

CASE STUDY: INNOVATIONS IN EMERGENCY DISEASE RESPONSES

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Executive Summary

This study seeks to analyse and explain how innovation works in emergency communicable disease responses. It does so through use of the concept of an *innovation ecosystem*, the set of factors and actors that come together in ways that might foster or inhibit effective innovation processes. It looks at innovations across the range of activities involved in communicable disease responses in emergencies, and seeks to better understand the ecosystem by reviewing both positive examples, where innovations have emerged and been successful, and more challenging examples, where innovations have not happened, or where they have not been successful.

By looking across such contrasting examples, the study aims for a rounded picture of innovation in emergency disease responses, highlighting both the strengths and the weaknesses in the system. There have been some notable successes, amongst them the development of new diagnostics for TB, or new approaches to prevention, for disease surveillance, and treatment and management. There have been successful innovations within crisis responses, such as the response to polio outbreaks in Syria. But there are also notable failures include ineffective utilization of innovations in rapid responses such as Ebola in West Africa, and cholera in Haiti.

The study reveals an innovation ecosystem that is good in certain parts, and at certain times, but which is heavily reliant on a number of critical internal actors, and on external capacities and resources. Moreover, the ecosystem is far from systematic, and is not always well suited to the nature and dynamics of emergency work.

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Acronyms

ARVs	Antiretroviral drugs
AusAid	Australian Agency for International Development
CDC	Centre for Disease Control
CENTRIM	Centre for Research in Innovation Management
DFID	Department for International Development

ELRHA	Enhancing Learning and Research for Humanitarian Assistance
FDA	US Food and Drug Administration
FIND	Foundation for Innovative New Diagnostics
GAVI	Global Alliance for Vaccines and Immunisation
HIV/AIDS	Human immunodeficiency virus infection and acquired immune deficiency syndrome
IMC	International Medical Corps
LSHTM	London School of Hygiene and Tropical Medicine
MDR-TB	Multi-drug resistant tuberculosis
MSF	Médecins Sans Frontières
NGO	Non-governmental organisation
OCV	Oral cholera vaccination
ODI	Overseas Development Institute
PCR	Polymerase chain reaction
PEPFAR	President's Emergency Plan for AIDS Relief
R&D	Research and development
SARS	Severe acute respiratory syndrome
SIAD	Short interval additional dose approach
SMC	Seasonal Malaria Chemoprevention
SMS	Short Message Service
SPEED	Surveillance in Post Extreme Emergencies and Disasters
TB	Tuberculosis
UN	United Nations
UNAIDS	The Joint United Nations Programme on HIV/AIDS
UNHCR	United Nations High Commissioner for Refugees
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
WHO	World Health Organization

Introduction

According to the World Health Organization (WHO), infectious diseases are a major cause of deaths and ill health in humanitarian crises.¹ The diseases most commonly associated with emergencies include diarrheal diseases, acute respiratory infections, measles and malaria, epidemic meningococcal disease, tuberculosis, relapsing fever cholera and typhus.² In recent years, disease such as Ebola, various strains of influenza and SARS have all triggered multi-country epidemics, resulting in emergency responses that have escalated beyond any one country or region to a global response. These major epidemic events are generally seen as humanitarian crises in their own right.³

The focus of this study is innovations in international humanitarian responses to these emergencies. Health work is a large part of the overall global humanitarian effort. It is the second largest sector of assistance, after food aid, receiving some \$7.3 billion through UN-coordinated appeals in the period 2009-2013.⁴ Managing communicable disease makes up a significant proportion of this work.

Although communicable diseases are no longer the threat they once were in developed countries, their impact is considerable in those countries that are most prone to humanitarian crises.⁵ Data from the WHO's Global Burden of Disease report shows that in low-income countries, 38% of all deaths and 6 of the top 10 causes of death are accounted for by infectious diseases. In lower-middle income countries, 24 % of all deaths and 5 of the top 10 causes of death were due to infectious diseases (See figure 1).⁶

