	18%	19%
Prevalence of wasting ^(b)	1%	32%
Growth chart ownership	71%	8%
Recent weight registered in growth chart	9%	50%
DPT vaccine coverage ^(c)	87%	10%
Measles vaccine coverage ^(c)	93%	6%
Increased fluids during diarrhoea ^(d)	49%	30%
Continued feeding during diarrhoea ^(d)	48%	31%
Annual rate of hospital admissions	7.5%	43%

- Notes
- a The estimates refer to reductions in the "negative" indicators (e.g., malnutrition, hospitalizations) and increases in the "positive" ones (e.g., breastfeeding, vaccinations, ORT) *1 relative to baseline eg for underweight $\rightarrow 26\%$ of 5%*
 - b Estimates based on comparison of two mean z-scores, transformed into prevalences below -2 z-scores
 - c Sample sizes corrected for the fact that indicator will be measured for children aged 12-23 months
 - d Sample sizes corrected for the fact that 20% (estimate) of the children will have presented diarrhoea in the preceding 2 weeks

APPENDIX F
Working Group Scenario II

Scenario II

Morogoro Rural District, Tanzania

1 Background information from an African IMCI Scenario

- 1.1 **Brief description** Morogoro Rural District in East Central Tanzania has a population of 525 000 living in 215 villages dispersed in an area of 19,250 km². It is typical of poor rural districts of the country. There is no urban capital or population covered by the District.
- 1.2 **Under-5 mortality rates** Mortality data are available from a district based direct Demographic Surveillance System (DSS) running continuously since 1992¹ on a sample of 100 000 in the District. Annual under-five mortality rates are estimated at 37.9 (males) and 34.4/1000/year (females). Probability of death before age five (5q0) is 18.8%. These 1995 directly measured rates in Morogoro Rural exceed those of Tanzania from 1965 up to the present. For 1997 the MOH and multi-lateral agencies estimate Tanzania's national IMR in the range of 82 - 115 per 1000 live births and the national U5MR in the range from 126 - 161 per 1000.
- 1.3 **IMCI implementation** Tanzania is presently in early stages of introducing IMCI in seven Districts of which Morogoro is the largest and most advanced in terms of IMCI implementation. The training component is well underway. Training is complete for eight national master trainers, for six Morogoro District TOTs (doctors and clinical officers, assistant medical officers) and for 31% (52/170) of District health workers (medical assistants, rural medical aides, and nurses). 43% (36 of 83) health facilities are trained so far and offer IMCI services. There are 117 front line workers remaining to be trained before July 1999. The two week course is being used. Supervision activities commenced immediately after training and installation of the first round of trainees starting in October 1997. Health facilities with IMCI trained staff are being minimally upgraded via community participation to support IMCI. All trained facilities have received IMCI equipment and now receive a monthly IMCI drug supplement kit additional to the EDP kit and regular supervision.

¹ Source: Ministry of Health Policy Implications of Adult Mortality and Morbidity. End of Phase I Report 1997 (AMMP)

- 1.4 **Partners** The District and DHMT are the implementors of IMCI. In the District all government, parastatal and NGO primary care facilities are being covered by IMCI. The district is highly motivated toward IMCI. It has made IMCI its first intervention priority and assigns the largest single share (19%) of its annual intervention budget to IMCI (US\$ 0.33 per capita or US\$ 2.20 per under 5 in 1998). About 41% of the IMCI budget still goes to training however this will revert to IMCI services as more IMCI health workers come on line. But even with this high commitment the IMCI

budget allocation share (19%) is less than the IMCI preventable disease burden share (24%) IMCI is also supported technically by the Ministry of Health/Tanzania Essential Health Interventions Program Canada's International Development Research Centre (IDRC) and WHO No other international agencies are involved in IMCI in this particular District

- 1.5 **Probability of political stability over next 5 years** Very high However most unpredictability pertaining to the health sector will come from the health reform movement towards decentralized priority setting and resource allocation the new sector-wide approach to health funding (SWAp) by donors civil service reforms and retrenchment and the institution of lay District Health Boards over DHMTs

