

# Clinical Research prioritization

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# Clinical research

- Branch of Medical science
- Systematic, observational and experimental biomedical studies
- Ultimate goal is to improve quality of life



Clinical research includes:

- Medical and behavioral research involving volunteer participants
- Investigations that are carefully developed and conducted with clinical outcomes recorded
- Identification of better ways to prevent, diagnose, treat, and understand human disease
- Trials that test new treatments, clinical management and clinical outcomes, and long-term studies
- Strict scientific guidelines
- Ethical principles to protect participants



# Clinical trial

- One form of clinical research
- Systematic experimental biomedical studies
- To evaluate the effectiveness and safety of medications or medical devices or biologics etc.



- What is prioritization?
- Prioritization is a process whereby an individual or group places a number of items in rank order based on their perceived or measured importance or significance.



# Prioritization methods

- Simplex method
- Nominal group technique
- Criteria weighting method
- Quick and colorful approach



- Research prioritization is one of the key nodal points in the research policy planning cycle, which encompasses research planning, research priority setting, strategies and implementation of research priorities, research utilization, research monitoring and evaluation (part of the research information system), and overall research policy management



# Research prioritization method

- Expert consultation
- Literature review method
- Quantitative prioritization ( MCDA)multi criteria decision analysis
- Interviews
- Survey
- CHNRI ( child health and nutrition research initiative) ?
- Delphi
- COHRED 3D ( council on health research and development 3D combined matrix approach)
  - Research prioritization methods extracted from WHO publications published 2002-2017





# CHNRI method

- Crowdsourcing
- 91 scorers
- Collective opinions
- Ranking all 205 ideas
- 20 ranked research ideas
- Concordance 75% ( IQR 14-16)
- Yes/No/Not sure/DK 1/0/0.5



- Criteria used are
- Criterion 1 Answerability
- Criterion 2 Efficacy/Effectiveness
- Criterion 3 Deliverability/acceptability
- Criterion 4 Maximum potential for disease burden reduction
- Criterion 5 Effect on equity



# PCORI ( patient centered outcome research institute)

- Approaches for topic generation through public engagement
  - Interviews
  - Photovoice
  - Observation
  - Documents
  - Questionnaires
- Use of gap analysis in establishing research priorities
  - Identify research gap
  - Transformation of research gaps into needs – use PICOTS framework ( population/ intervention/comparator/outcome/time frame/ setting)



- Value of information analysis
  - CBA
  - Harm-benefit ratio
  - Multi criteria decision analysis
- Peer review of research funding proposal for research priority



- In recognition of the resource, human, and financial costs of conducting research, the changing determinants and pattern of diseases or conditions and their effect on the population at large, and the evolving body of evidence, prioritization of future research needs must be responsive and dynamic and should be periodically reviewed and updated.
- Priority-setting processes should be guided by ethical principles, including careful attention to conflicts of interest. Documentation of the process leading to a particular proposal being selected should be explicit and transparent. Other key principles for the priority-setting process include flexibility, adaptability to dynamic advances, and accountability.



- Research prioritization takes place within the framework of the national health policies and national health research policies.



# Research problem

- Size
- Impact
- Currentness
- Distributions
- others



# selection

- Uncertainty
- Cost
- Public interest
- Individual interest
- Others
- Consensus
- Informal
- Systematic LR





# Selection criteria

- Common cause of death
- Common diagnosis for hospital admission
- Common health related causes of absence from work
- Common diagnosis
- Common cause of medication prescription



## Examples of broad research priority areas identified in selected developing countries

Country	Research priority areas
Caribbean	<ul style="list-style-type: none"> <li>• Epidemiology of most common diseases</li> <li>• Access to health care facilities</li> <li>• Cost-benefit and outcome measurements of health policies and practices</li> <li>• Effects of environmental, ethnic, economic, social, and behavioural factors on incidence and prevalence of specific diseases</li> </ul>
Guinea	<ul style="list-style-type: none"> <li>• Research capacity strengthening</li> <li>• Malaria, diarrhoea and other priority health problems</li> <li>• Quality and financing of health care, human resources</li> <li>• Traditional health care: quality, collaboration, medicinal plants</li> </ul>
Nicaragua	<ul style="list-style-type: none"> <li>• Mother and child health</li> <li>• Communicable diseases</li> <li>• Drug addiction/alcoholism</li> <li>• Health care financing</li> <li>• Human resources development</li> <li>• Community involvement</li> </ul>
Philippines	<ul style="list-style-type: none"> <li>• Health care delivery</li> <li>• Product research and utilization</li> <li>• Health sector organization and management</li> <li>• Economics of health care</li> </ul>
Uganda	<ul style="list-style-type: none"> <li>• Maternal and child welfare and nutrition</li> <li>• Water and sanitation</li> <li>• Communicable diseases, including HIV/AIDS</li> <li>• Health systems and policy analysis</li> </ul>

The Working Group on Priority Setting, 2000

<sup>a</sup> It should be noted that some research priorities identified by the countries are not mutually exclusive. The above examples are indicative of the beginning process of priority setting, but more work needs to be done to refine and prioritize the research areas and questions.