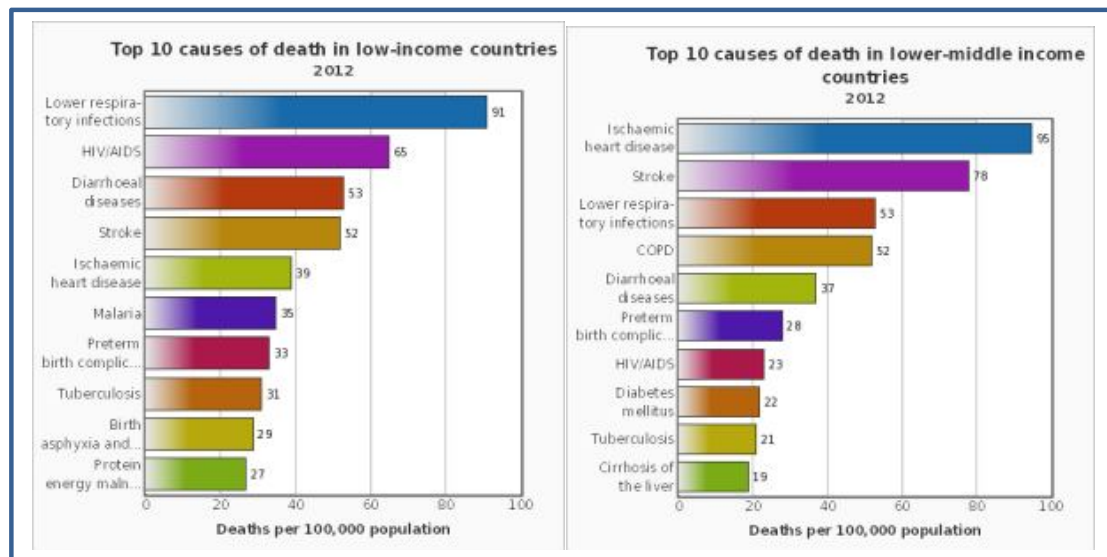


Figure 1: Deaths in Low Income and Lower Middle Income Countries

¹ Smith, R. Woodward, D, Acharya, A, Beaglehole, R and Drager, N (2004) Health Policy and Planning 19(5): 271–278, Oxford University Press

² Doherty, P (2013) Pandemics: What Everyone Needs to Know, OUP

³ Institute of Health Metrics and Evaluation (2013) Financing Global Health <http://vizhub.healthdata.org/fgh/>

⁴ Development Initiatives (2013) Global Humanitarian Assistance Report

⁵ Lozano R, Naghavi M, Foreman K, Lim S, Shibuya K, Aboyans V (2010) Global and regional mortality from 235 causes of death for 20 age groups in 1990 and 2010: a systematic analysis for the Global Burden of Disease Study Lancet 80:2095–128

⁶ WHO (2007) The World Health Report 2007: A Safer Future

Because of the Ebola response that is ongoing at time of writing, innovations in communicable disease responses are high on the agenda in the humanitarian sector, and across the international community more widely. In particular, there has been an emphasis on drug development to better treat infected patients, who face shockingly a high risk of death. However, effective treatments are just one part of humanitarian communicable disease responses. The WHO guidance states that effective humanitarian management of diseases consists of five sets of activities: diagnostics and assessment, prevention, surveillance, outbreak control and disease treatment and management.⁷ As this study will show, effective innovations in humanitarian responses to infectious disease outbreaks can fall into any one of these specific areas of work.

This study looks at innovations across this range of activities, to better understand how the 'innovation ecosystem' works in this subsector of humanitarian response. The aim of the study is to explain the *state of play* for innovations in this area, and generate insights into how innovations might be strengthened, both in this specific area of work, as well as across the humanitarian sector as a whole.

This is one of five parallel case studies being undertaken as part of a larger Brighton University study on innovation ecosystems in international humanitarian aid.

Concepts and Frameworks

Innovation ecosystems

The concept of an *innovation ecosystem* is relatively recent but has a long intellectual history. For some time now there has been a move away from the traditional linear view of innovation resulting from investments in research and development in a sequential and predictable fashion. The analogy of the ecosystem can therefore be seen as the latest stage in the evolution of a broader intellectual approach to understanding how innovation takes place.

The recent use of *innovation ecosystems* has roots in the growing scientific understanding of complex social systems, and how change takes place in such settings. These include studies on the economy as ecosystems such as the work of Harvard University on economic growth as an evolutionary process in a complex system. Studies of emergent and non-linear change, popularized as *tipping points*, also utilise some elements of ecosystem approach.