2 Availability of baseline information

- 2.1 **Mortality data** Most (77%) of the burden of disease in Sub-Saharan Africa is contributed by premature mortality and 23% by morbidity DALY estimates indicate 50% of the total disease burden is carried by under-fives 25% by infants Hence the choice of intervention priorities and the measure of their ultimate effectiveness will likely be driven largely by mortality in the early years of IMCI in Africa Vital registration is non-existent in Tanzania and most of Sub-Saharan Africa However Tanzania is rich in community based mortality data deriving from eight districts (including two IMCI Districts Morogoro Rural and Rufiji Districts) running large scale continuous longitudinal direct demographic surveillance systems (DSSs) with verbal autopsy for all deaths (community and facility) in sentinel populations An increasing number of African countries are also now running DSS at district scale For Morogoro Rural District mortality data by age sex and cause are available on a sample population of 100 000 since 1992 (over 500 under-five deaths per year from the sample) In Morogoro District, the top five causes of child mortality are acute febrile illness including malaria acute diarrhoeal disease pneumonia malnutrition and AIDS In addition at national level indirect demographic and health surveys (DHS) are conducted every two years providing lagged retrospective cross-sectional mortality and morbidity data to the Regional level
- 2.2 **Morbidity data** Surveys and data from the DHMT/Health Management Information System (HMIS) the Demographic & Health Surveys the Morogoro DSS (AMMP) the UNICEF Child Survival & Development Program the Tanzania Food & Nutrition Centre and the EPI/NID programs provide information of varying quality on morbidity including prevalence of malnutrition prevalence of anemia causes of health care seeking and hospital admissions
- 2.3 **Coverage data** Surveys and data from the DHMT/HMIS the DHS the UNICEF CSDP and the EPI/NID programs also provide information of varying quality on coverage of vaccinations growth monitoring and breast feeding prevalence Stratified community and facility based surveys in the TEHIP Health Systems and Health Behaviours research programs are funded and underway from 1998 - 2001

- 2 4 **Health services data** Data from the Morogoro DSS indicates that 84% of deaths of under-fives occur at home. Of these 28% of under-five deaths had no prior contact with formal health facilities in the illness leading to death. Preventable acute febrile illness (including malaria) was the cause of 40% of the deaths in under fives who had no contact with health facilities despite 58 % of the population being within 5 km (1 hour) of a health facility. This feature and the high mortality in both attenders and non-attenders indicate gross under-utilization of existing health facilities and poor quality services and referral at these facilities. Improving utilization and quality will be important process indicators for IMCI if IMCI is to have a chance to reduce under-five mortality in the population at large. It is unlikely these weaknesses are unique to Tanzania.

3 Study design

Due to the existence of baseline information on cause specific mortality, malnutrition, breast feeding and programme coverage, the proposed evaluation employs a longitudinal design.

3 1 Longitudinal (historical) design (with geographic comparison)

- 3 1 1 **Design** This can consist of a before-and-after or trend analysis based on the hypothesis that IMCI implementation will lead to improvements in impact and process indicators listed below. Mortality data from non-IMCI geographic comparison districts will be available for the plausibility analysis.
- 3 1 2 **Impact Indicators** At the *household level* impact indicators can address **mortality** (all cause/broad cause/cause specific child mortality) through continuous demographic surveillance and **selected morbidity** (malnutrition, anemia) through periodic surveys.
- 3 1 3 **Process Indicators** At the *facility level* the evaluation can cover indicators of quality service provision, eg. quality of facilities, training, supervision, services and referral provided, adequacy of drugs and supplies, provider compliance, provider satisfaction, costs, coverage and community participation. At the *household level* process measures start to blur with impact measures but include health seeking behaviour (eg. early recognition and appropriate action for childhood illnesses, breast feeding, ITN purchase, maintenance and use by mothers and under-fives), IMCI utilization, user satisfaction, user compliance, access and equity.
- 3 1 4 **Type of inference** The first level of inference will consist of adequacy statements. The *process indicators* of provision, utilization, coverage, etc. can first be compared with performance standards. If achievements in terms of adequacy criteria are satisfactory, a plausibility analysis can be carried out. This will entail attempting to rule out the effect of external factors that may have accounted for the observed improvements in *impact indicators*.

