FURTHERING THE RESEARCH AGENDA FOR WORLD HEALTH

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Outline

I. Research - part of outbreak preparedness and response
II. EC strategy and funding instruments
III. Participation in international initiatives
IV. Beyond research
V. Challenges
VI. EU added value
I. Research part of response
Ebola 2014-2016

• Magnitude
  • 28,646 cases – incl. 11,323 deaths (39.5%)

• Health system impact
  • 881 confirmed health worker infections, 513 deaths
  • Disruption of basic health services, e.g. vaccination

• Socio-economic impact
  • 16,000 orphans
  • Long term sequelae and stigma
  • Cost of response > $3.6 billion
  • $2.8 billion in lost GDP for 2014-2016 period

• Absence of
  • Rapid diagnostics, treatment, prophylactic vaccination
I. Research part of response
SARS 2002-03

• Magnitude
  • 8,096 infections, 774 deaths (9.6%)
  • Health workers accounted for a fifth of all cases globally
  • 26 countries affected

• Socio-economic impact
  • Travel and tourism affected
  • Global cost of roughly $80 billion: to medical expenses, travel and related services, consumer confidence and investment

• New disease
  • Understanding of transmission mode, pathogenesis, etc.
  • No diagnosis, treatment or vaccine

"(…) multinational, collaborative, and coordinated surveillance, research, and containment measures greatly limited the spread of Sars-CoV."
II. EC research strategy & instruments

**Overall objectives**

- Improve prevention and early detection of infectious disease threats in Europe and globally
- Promote a 'One Health' approach

**Specific objectives**

- Develop the pipeline of medical countermeasures against prioritised (and unexpected/unknown) pathogens
- Ensure that a comprehensive research response is swiftly launched in case of an outbreak
- Facilitate global collaboration
Research Priorities

'Drivers' of outbreaks (climate change, vectors, host and pathogen factors)
One Health (zoonoses - species barriers)
Vector control, Vaccines

Pathogen prioritization
Improved surveillance systems
Risk modelling/anticipation
Simple, point-of-care diagnostics and diagnostics 'platforms'
Syndromes definitions and differential diagnosis (e.g. Hemor. fever, flu-like)

Advance the pipelines (vaccines/treatments)
Clinical research during outbreaks (e.g. syndrome characterization, risk assessment, phase II/III clinical trials)
Research on disease management
Social Sciences (= communication, community impact/engagement)

Partnerships/coordination/knowledge transfer

Country-owned research capacity (= human resources and infrastructure)
EC funding instruments for feeding the pipeline

Risk level

Discovery, PoC → Preclinical → Clinical Phases 1-3 → Upscaling Manufacturing → Uptake Delivery

Resources required

PUSH → PULL

IMI2

H2020 Grants → EDCTP2

InnovFin ID

SME-Instrument
Main funding instruments under Horizon 2020 for preparedness research and response

- **Collaborative research** *(Countries, Sectors, Disciplines)*
  - SC1 (Health), SC2 (Bio-economy), SC6 (Societies), SC7 (Security), Research infrastructures

- **Innovative Medicines Initiative** *(IMI2)*
  - Public-private partnership between EC and pharma industry in Europe

- **European and Developing Countries Clinical Trials Partnership** *(EDCTP2)*
  - Partnership between 14 European and 14 African countries

- InnovaFin Infectious Diseases
European and Developing Countries Clinical Trials Partnership (EDCTP)

EDCTP2: 2014-2023

Capacity for Clinical Trials in Africa

Clinical Trials in Africa on PRDs

Third parties
- Private sector
- PDPs
- International Development Partners

€ 683 M

€ 500 M

Research and Innovation
Diseases: HIV/AIDS, TB, Malaria, NIDs, emerging infectious diseases of particular relevance for Africa, including Ebola

New tools and interventions: Diagnostics, drugs, vaccines and microbicides

Capacity Development: Fellowships, Networks, Ethics, Regulatory
• **Innovative Medicines Initiative (IMI)**
  - Europe's largest public-private initiative
  - Aims to speed up development of better and safer medicines for patients

• **InnovFin ID**
  - Provides loans between €7.5m and €75m
  - To innovative players in development of vaccines, drugs, medical devices, and research infrastructure for combatting infectious diseases
  - For projects that have completed pre-clinical stage and for which clinical validation is needed for further development
Instruments for swifter research response to an outbreak

