Good Participatory Practices: Lessons Learned from HIV Prevention Research to be Applied to Emerging Pathogens

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Presentation Highlights

• Good Participatory Practices (GPP) – an overview
• Lessons learnt about GPP in prevention and treatment trials for HIV
  – Successes
  – Challenges
  – Recommendations
• Lessons for emerging pathogens research
Overview of GPP guidelines

GPP Guidelines:

*Why? What is different?*

Developed to provide systematic guidance on how to effectively engage with stakeholders throughout the research life cycle.
GPP Structure

**Section 1:** The Importance of Good Participatory Practice
- Who are Stakeholders?
- What is Stakeholder Engagement?
- The Wider Context of HIV
- The Dynamics of Biomedical HIV Prevention Trials
- Rationale for GPP Guidelines
- Applying GPP

**Section 2:** Guiding Principles of GPP in Biomedical HIV Prevention Trials
- Respect
- Mutual Understanding
- Integrity
- Transparency
- Accountability
- Community Stakeholder Autonomy

**Section 3:** Good Participatory Practices in Biomedical HIV Prevention Trials
- Formative Research Activities
- Stakeholder Advisory Mechanisms
- Stakeholder Engagement Plan
- Stakeholder Education Plan
- Communications Plan
- Issues Management Plan
- Site Selection
- Protocol Development
- Informed Consent Process
- Standard of HIV Prevention
- Access to HIV Care and Treatment
- Non HIV-Related Care
- Policies on Trial-Related Harms
- Trial Accrual, Follow-Up and Exit
- Trial Closure and Results Dissemination
- Post-trial Access to Trial Products or Procedures
Lessons in HIV - Success

• Strengthened systematic planning and budgeting for broader community engagement

• Community stakeholders gaining greater interest & demanding greater involvement in research processes

  – Protocol development

    • G10 & SiVET (Kenya)
    • VARG & AMP (South Africa)
    • Key Pops & ECHO (Uganda)
Lessons in HIV - Success

• Formative research (developing own research agenda)
  – GALCK/G10 (Kenya)
  – ICW

• Results dissemination
  – Utafiti Pwani & KEMRI (Kenya)
  – National Cross-CAB Network (Uganda)
Lessons in HIV - Success
Lessons From HIV - Limitations

- Planning CE aligned to GPP viewed as cumbersome – potential for push back
- Challenging to discrete recruitment & retention from Community stakeholder engagement
Lessons From HIV - Limitations

Complex with overlap - potential for confusion

Stakeholder Engagement Vs Education Vs Community Advisory Mechanisms

Communications Vs Issues Management

Layering of stakeholders does not exactly reflect reality
Lessons From HIV – Limitations

- Community/stakeholder involvement negotiating medical aspects of clinical trial conduct challenging
  - Standard of prevention, Standard of care, Policies on trial related harm

- The question of gender is silent.

- Trial implementers prioritizing some optimal practices than others. What does this tell us?
Lessons From HIV - Recommendation

- Critical to educate trial funders, sponsors and PI’s for buy-in
- GPP will be successful if required & monitored (GCP, GCLP or GMP)

Where are the Resources?

*Funds*

*Time*

*Staff*
Lessons for Emerging Pathogens (EP)

• Applying GPP in EP: “Normal” Vs Emergency situations…… Business as Usual?

Re-evaluate

– GPP/EP place equal role/focus on community stakeholders just as trial funders, sponsors and implementers

– Address the Gender question *(Postponement of pregnancy in Zika afflicted areas, low female pax in research, care givers/takers role, Data disaggregation)*
Lessons for EP

• Do not wait for Outbreaks to Engage! (*Scientific urgency Vs meaningful engagement*)
  – Optimize disease-free periods
  – Map hot spots, stakeholders, skill sets available

• Simple Vs Complex demarcations (*Collapse optimal practices to minimize overlap & confusion*)

• Funds, staff and time crucial elements
Conclusion

• Meaningful and sustained community and stakeholder engagement facilitates ethical conduct and scientific quality of research.

• GPP are instrumental in facilitating this process.

• Applying GPP to EP research will require re-evaluation to reflect the reality of emergency situations during outbreaks.
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