4 Data collection

4.1 Health Impact Indicators

4.1.1 **Mortality** Information on mortality in under-fives can be obtained from two IMCI and any of six non-IMCI Districts running already funded continuous community based DSS. The DSS can provide information on time trends in proportionate mortality rates for acute febrile illnesses including malaria, diarrhoea, pneumonia, malnutrition, anemia and measles with the usual caveats for verbal autopsy. Nested case-control studies of deaths could be used to assess risk factors associated with IMCI users and non-users within the IMCI Districts.

4.1.2 **Hospital morbidity** Facility based morbidity and mortality data in Africa is subject to enormous bias. For IMCI perhaps such data should only be collected to examine the impact of IMCI on improving referral (ie a process indicator). When facility utilization is low as it is in Africa it is not evident that a reduction or an increase is the desired outcome.

4.1.3 **Community morbidity** Prevalence of malnutrition, anemia and breast feeding practices can be assessed through nutrition surveys.

4.2 Process Indicators

4.2.1 **Sources of data** Data for the evaluation of process indicators can include documentary analysis of reports and HMIS returns (eg on IMCI training and supervisory activities on utilization of health services) surveys. For maximum plausibility the survey sampling and pattern should be designed in order to detect trends in process and impact measures over a 4 year period with steadily improving quality and coverage of IMCI implementation. The analyses must feed regularly back to the DHMTs to assist in optimizing the delivery of IMCI.

4.2.2 **Provision of Services** Data on availability of IMCI (number of HWs/HFs trained, geographical distribution) can be obtained from DHMT reports. Quality of care (use of integrated approach, correct treatment, missed opportunities for immunization, avoided, effective counseling provided) the existence of supervision and adequacy of drugs, equipment and supplies can be assessed from supervision records and through HF surveys. If cost data can be reliably collected it will be useful in estimating cost-effectiveness of IMCI. In Morogoro a cost-tracking system has been introduced in all facilities.

- 4 2 3 **Utilization of Services** Utilization data can be derived from HF reports to the HMIS as well as from household surveys. The DSS can also collect data on utilization and could include nested case-control studies. Household surveys will be important to understand determinants of utilization.
- 4 2 4 **Coverage** Data on programme coverage (vaccines, growth monitoring, ORT use) can be obtained through DHMT driven surveys.
- 4 3 **External confounding factors** Data on potentially confounding factors that might account for changes in the health impact and process indicators under study, including health reforms (e.g. user fees), epidemics (e.g. dysentery, cholera), socioeconomic and demographic factors (e.g. SAPs), developments in other sectors (e.g. water and sanitation), civil strife, etc. can be collected as appropriate. Trends in under-five mortality can be obtained from six "control" districts in Tanzania running DSS without IMCI.

5 Sample sizes

- 5 1 **Mortality Impact Indicators** DSS data are usually collected on either a total or on a large purposive but non-random sample of sub-district divisions representing the major geographic and socio-economic strata of the district. All deaths in the sample are included (approximately 500 under-five deaths per year in the sample population at baseline in Morogoro). The large sample sizes of DSS are more than adequate to analyze the relatively frequent causes of under five mortality.
- 5 2 **Survey-based Morbidity and Process Indicators** These should be elaborated at the meeting. See section 7 for a preliminary perspective.

6 Data analysis

The data analysis can include the following components:

- 6 1 **Analysis of mortality data** Yearly data on the cause-specific numbers of deaths and the population of children can be entered in a spreadsheet and converted to standardized years of life lost (YLLs). Proportionate mortality burdens and population-based mortality rates can be calculated and trends can be analyzed.
- 6 2 **Survey analyses** Coverage indicators must be calculated in a comparable way for both before and after surveys. The results will be assessed through significance testing using standard statistics (comparison of two proportions or for anthropometric indicators of two means). If the data allow, breastfeeding duration will be analyzed through survival techniques.
- 6 3 **Plausibility analyses** Changes in the above indicators can be further assessed through

multivariate methods (such as logistic or multiple linear regression as applicable) to allow control of confounding factors. For time trend data, simulations can be carried out to estimate the impact of changes in such external factors.

7 Conclusions

Based on this Tanzanian case study, the following provides some reflections on what may be some of the opportunities and constraints regarding IMCI evaluations in Africa.

