Why Culture Matters in Cancer Research

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Need for international research collaboration in cancer

- We need to understand disease etiology, biology, and response to treatment across different countries and among different populations
- We need to share expertise, pool resources, and build capacity for research
- We need to develop new ways to prevent, diagnose, treat, and palliate cancer as soon as possible

Global burden of cancer and NCDs

- Commonwealth Health Ministers yearly meetings in 2011 and 2012 focused on NCDs
- Asia-Pacific Economic Collaboration (APEC) Health Ministers endorsed APEC NCD Action Plan in 2011
- UN convened High-Level Meeting on NCDs in 2011
- World Health Assembly endorsed NCD Action Plan May 2013

Influence of culture

- Personal, family, and community level
- Level of local health system and health care providers
- National ethical and regulatory review
- National scientific review and prioritization
- National support for research
- International research collaborations
- Partnerships between government, academia, and industry

Individual, family, & community

- Community understanding of need for health research & structure of health research
  - Dialogue with community leaders
- Family involvement in health research
  - Pediatric vaccines, interventions to reduce in-door air pollution through improved cookstoves, verbal autopsy, etc
- Individual understanding of risks, benefits, and requirements for research

Health care providers and health system

- Do doctors, nurses, and other members of the health care team understand the importance and the nuts-and-bolts of clinical research?
- Do members of the health care team have adequate time and support to conduct the research well?
- Does the leadership of the health clinic, hospital, and system support research?

Culture of health system

- Is there multidisciplinary support and engagement for research?
- Are all medical records linked to a national unique individual identifying number?
- Is the experience of the patient and family valued?
- What resources for clinical research are in place?
  - Informatics, biobanking, clinical trials office, etc

National ethical and regulatory review

- World Medical Association Declaration of Helsinki
  - Adopted 1964, 6th revision 2008
- Council for International Organizations of Medical Sciences (WHO & UNESCO)
  - International Ethical Guidelines for Biomedical Research Involving Human Subjects, adopted 1993, updated 2002
- International Conference on Harmonization for Technical Requirements for Registration of Pharmaceutical for Human Use (ICH)
  - US FDA, EU European Medicines Agency, Japan PMDA

Critical questions

- How onerous is the burden of paperwork for ethical and regulatory review?
- What is the timeline for ethical and regulatory review?
- Does the culture of the review process include patient protection and urgency of health needs?

Critical questions: II

- What is the cost for ethical and regulatory review? Who pays for it?
- Is indemnity insurance required for individuals and institutions?
- Is the level of regulatory review tailored to added risk of the study? (First-in-human trials versus prospective cohort studies)

Culture of national scientific review and prioritization

- Is there a process for national scientific review and prioritization?
  - What are the most important studies needed to improve health across the country?
- Who pays for research studies critical to health?
    - Government? NGOs? Partnership with industry?

Bamako Call to Action, 2008

- Bamako Call to Action for Research for Health
  - Strengthening research for health, development, and equity
  - Ministers and reps from ministries of health, S&T, education, foreign affairs, and international cooperation from 53 countries
- Need to mobilize all relevant sections (public, private, civil society) to work together to find needed solutions

Bamako Call to Action

- National governments should
  - allocate at least 2% of budgets of ministries of health to research
  - Identify national research priorities
  - Promote knowledge translation
  - Strengthen research capacity
- Funders of research and international development agencies should
  - Invest at least 5% of development assistance funds earmarked for the health section to research

OECD Global Science Forum

- Organization for Economic Cooperation and Development Global Science Forum
  - Report on Facilitating International Co-operation in Non-Commercial Clinical Trials, October 2011
  - Recommendation on the Governance of Clinical Trials, January 2013
  - www.oecd.org -> search ‘clinical trials’ or Google ‘OECD clinical trials’

Culture of national support for research

- Education of health care professionals about clinical research
  - Undergraduate and post-graduate training
- Support for research infrastructure
  - Timely ethical, regulatory, and scientific review
  - Informatics, biobanks, biostatistics, meetings, etc
  - National health insurance payment for routine patient care costs associated with clinical research
- Civil society support for clinical research

International research collaborations in cancer

- International Cancer Genome Consortium
  - www.icgc.org
  - Designed to identify genetic and epigenetic changes in 50 different tumor types of clinical importance across the globe; labs in 14 countries
- International Rare Disease Research Consortium
- Breast cancer clinical trials
  - International Breast Cancer Study Group
  - Breast International Group

Culture of partnerships between government, universities, and industry

- Training of health care providers about conducting clinical research
- Preclinical and clinical development of research arising from university laboratories
- Evaluation of novel interventions in combination with standard care
- Roll-out of new interventions into standard practice

US National Cancer Institute

- National Clinical Trials Network for phase III trials and phase II studies of rare diseases
  - 2000+ sites; NCI-designated Cancer Centers, university hospitals, community hospitals, private clinics; 20,000 patients per year on trial
- 14 early-phase clinical trials sites at NCI-designated Cancer Center
- 9 multi-institutional consortia for phase II trials

US NCI partnerships with industry

- Model agreements for collaborations with industry in drug development
  - NCI-industry
  - Industry-universities (developed in collaboration with CEO Roundtable
- NCI holds 80+ INDs for new drug development; 80-100 Clinical Trials Agreements with industry; trials for secondary indications; combination studies with experimental agents from 2 different companies; phase I, II, and III clinical trials

Thank you

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