It is with noting that the academic understanding of the ecosystem approach has been made more challenging because of the widespread use of the term as management jargon, especially in technology and social media. Ecosystems are used to describe everything from the rise of mobile technology software applications (*the app ecosystem*) to the competitive strategies of specific technology firms (*digital ecosystem strategies*).

Studies that take an innovation ecosystems approach in generally work with two key principles:

⁷WHO (2006) A field manual - Communicable disease control in emergencies

1. .Understanding the different components of the innovation ecosystem: e.g. operations, research and development (R&D), manufacture, marketing, intellectual property, regulation, networks and collaborations;
2. Understanding how these components interact and are interdependent, and how they support/inhibit the innovation process from the identification of needs/opportunities, the invention and development of new approaches, implementation and testing, diffusion and adoption.⁸

Formal methods for systemic analysis – ranging from system dynamics, network analysis, agent-based simulations and data science/big data – are often applied to further an understanding of innovation ecosystems.⁹ There is also a wealth of literature that uses a more qualitative approach to understanding and enhancing these ecosystems.

Innovation ecosystems in health

This study focuses on the innovation ecosystem that works to improve humanitarian responses to infectious diseases. This is one specialized area within the much bigger area of health innovation, which is the focus of substantial academic and private sector research. Within this field it is possible to see a number of ways in which the idea of an innovation ecosystem has been utilized. For example, health innovation ecosystems may refer to:

- A geographical or thematically focused areas of high innovation density – such as the development and trialing of specific Ebola drugs by public sector actors, humanitarians and pharmaceutical firms working in West Africa;
- An network of actors cooperating in innovation with a given firm or organisation, such as the teams working to develop new protocols for treating HIV-AIDS in emergencies through minimum standards for ante retro virals;
- A system of all relevant innovating actors and factors making up the value chain/value network of a firm / industry innovation efforts initiative e.g. the campaign to bring artemsin-based malaria treatments into humanitarian responses in refugee camps;
- A network of loosely coupled actors with differing interests, but bound together in a collective whole, therefore sharing a common ‘innovation fate’ e.g. the development of low cost vaccines by coalitions of public and private actors.¹⁰

Of relevance for this study is the strand of literature on health innovation ecosystems that distinguishes between those operating in high and low income countries. Table 1 gives a generalized comparison between the two.

⁸ Bessant et al (2014) Innovation Management, Innovation Ecosystems and Humanitarian Innovation CENTRIM Paper

⁹ See Ramalingam, B (2013) Aid on the Edge of Chaos, OUP: Oxford

¹⁰ Roscigno, G et al (2013) Innovation and new technologies to tackle infectious diseases of poverty, TDR Global Report

High income health innovation ecosystems	Low income health innovation ecosystems
Funding and infrastructure provided by actors from multiple sectors and disciplines	The public sector provides most, if not all, funding and infrastructure
Training and basic research are funded by the public sector through universities and government research institutions	Research is conducted largely in academic institutions
Translational research, product development, prototypes conducted by industry e.g. pharmaceuticals, etc	Lack of capacity to conduct translational Innovation and research
Extensive manufacturing capacity available	Limited manufacturing capacity, mostly technology transfer from developed countries
Strong private sector involvement in health innovation	Absence of domestic private sector institutions engaging in health innovation
Very strong regulatory and intellectual property regimes	Weak regulatory and intellectual property management

Table 1: High and Low Income Innovation Ecosystems compared¹¹

The conceptual frameworks developed for this study

In starting to map the dynamics of the humanitarian innovation ecosystem, the Brighton study identified a series of components which need to be explored more thoroughly in order to understand why the humanitarian innovation ecosystem currently operates as it does. This is seen a necessary step in illuminating the strengths and weaknesses associated with the ecosystem, and by extension, understanding how the innovation system might be strengthened. These components included the following 'R's:

- Resources: what resources - finance, time, knowledge, technologies - are available for humanitarian innovation, and how are these deployed?
- Roles: who plays what roles in innovation efforts and processes? Are there observable patterns? What, specifically, are the roles of innovators, end-users, front-line workers, brokers, researchers, private sector and non-traditional actors?
- Relationships: what kinds of relationships and networks exist between actors in the innovation ecosystem (competitive, collaborative, contractual, commercial, etc.), and how do these shape innovation efforts?