- 7.1 **A focus on mortality reduction as the main measure of IMCI effectiveness.** Sub-Saharan Africa has the highest child mortality rates in the world. This high U5MR has preventable over-disbursed causes, most of which are addressed by the IMCI package. The two simplest measures would be: 1) the net change in all-cause U5MR, and 2) the change in ratio of IMCI to non-IMCI causes within the under-five mortality. Cause-specific mortality will be complicated by the high prevalence of malaria mortality.
- 7.2 **Taking advantage of DSS Sites for mortality impact measures.** Since the main impact of IMCI in high child mortality settings must be reduction in mortality, we must find an affordable way to assess changes in child mortality. Indirect methods may be valuable but do not give results contemporary with program changes. Direct methods are costly. However, a growing number of sites in Africa now run continuous DSS for various purposes (adult mortality, fertility and family planning studies, intervention trials, etc). Early introductions of IMCI could be directed to such sites to take advantage of virtually free, high-quality data on child mortality. Such sites might be ideal for measuring effectiveness of the main impact of IMCI and also provide opportunities for cost-effective nesting of case-control studies of risk factors.
- 7.3 **Possible constraints to mortality impact.** In Africa, malaria dominates under-five mortality and morbidity, both directly and indirectly, and may account for 20 to 30% of all under-five mortality. The effectiveness of the IMCI package in Africa will, in large measure, be determined by the effectiveness of its interventions against malaria and will be constrained by the impact of the evolution of anti-malarial drug resistance.
- 7.4 **Morbidity Indicators.** Since most causes of morbidity addressed by IMCI are also associated with mortality, if we are able to document mortality reduction, can we assume associated morbidity reduction? Such considerations may be useful in selecting the minimum number of morbidity indicators to monitor. Those which are important risk factors for mortality (eg. malnutrition, anemia) might be the best candidates.
- 7.5 **Mortality and Morbidity Data from Facilities.** Facility-based morbidity and

mortality data in Africa is subject to enormous bias. For IMCI perhaps such data should only be collected to examine the impact of IMCI on improving referral (ie a process indicator). When facility utilization is low as it is in Africa it is not evident that a reduction or an increase is the desired outcome.

- 7.6 **Process Indicators** In Africa both quality and utilization of most curative child health services are still low. Therefore IMCI has high potential to make dramatic impacts on mortality in a relatively short time if the process/impact questions of IMCI *utilization* and *quality* can be addressed at the primary care and household levels.
- 7.7 **Putting More Resources on Understanding Determinants of Utilization** The technical specifications of IMCI are well elaborated. How we maximize utilization is less so. Therefore a focus on the process indicators surrounding quality of care and household perceptions of IMCI are critically needed and should not be neglected in measuring the effectiveness of IMCI. We need to be able to collect baseline and trend information on indicators such as proportion of children with selected signs and symptoms who are promptly brought to IMCI services, the proportions of such children correctly managed or referred by IMCI, etc. Perhaps not all of the indicators in Tables 1 and 2 are necessary. Some could be replaced by others which focus most specifically on the most important process measures.
- 7.8 **Perceived Quality as a determinant of utilization** Additional quality indicators may emerge which add value and cost-effectiveness to IMCI. For example the stronger supervision and more rational prescribing practices of IMCI might reduce or eliminate the chronic drug shortages which undermine community confidence and utilization of local primary health services. Such indicators may be worth tracking.
- 7.9 **"Universal" Coverage** A working definition of universal coverage might be set at 80% since the marginal cost-effectiveness of extending individual interventions beyond 80% starts to fall away. In overall resource allocation, if we are interested in maximizing population health for under-fives, once individual intervention coverage reaches 80% (e.g. immunization) child health might be more cost-effectively enhanced by investment in raising the coverage of other interventions still below 80% rather than continuing to push coverage beyond 80% for the leading intervention. If so, trends in improvement in high coverage interventions are not useful process indicators of IMCI success (and require high sample sizes).
- 7.10 **Process Indicators support plausibility** Reductions in IMCI preventable mortality in themselves are insufficient to attribute to IMCI. Association of the reductions with important changes in IMCI provision, utilization, coverage, quality, satisfaction, compliance, etc. add plausibility, especially if other confounding causes of mortality are accounted for in the analysis.
- 7.11 **Conclusion** The Morogoro Scenario (DSS plus/minus IMCI) may be typical of opportunities in a dozen or so African countries over the next few years. Although such sites may have relatively good baseline information and may be motivated to

move rapidly with IMCI it is likely that the sites were chosen for both DSS and IMCI because health indicators were still poor. Therefore the potential of measurable impact of IMCI should remain high even in such sites and sample sizes should be manageable.

