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
- 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 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
  – 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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