¹¹ Extracted and adapted from Roscigno, G et al (2013) Innovation and new technologies to tackle infectious diseases of poverty, TDR Global Report

- Rules: what formal and informal rules pertain to humanitarian work and humanitarian innovation specifically, and how do they serve to shape roles, determine relationships, resource allocations, and shape innovation processes?
- Routines: what are the specific ways in which innovation processes work in the sector, and how well do these work? What are the dynamics of these routines - e.g. linear, predictable; non-linear, unpredictable?
- Results: how do innovation results get determined, and by whom, and how does this impact on the success or otherwise of innovations?

The Brighton study has also utilised the principles and methods of system dynamics to develop a model of how the innovation ecosystem maps onto the innovation process (see figure 2).

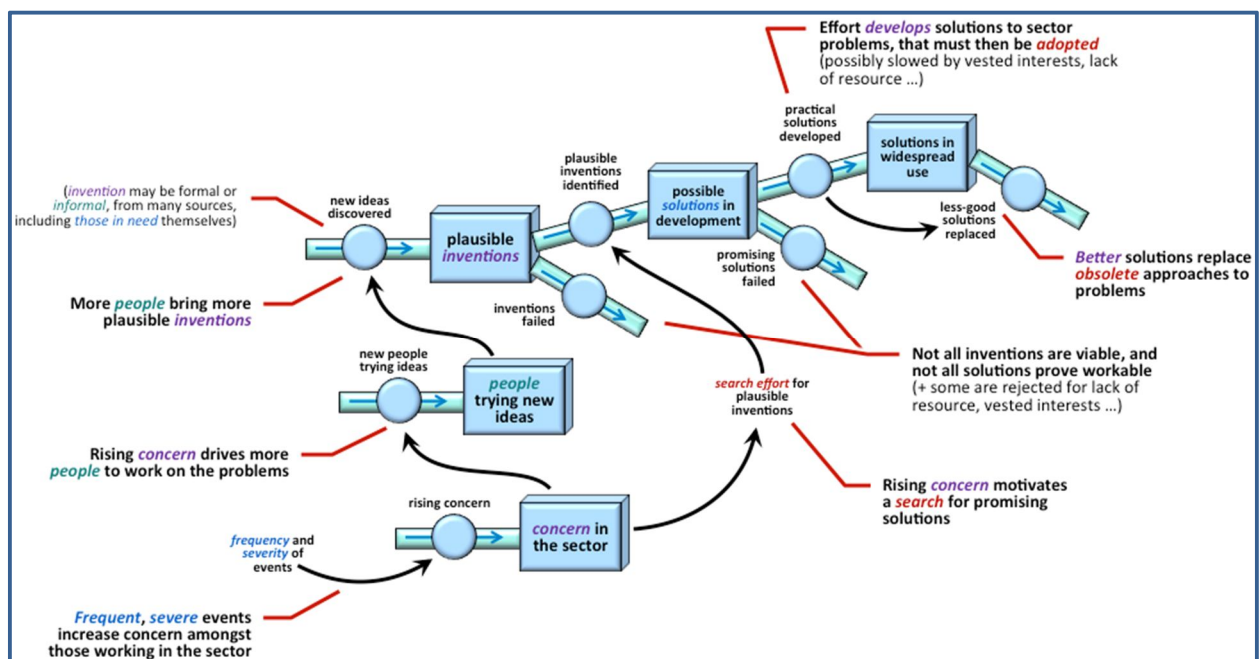


Figure 2: The Humanitarian Innovation Ecosystem

This shows how the different stages of the innovation process map onto ecosystem of actors and factors, covering the following stages:

- **Search:** this stage is composed of rising concern about a given issue or problem, which then motivates a search for possible solutions;
- **Select and Development:** Successful search processes should lead to new solutions being invented and tested in *laboratory conditions*;
- **Implementation:** plausible solutions should then be trialed in real-world settings, often through small-scale pilots. This will see some solutions fail, and others move forward;
- **Scaling:** this set of activities will see solutions in widespread use, through a variety of mechanisms from open-source dissemination, replication, incorporation into government structures and commercialization.

