The Benefits and Challenges with using Quasi-Experimental and Non-Experimental Designs to Inform Policy and Service Delivery Guidelines for Reproductive Health Programmes in Developing Countries

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Second Global Symposium on Health Systems Research, Beijing, China:

31 October – 3 November 2012

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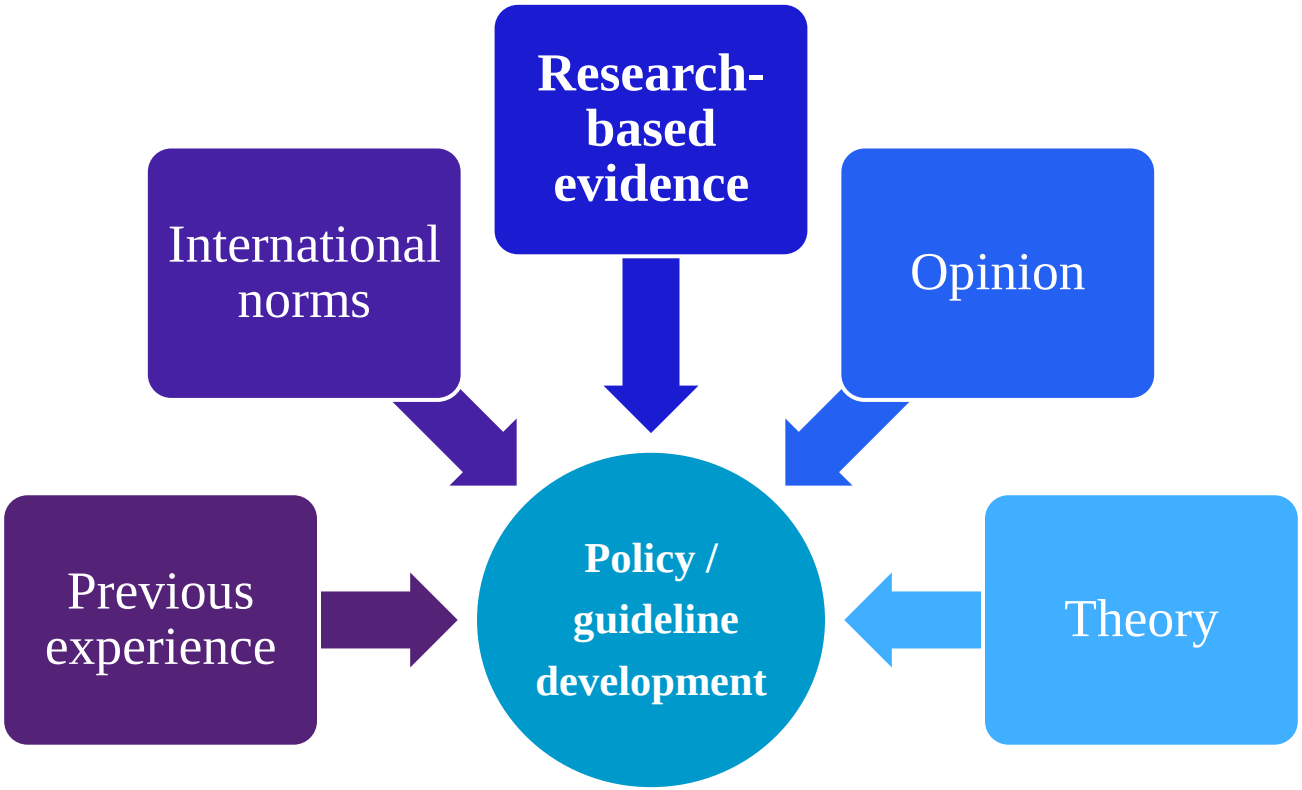
Research- based evidence:

One factor among many influencing the design and implementation of service delivery guidelines and policy



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‘Guidelines’ or ‘Guidance’?
Service delivery or systems strengthening?

- Clinical practice guidelines:
  - Systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances
- Health systems guidance:
  - Systematically developed statements produced at global or national levels to assist decisions about appropriate options for addressing a health systems challenge in a range of settings and to assist with the implementation of these options and their monitoring and evaluation

Bosch-Capblanch X, Lavis JN, Lewin S, Atun R, Røttingen J-A, et al. (2012) Guidance for Evidence-Informed Policies about Health Systems: Rationale for and Challenges of Guidance Development. PLoS Med 9(3): e1001185. doi:10.1371/journal.pmed.1001185

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Research domains for developing guidance