- **Flexibility built into ongoing projects**  
  Possibility for the EC or the participants to change research agenda in case of an outbreak

- **Article in the Financial Regulation providing flexibility**  
  Foresees the possibility to award grants without a call for proposals in exceptional and duly substantiated emergencies
Some examples
Ebola research response

• **Budget**
  - €189 Mn
  - + €100.8 Mn EFPIA contribution

• **Combination of different instruments**
  - H2020 : €24.4 Mn
  - IMI : €113.9 Mn
  - EDCTP : €1 Mn
  - FP7 : €49.7 Mn

• **Covering wide range of needs**
  - Vaccine development (6)
  - Therapeutics (3)
  - Diagnostics (3)
  - Basic research (3)
  - Preparedness (3)
  - Social sciences (3)
Addressing Zika research gaps (H2020)

- 3 EU funded consortia
- Addressing Zika research gaps
  - Clinical studies: prospective cohorts of pregnant women and newborns, adults with CNS involvement
  - Studies on natural history and clinical spectrum of disease, transmission modes, pathogenesis & immunological consequences of infection, diagnostics development, mathematical modelling, animal reservoirs, vector competence and control, social studies, ...
  - Harmonization of data collection & data sharing roadmap
- Develop LAC region preparedness research network
Building capacity and tools

• **COMPARE** (H2020)
  - Aims for an enabling analytical framework and *globally linked data and information sharing platform* system for *rapid identification*, containment and mitigation of outbreaks
  - Combine *sequence-based pathogen data* and associated (clinical, epidemiological, etc.) data

• **PREPARE** (FP7)
  - A European clinical research framework covering *primary care and hospital care* in the EU
  - Implements large *inter-epidemic clinical studies* and develops new diagnostic tests for diseases
  - Aims to ensure a *rapid, coordinated deployment* of *clinical investigators* within 48 hours of a severe infectious disease outbreak in Europe
III. Participation in international initiatives

- Global Research Collaboration for IDs Preparedness
  [http://www.glopid-r.org/](http://www.glopid-r.org/)

- International Research Consortium on Animal Health
  [http://www.star-idaz.net/](http://www.star-idaz.net/)

- Coalition for Epidemic Preparedness Innovations
  [http://cepi.net/](http://cepi.net/)
GLOPID-R : Global Research Collaboration for Infectious Disease Preparedness

- Brings together 25 major funders of preparedness research whose involvement is crucial for a comprehensive and rapid global outbreak response

- Specific objectives
  - Facilitate the exchange of information
  - Address scientific, legal, ethical and financial challenges
  - Implement a ‘One Health’ approach
  - Establish a strategic agenda for research response
  - Connect infectious disease research networks
  - Actively involve developing countries
GloPID-R Members

23 research funders worldwide, with active engagement of developing countries

Observer Status: World Health Organization (WHO)
IV. Beyond research

• Data and sample sharing framework needed
• Regulatory: accelerating licensing without compromising safety
• Liability and insurance issues in pandemic setting
• Large-scale manufacturing, QA, access
• IP matters
• Infrastructure resources for rapid vaccine deployment
• Post-licensure commitments
• ...
VI. Challenges

I. Big data and data sharing

• Great efforts underway
• Need appropriate tools and technologies
• Need for operational and legal framework
Data sharing

3 EU funded consortia on Zika

- Harmonise protocols & tools for data capture & management
- Set up joint harmonised platforms for clinical research
- Share data in real time between the 3 consortia
- Prepare for sharing data with scientific community & public health officials

GloPID-R working group

- Aims to design a system for data sharing in public health emergencies to support the research response
  - Principles for data sharing in public health emergencies
  - Decision tree to identify data to be shared in particular context
  - Case studies to document data sharing experience
Key principles for data sharing in a public health emergency

Timely

Ethical

Equitable

Accessible

Transparent

Fairness

Quality
II. Involvement and capacity of affected countries

- Cf. EDCTP strong capacity building aspect
- EDCTP governance by 14 European and 14 African Participating States, through the General Assembly
V. EU added value

• EU level data collection and analysis
  • Cf. ECDC risk assessments, EFSA scientific opinions
  • Gathering of best researchers, across Europe and internationally – e.g. Zika consortia

• International exposure of EU funded researchers
  • Publication in higher impact journals
  • GloPID-R Zika research workshop in São Paulo, to foster collaboration between research groups

• Rapid mobilisation of funds
  • Complementarity with other funders
Thank you!