Across these stages, the ecosystem should in theory work to bring together sufficient resources, actors playing a diversity of roles and with effective relationships, applying routines, and in accordance with a range of rules, in ways that generate results of effectiveness and also overcome any institutional or professional barriers to new approaches.

These two frameworks, developed for this study, together fulfil the two principles of innovation ecosystems approaches described earlier, namely: understanding the components of the ecosystem, and how they interact in ways that enable or facilitate innovation processes.

In the next section, a number of successful and failed examples of communicable disease innovations will be looked at, in order to draw general conclusions about the innovation ecosystem within this sub-sector of humanitarian aid.

Innovations in humanitarian communicable disease responses

This section seeks to explore the innovation ecosystem within humanitarian communicable disease responses. It will do so by looking at a number of different innovation processes that have taken place in the past decade. The focus on recent innovations was primarily to get as current an understanding of the state of the innovation ecosystem as possible.

At least five different types of actors work in emergency infectious disease responses, and they all play a role in the innovation ecosystem. These include:

- Intergovernmental organisations with either wholly or partially health-related mandates, including the World Health Organization, the World Bank, UNAIDS and UNICEF;
- National governmental organisations operating internationally in the field of infectious disease control, including donors such as USAID and the UK Department for International Development; disease control agencies such as the US Centers for Disease Control and new global programmes such as the US Presidential Emergency Program for AIDS Relief (PEPFAR);
- Non-Governmental organizations, such as Médecins Sans Frontières, the Malaria Consortium, the International HIV/AIDS Alliance, PATH, Oxfam;
- Private foundations, much the largest of which is the Bill and Melinda Gates Foundation;
- Public-Private Partnerships and consortia such as the Global Fund to Fight AIDS, Tuberculosis and Malaria, UNITAID, the Global Alliance for Vaccines and Immunisation (GAVI), the Stop TB Alliance.¹²

¹² House of Lords Intergovernmental Committee (2008) Diseases Know No Frontiers: How effective are Intergovernmental Organisations in controlling their spread?

Across these actors, there is a widespread view that there is not sufficient coordination in either policy or operations, with the sector seen as dominated by "*competition and turf battles, and far too little genuine collaboration*". As will be noted in the case studies that follow, these actors come together in a variety of ways in innovation processes, sometimes so as to echo the above criticism, but also in ways that reveal a collective ability to transcend it.

The case studies span the range of activities undertaken in humanitarian communicable disease responses. As noted earlier, these fall into the following five areas:

- 1) Diagnostics and assessment;
- 2) Prevention;
- 3) Surveillance;
- 4) Outbreak control;
- 5) Disease treatment and management.¹³

Delivery of activities in each of these areas is complicated by emergency contexts, where information is scarce, there are significant resource constraints in terms of people and money, there is a very short time frame in order to make decisions, and there are demands for incredibly rapid responses that are still efficient and effective. These extreme pressures serve to limit the possibilities for innovation: many actors in such settings understandably seeking to apply known solutions than to explore uncertain and unknown areas. However, a number of respondents noted that it is precisely these conditions of emergencies that make innovation so important and vital, because of the potential contribution to saving lives and restoring health.

In the cases looked at below, effort has been made to look at both successful and unsuccessful examples of innovation. In the latter case, it may be that there were innovations that were not used, or it may be that innovation is noticeable by its absence. This approach was taken because it is likely to produce a more rounded and accurate picture of the ecosystem than simply focusing on the positive cases.

Disease Diagnostics and Assessments: From TB Tests to the Wild Wild West

Activities falling into the category of diagnostics and assessments involve identifying the communicable disease threats faced by vulnerable populations, especially those with epidemic potential, and using a variety of methods and tools to define and measure the health status of the population in relation to these threats. In emergency settings, the fundamental requirement is for quick, effective and cheap tests that can be deployed with minimal or low levels of technological and training requirements.

