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BIOETHICS AS A DRIVER OF RESEARCH FOR HEALTH

Conduct of research for health is essential to
produce information for improvements in health
care and the maintenance of wellness but....

at what cost???????

Whose responsibility is it to protect the rights and dignity of research participants (and the vulnerable in society) throughout the research process from recruitment to dissemination and use of the findings? In particular, who will ensure that not only care professionals and policy makers have access to critical information, in a format that they can understand?

Who is our brother's keeper?

OVERVIEW

- ✘ Context of the Caribbean
 - + Challenges and possible solutions
- ✘ Drivers of research for health
- ✘ Community participation in the process
- ✘ Key role of bioethics

SPECIAL SITUATION IN CARIBBEAN

- ✘ Small Islands Developing States (SIDS)
 - + Special UN designation
 - ✘ Includes Belize, Guyana and Suriname
 - ✘ Unique situation – especially vulnerability
 - ★ Hurricanes, global warming, economic shocks
- ✘ Most with populations less 200 000
 - + Implications for capacity and resources
- ✘ Integration and sustainable partnerships critical

CARIBBEAN HEALTH RESEARCH COUNCIL

- ✘ Regional Health Institution serving the Caribbean Community (CARICOM)
- ✘ Serves 20 member countries
 - + Mainly English and Dutch speaking
- ✘ Established in 1955

“To advise on the needs for medical research, on the needs for ensuring that the results of research are applied in practice, and to keep under review the facilities for inter-territorial collaboration in medical research”

CORE FUNCTIONS

- ✘ Advise governments and other decision makers
- ✘ Stimulate and enable original research
- ✘ Build/strengthen research and M&E capacity and systems
- ✘ Facilitate communication and sharing of outputs (strategic information)
- ✘ Build/strengthen research and M&E culture
- ✘ Supplement financial resources of the Council

SERVICES *(inter alia)*

- ✘ Annual Health Research Conference
 - + Forum for sharing research findings, collaboration between researchers and policy makers
 - + Important mechanism for dissemination in Caribbean
 - ✘ Low rate of conversion to publications
 - ✘ Challenge to conduct 'essential' or 'publishable' research
 - ✘ ?role for non-traditional publication facilities to make info available to users
 - + Every year since 1956
 - + 54th in Turks and Caicos Islands (April 2009)

CHALLENGES FACED IN THE CARIBBEAN

- ✘ Research (evidence driven) culture
- ✘ Capacity
- ✘ Financial support
- ✘ Knowledge transfer
 - + Inadequate use of research evidence in decision making by care providers, policy makers and program managers
 - + Partly because evidence not available in friendly format

SOLUTIONS

- ✘ Development of Health Research Policy
 - + About to be adopted
 - + 8 Strategies
 - ✘ Strengthen mechanisms for knowledge management
 - * Institutionalise use of research evidence in policies and practice
 - * Repository for research, databases of Caribbean research
 - * need to consult with information brokers
- ✘ Strengthening Health Research Systems
 - + Integral component of Policy

HEALTH RESEARCH SYSTEM

‘the people and institutions that govern, manage, demand, generate, communicate or use research evidence to promote, restore, improve or maintain the state of health and development of a population’

DRIVERS OF RESEARCH FOR HEALTH

- ✘ Policies: health, research, health research
- ✘ Research agenda
 - + Priority setting process includes analysis of burden of disease and risk factors, availability of relevant data, perceptions of need (political expedience)
- ✘ Funding availability
 - + Donors often determine ‘priorities’ in developing countries
- ✘ Others such as personal interests of researchers

COUNCIL ON HEALTH RESEARCH FOR DEVELOPMENT (COHRED)

- ✘ Concept of Essential National Health Research (ENHR)
 - + Main players – researchers, policy makers and community
 - + Role of community underscored but often the rules of engagement are unclear

- ✘ Health Research or Research for Health?
 - + Appreciation of the wide range of determinants of health
 - ✘ Social, economic, education, agriculture, environment sectors etc.
 - + Promotion and support for research beyond biomedical investigations

COMMUNITY PARTICIPATION

- ✘ Stakeholder consultations
 - + Development of policies, research agenda
 - ✘ Key but sometimes overlooked
 - ✘ Impact on policies unclear
- ✘ Members of bioethics committees
 - + Protect the interests of the population
 - + Critical role even though often unappreciated

ETHICS

- ✘ the study of the fundamental principles that define values and determine moral duty and obligation
- ✘ a set of moral principles or values
- ✘ the principles of conduct governing an individual or group; concerns for what is right or wrong, good or bad
- ✘ Very subjective and specific to a country's values and culture

HISTORY OF RESEARCH ETHICS

- ✘ Nazi medical war crimes (WWII)
 - + Experiments on prisoners in concentration camps
 - + Injection with viruses, immersion in ice, etc.
- ✘ Nuremberg Code (1947)
 - + After trial of 23 persons for ‘crimes against humanity’
 - + Basis of international ethics codes
 - + Voluntary consent of the person is absolutely essential
- ✘ Such atrocities no longer present?
 - + Genocide, disregard for welfare of some groups
 - + Equality an unrealistic expectation?
 - + Role of publishers, info professionals

RELEVANT BIOETHICS ISSUES

- ✘ Relevance of research
 - + Who is the driver?
 - + Value in local community?

- ✘ Approval of local Ethics Committees
 - + Should not depend on approval from external sources
 - + Many Caribbean countries without RECs

- ✘ Informed consent

- ✘ Clinical trials

INFORMED CONSENT

- ✘ Individual have right to choose whether to participate (un-coerced) and to stop at any time without any penalty (care provider – patient challenge)
- ✘ Must be informed about purpose, methods, risks, benefits, alternatives and must understand what is being said
- ✘ Special situation for persons with diminished capacity and children (below 18y)
 - + need permission of guardian
 - + Must also give assent

CLINICAL TRIALS

- ✗ Recruitment of research participants
 - + Conflicts of interest
 - ✗ Financial, career
 - + Equitable
 - ✗ Fair procedures and outcomes in the selection of subjects
 - ✗ Must consider vulnerable populations
 - + Incentives – volunteers, money
- ✗ Access to treatments after trials
 - ✗ Cost of drugs, etc.

ETHICS COMMITTEES / INSTITUTIONAL REVIEW BOARDS

- ✘ Must review protocol and give permission before data collection begins
 - + Can request changes or refuse to allow unacceptable research
- ✘ Also has role to monitor research to ensure subject's rights not violated
 - + Investigator has duty to properly record and store all data and supply committee with monitoring info e.g. adverse events
- ✘ All research on human subjects should be submitted for approval
 - + Let committee decide if need approval

DISSEMINATION OF FINDINGS

- ✘ Format/presentation is important
 - + Medium and language
 - + Should not exclude the vulnerable and disadvantaged
- ✘ Accessibility of findings by all stakeholders is critical but must maintain confidentiality of personalized data
- ✘ Participants must be aware of results
- ✘ Resist attempts at suppression of unfavorable results
 - + By sponsors, State..

WAY FORWARD

- ✘ Information is power
- ✘ Information specialists are very influential
- ✘ Role of CRICS, BIREME, etc. to make professionals aware of responsibility
 - + Increased awareness of ethics (code)
 - + Advocate and promote accessibility and use of data to address inequities, guide policy and practice
 - + Membership on ethics committees

We all have an ethical responsibility

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THANK YOU