Research domain	Evidence generated	Users of evidence	Research methods
Operational	Solutions to operational problems of specific health programs or service delivery components of the health system	Service providers Program managers	Readiness assessments Systematic monitoring Small-scale experimental studies Qualitative studies Modelling
Implementation	Strategies to improve access to and use of available or new interventions by the populations in need	Program managers Policy makers	Prospective experimental designs Multi-centre, multi-disciplinary studies Economic analyses
Health system	Understanding of the health system adaptations needed to integrate and routinely offer new interventions	Policy makers	Organizational research Policy analyses Economic analyses

Adapted from: Remme J, Adam T, Becerra-Posada F, D'Arcangues C, Devlin M, et al. (2010) "Defining Research to Improve Health Systems", *PLoS Medicine* 7(11)

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Why are RCTs / c-RCTs considered the 'gold standard' for generating experimental evidence?

- ✓ **Theoretical control for internal validity; rigorous design; quantifiable evidence**

- ✓ *Understandability* by national decisions-makers with medical / statistical training
- ✓ *Publishability* of findings for academic researchers
- ✓ *Usability* as evidence base for systematic reviews

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However, non-randomized "quasi-experimental" designs are frequently used for generating evidence about RH service delivery interventions

- Controlled Before-After:
  - An "RCT" using matching rather than randomization
- Interrupted Time Series:
  - An extended Before-After, with or without a control
- Post-test only with control:
  - An RCT without a Before
- Prospective cohort, with or without control

Why are matched controlled before-after designs popular in RH intervention testing?

- Ensure rigour equivalent to an RCT
- Generate quantifiable evidence amenable to statistical analyses
- Allows programme managers some influence over intervention sites
- Reduces possibility of ethical issues
- Randomization still feasible through multi-stage sampling
- Emphasis on documenting implementation process acceptable

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Common challenges facing both randomized and non-randomized designs

- Contamination
  - Similar implementation activities by health system
  - Provider-initiated activities at individual sites
- Intervention implementation
  - Incorrect
  - Incomplete
  - Variation between units and over time
- Other potential influences experienced non-uniformly
- Weak measures of outcome variables
- Ineffective theory of change

Plausibility rather than Probability

- Non-randomized and other quasi-experimental designs
- Multiple research methods are used to converge evidence
  - Of influence
  - Of implementation
- Especially when:
  - Intervention is complex
  - Scaling-up proven pilot interventions
  - Ethical concerns preclude randomization

Victora CG, Habicht JP, Bryce J. Evidence-based public health: moving beyond randomized trials. Am J Public Health 2004; 3:400–40540.

Challenges for the RH community

- Long history of using experience, non-experimental and quasi-experimental 'operations research' to inform service delivery guidelines and policy
- Now embracing health systems strengthening approaches to improve services
- Also embracing evidence-based decision-making paradigm
- Which brings challenges:
  - Greater rigour in guidance development
  - Greater use of systematic reviews (RCT as gold standard)
  - Greater attention to complex interventions

Uncertainty about how to proceed

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Four suggestions:

1. Promote perspectives of ‘guidance’, and of ‘plausible’ evidence from non-randomized yet rigorous research
   - Communicate HSS/HSR perspectives widely
   - Act on recommendations in recent *Plos Med* series on *Guidance for Evidence-Informed Policies about Health Systems* (March 2012 | Volume 9 | Issue 3)
   - RFPs to require **and fund** matched designs, stronger analyses, rigorous documentation of implementation processes, clearer descriptions of design (PICOT, TREND)
2. Decide on a uniform definition of “best practice” determined by an agreed quality of evidence and strength of recommendation

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Four suggestions (2)

3. Commission and use systematic reviews that:
   - Include evidence from non-randomized designs
   - Use less pejorative language for evidence and recommendations based on NRDs
4. Pay closer attention to messages that communicate evidence from researchers via intermediaries to decision-makers, especially at national levels
   - GRADE, TREND and other tools for summarizing evidence and recommendations
   - Policy and evidence briefs
   - Peer-reviewed journals

Conclusions

1. Many factors sustain RCT-based evidence as the only high quality evidence on which strong recommendations can be based
2. NRDs / Q-Es, within a multiple methods approach, can provide evidence of plausibility for guiding health systems strengthening that is of high quality and allows strong recommendations
3. Summarizing and communicating evidence for guidance needs greater attention
4. This is **not** an endorsement of low quality research!

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STRENGTHENING EVIDENCE FOR PROGRAMMING ON UNINTENDED PREGNANCY

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The **STEP UP (Strengthening Evidence for Programming on Unintended Pregnancy) Research Programme Consortium** generates policy-relevant research to promote an evidence-based approach for improving access to family planning and safe abortion. STEP UP focuses its activities in five countries: Bangladesh, Ghana, India, Kenya, and Senegal.

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