There have been a number of examples of such tests being developed and subsequently

¹³ WHO (2006)

deployed in humanitarian responses. Perhaps the most significant of these in recent years has been the rapid assessment for tuberculosis (TB), both typical and multi-drug resistant tuberculosis (MDR-TB). Tuberculosis is a leading cause of morbidity and death worldwide, with approximately two billion people infected and approximately two million annual deaths attributable to it. The vast majority of these cases (95%) and deaths (98%) occur in low and middle-income countries.¹⁴ TB is recognized as a major cause of mortality in humanitarian crises, especially in complex emergencies that are the focus of the majority of humanitarian expenditure, but there are considerable challenges to correctly identifying and treating TB in emergencies.¹⁵

The issues around treatment will be discussed later on (see section 3.5) but here the focus is on diagnostics. Unlike HIV and malaria, the other two major killers in developing countries, there was until very recently no rapid diagnostic test for TB. The most commonly used diagnostic involves taking multiple samples of sputum from suspected carriers, and applying microscopic analysis to identify the presence of the TB bacterium. This method, which is over 125 years old, is cheap but is subject to human error. It is also not effective for all types of patients - in particular, children, patients with MDR- TB, or who also have HIV-AIDS.¹⁶

The lack of rapid diagnostics is widely seen as contributing to the global caseload for TB, because of the high levels of undiagnosed and therefore untreated cases. Although efforts were made to strengthen laboratory capacity to diagnose these patients, the cost has been prohibitive in many settings. These challenges also extend into treatment, and have meant that many humanitarian organisations have traditionally chosen not to implement TB programmes,¹⁷ focusing instead on more obvious and treatable diseases such as diarrhoeal diseases, measles, acute respiratory infections and malaria. However, in recent years, a number of agencies had taken up the mantle, and sought to overcome the challenge of delivering TB programmes in emergencies. This meant *searching* for better diagnostics, as well as meeting a variety of standards for treatment and care.

The rising level of concern amongst humanitarian agencies was not, however, the major driver of the development of a new test. Instead, there was significant campaigning and concern raised in the wider public health arena, which led to a sustained attempt to *select and develop* a new solution for TB testing. This invention process was largely initiated and conducted outside of the humanitarian sector, initiated by the public-private partnership, FIND, in 2006, working in collaboration Cepheid, a leading US medical diagnostics firm, and the laboratory of Professor David Alland at the University of Medicine and Dentistry of New Jersey. Additional financial resources came from the US National Institutes of Health. The stated aim was to develop a rapid diagnostic molecular test, which would not be subject to human decision-making and therefore less prone to error. It was also intended for use in detection of drug-resistant TB, and for TB in HIV-AIDS sufferers.

¹⁴Desikan, P (2013) Sputum smear microscopy in tuberculosis: Is it still relevant? Indian J Med Res. 2013 Mar; 137(3): 442-444.

¹⁵Grange, John M et al (1999) Paradox of the global emergency of tuberculosis, The Lancet , Volume 353 , Issue 9157 , 996

¹⁶ WHO (2006) *Global tuberculosis control. Surveillance, planning, financing.*

¹⁷ Biot, M, CHandramohan, D and Porter, JD (2003) Tuberculosis treatment in complex emergencies: are risks outweighing benefits? Trop Med Int Health. 8(3):211-8.

After an intensive three-year development and testing process, a new molecular test, known as Xpert MTB/RIF, received accreditation by the EU as an approved diagnostic. The test underwent demonstration *trials* in a number of laboratories around the world, and was found to detect 92.2% of TB, including 73% of those cases that were negative with the traditional microscopy test. In comparison to the microscopy method, the new test was fully automated and not as susceptible to human error. It also identified both the presence of TB and resistant TB.

While this initial trial process was vital for the initial validation of the test, there was a need for *further trials* if the test was to be used in developing countries. Specifically, despite the positive results, there were still questions about the utility of the test in a variety of low resource settings, including humanitarian emergencies. The original demonstration tests had been conducted in 'near ideal' reference laboratories. In order to test its efficacy away from such settings, FIND led a major trial of the test in health facilities in resource poor settings, with a specific focus on measuring the operational feasibility and effectiveness. A humanitarian agency, Médecins Sans Frontières (MSF), was one of the collaborators. This study, published in the Lancet, assessed adults with suspected TB or MDR-TB in South Africa, India, Peru, Azerbaijan, the Philippines and Uganda. The trial compared the Xpert MTB/RIF results to microscopy results in laboratories adjacent to the study sites, and also undertook a validation test using culture analysis. Covering some 6648 participants, the trial found that the test detected 90% of tuberculosis cases, compared with 67% for microscopy. It was also not significantly lower in patients with HIV co-infection, unlike the microscopy results. The results were also available within a matter of hours, rather than days for microscopy. For those cases that tested negative on microscopy, the use of the MTB/RIF test reduced median time to treatment from 56 days to 5 days. The test was also found to be usable outside of conventional laboratories because it was self-contained and did not require specialized training.