## Newborn health research priorities for Pakistan

	Individual, household and community	Ministry of Health and other health institution	Organizations outside ministry of health	Macroeconomic policies
Diseases Burden	2	2	2	1
Determinants for persistence	2	3	1	3
Present level of knowledge	2	4	4	2
Cost-effectiveness for future or possible interventions	4	4	4	4
Research resource flows	2	4	1	4

1 = Sufficient data available; 2 = Some data available; 3 = Insufficient data (need for more research); 4 = No information / critical gap / high priority research

Abdul Ghaffar, 2007



# Prioritization Criteria Methodology for Future Research Needs Proposals Within the Effective Health Care Program

- 5 domains with 18 criteria
- Appropriateness (three criteria),
- Importance (seven criteria),
- Duplication (one criterion),
- Feasibility (one criterion), and
- Potential Value (six criteria).



# Appropriateness

- Represents a health care drug, intervention, device, or technology available (or soon to be available) in the United States.
- Represents a health care drug, intervention, device, or technology available (or soon to be available) in the United States.
- Represents one of the priority health conditions designated by the Department of Health and Human Services.



# Importance

- Represents a *significant disease burden* affecting a large proportion of the population or a priority population (e.g., children, elderly adults, low-income, rural/inner city, minorities, or other individuals with special health care or access issues).
- Is of *high public interest*, affecting health care decision making, outcomes, or costs for a large proportion of the U.S. population or for a priority population in particular.
- Was *nominated/strongly supported by one or more stakeholder groups*.
- Represents *important uncertainty* for decisionmakers.



- Incorporates issues around both *clinical benefits and potential clinical harms*.
- Represents *important variation* in clinical care or controversy in what constitutes appropriate clinical care.
- Represents *high costs* due to common use, high unit costs, or high associated costs to consumers, patients, health care systems, or payers.



# Duplication/ Desirability of new research

- *Potential for redundancy* (i.e., whether a proposed topic is already covered by an available or soon-to-be available high-quality systematic review by AHRQ or others)





# Feasibility

- *Effectively utilizes existing research and knowledge* by considering:
  - Adequacy (type and volume) of research for conducting a systematic review.
  - Newly available evidence (particularly for updates or new technologies).



# Potential values

- *Potential for significant health impact:*
  - To improve health outcomes.
  - To reduce significant variation in clinical practices known to be related to quality of care.
  - To reduce unnecessary burden on those with health care problems.
- *Potential for significant economic impact:*
  - To reduce unnecessary or excessive costs.
- *Potential for change:*
  - Proposed topic exists within a clinical, consumer, or policymaking context that is amenable to evidence-based change.
  - A product from the EHC program could be an appropriate vehicle for change.



- *Potential risk from inaction:*
  - Unintended harms from lack of prioritization of a nominated topic.
- *Addresses inequities, vulnerable populations* (including issues for patient subgroups).
- Addresses a topic that has *clear implications for resolving important dilemmas in health and health care decisions* made by one or more stakeholder groups.

- AHRQ agency for healthcare research and quality
- EPC evidence based practice center



# PiCMe ( prioritization criteria method)

## potential value criteria

- Potential for new knowledge (Research would not be redundant: Strength of evidence is not high for specific outcome [confidence in the estimate of effect is moderate or low]; Question not sufficiently researched, including completed and in-process research; Utility of available evidence limited by changes in practice, e.g., disease detection or evolution in technology); more evidence needed about values and preferences influencing balance of benefits and harms/risks.
- Potential for significant health impact on the current and projected health status of people with respect to burden of the disease and health outcomes: mortality, morbidity, and quality of life.

- Potential to reduce important inappropriate (or unexplained) variation in clinical practices known to relate to quality of care. Potential to resolve controversy or dilemmas in what constitutes appropriate health care. Potential to improve decision making for patient or provider, by decreasing uncertainty
- Potential for significant economic impact related to the use of health service resources. Many healthcare resource use factors may be expressed as cost. Potential to reduce unnecessary or excessive costs; to reduce high costs due to high volume use; to reduce high costs due to high unit cost or aggregate cost. Costs may impact consumers, patients, caregivers, employers, health care systems, or payers



- Potential risk from inaction: Unintended harms from lack of prioritization of proposed research; opportunity cost of inaction; potential to allow assessment of ethical, legal, social issues pertaining to the condition
- Addresses inequities, vulnerable, diverse populations (including issues for patient subgroups); potential to reduce health inequities; potential to allow assessment of ethical, legal, social issues pertaining to the condition.



# Prioritizing future research needs

- first working with stakeholders to consider potential value and desirability, and then considering study design and feasibility as the subsequent step.



- Thank you