The most plausible assessment of IMCI effectiveness in operational settings would be a pragmatic combination of direct measures of mortality impact with carefully selected measures of process impact and confounding factors.

Table 1 Some Baseline Indicators in Tanzania and Morogoro

Impact and Process Indicators	Age group	Pre-IMCI 1997
Premature Mortality		
Distribution of U5M burden (YLLs)		
IMCI	< 5 yr	72%
YLLs	< 5 yr	45%
Acute Febrile Illness including Malaria	< 5 yr	10%
Malnutrition	< 5 yr	7.7%
Diarrhoea	< 5 yr	7.3%
Pneumonia	< 5 yr	1.1%
Measles	< 5 yr	1.1%
Anemia	< 5 yr	28%
Non-IMCI YLLs		
Percent of children with IMCI indications promptly brought to IMCI (include gender analysis)	< 5 yr	0%
Percent of IMCI children (eg NPO) correctly managed and referred by IMCI	< 5 yr	0%
Percent of IMCI users correctly complying with IMCI management	< 5 yr	0%
Percent of IMCI providers meeting standard	n/a	0%
Percent of children sleeping under ITNs	< 1 yr < 5 yr	2% 1%
Percent of mothers completing pregnancy under ITNs	15-45 yr	2%
Percent of children breast fed	0-3 mos	73%
Prevalence of underweight (mod & severe)	< 5 yr	36%
Prevalence of stunting (mod & severe)	< 5 yr	47%
Prevalence of wasting (mod & severe)	< 5 yr	6%
Growth card ownership	< 5 yr	xx%
Recent weight registered in growth chart	< 5 yr	xx%
Percent of children fully immunized	12-23 mos	70%
Diarrhoea management ORT use rate	< 5 yr	76%

**Table 2 Sample sizes required for detecting a significant improvement
(5% significance, 80% power design effect of 1.5)**

Indicator	Expected Baseline Level	Sample sizes required for detecting improvements of		
		10%	20%	30%
IMCI Preventable mortality burden	72%	n/a	n/a	n/a
Percent of children with IMCI indications promptly brought to IMCI	20% ^(a)	163 ^(c)	44 ^(c)	20 ^(c)
Percent of IMCI children (eg NPO) correctly managed and referred by IMCI	10% ^(a)	104 ^(c)	30 ^(c)	15 ^(c)
Percent of IMCI users correctly complying with IMCI management	50% ^(a)	230 ^(c)	56 ^(c)	23 ^(c)
Percent of IMCI facilities meeting performance standards	50% ^(a)	230 ^(c)	56 ^(c)	23 ^(c)
Percent of children sleeping under ITNs	5% ^(a)	66 ^(c)	21 ^(c)	11 ^(c)
Percent of mothers completing pregnancy under ITNs	5% ^(a)	66 ^(c)	21 ^(c)	11 ^(c)
Percent of children breastfed for ≥6months	xx%			
Prevalence of underweight ^(b)	36%			
Prevalence of stunting ^(b)	47%			
Prevalence of wasting ^(b)	6%			
Growth chart ownership	xx%			
Recent weight registered in growth chart	xx%			
Percent of children fully immunized ^(d)	70%	1479	143 ^(c)	74 ^(c)
Increased fluids during diarrhoea	49%	230 ^(c)	56 ^(c)	23 ^(c)
Continued feeding during diarrhoea	xx%			

Notes * The estimates refer to reductions in the "negative" indicators (e.g. malnutrition) and increases in the "positive" ones (e.g. ITN use, breast feeding, vaccinations, ORT)

a Postulated starting point at beginning of IMCI

b Estimates based on comparison of two mean z-scores transformed into prevalences below -2 z-scores

c Percentage point change rather than percent change

d Sample size for children aged 12-23 months

e Coverage would exceed 80%