These findings were published in 2009 and 2010, and subsequently validated in leading medical journals in 2010, following which a recommendation was made to the WHO to approve the test for use globally. The WHO's Strategic and Technical Advisory Group for TB took up the mantle in September 2010, reviewed the evidence and held a global consultation, before making a policy recommendation in December 2010 for Xpert MTB/RIF to be used as the initial diagnostic test in suspected TB cases, especially for cases of MDR-TB or HIV/TB. The initial recommendation anticipated that the test could lead to a three-fold impact in diagnosis of MDR-TB and doubling of TB/HIV diagnosis.¹⁸

This meant that the test could be potentially used in low and middle-income countries, there were a number of further trials required for the test to be deployed in emergency settings. Between 2011-2012, MSF undertook a large multi-country study of the test, working in 25 MSF projects across 14 countries.¹⁹ The study showed an average 50% increase in the use of the test compared to the microscopy approach, but with high degree of variability in take-up from 10% in some sites to 115% in others. A number of these were in complex emergency settings, such

¹⁸ Cohen, D & Corbett, E (2013) Evidence supports TB test, so what now?[editorial]. Cochrane Database of Systematic Reviews 2013

¹⁹ MSF (2012) Implementation new test increases diagnosis, Press Release, November 2012

as Zimbabwe, where there was a quadrupling of cases diagnosed, and Swaziland, where the delay to treatment was reduced from 66 days to 14 days (79% reduction). The conclusion of this round of tests was that the MTB/RIF test could be used effectively in a range of emergency settings to *simplify patients* access to early and accurate diagnosis, thereby potentially decreasing morbidity associated with diagnostic delay, dropout and mistreatment."²⁰

With the evidence in place, the next barrier was around *scaling up* the use of the test across countries where TB was a major problem, and by operational aid agencies in such settings. However, this led to an issue of access to the test: the test was not initially affordable for many governments and humanitarian organisations. In August 2012, a public-private partnership announced between the United States President's Emergency Plan for AIDS Relief (PEPFAR), the United States Agency for International Development (USAID), UNITAID, and the Bill & Melinda Gates Foundation. This arrangement, which was to remain in place until 2022, allowed for a drop in price of the test cartridges from over 40% from \$16.86 to \$9.98, specifically for use the public sector of 145 high TB burden and developing countries plus NGOs and other non-profit agencies operating these countries.²¹

The role of UNITAID as an innovative financing mechanism focused on enhancing access to disease-focused innovations in is of central importance here. UNITAID has also recently supported the development of point-of-care diagnostics for HIV-AIDS, which have also been trialed in humanitarian programmes, with evidence still being produced at time of writing.

By June 2013, 88 countries around the world had procured 1,402 GeneXpert instruments and over 3 million of the test cartridges were being used by the public sector and NGOs under the concessional pricing structure.²² According to Mario Raviglione, director of the WHO Stop TB Department, "*This is a game-changer for TB and MDR-TB [multidrug-resistant TB] care delivery. [We have seen] innovation happening in real time - scientific evidence rapidly translated into policy, policy quickly adapted into practice, and scale-up significantly accelerated by innovative funding mechanisms effectively addressing cost and affordability.*"

This is perhaps the most successful recent example of innovations in diagnostics in emergency disease responses. It reveals some interesting features of the innovation process, and by extension, the supporting innovation ecosystem.

While this was an innovation that has been used in humanitarian contexts the humanitarian sector was not the main instigator of the innovation process. Some recognition of the problems and opportunities around TB testing did indeed take place in humanitarian settings, this was not sufficient to trigger a process of selection and invention. Instead, the development of the test happened in a separate innovation process, involving public health campaigns and advocacy, public-private partnerships and commercial entities.

²⁰Boehme, Catharina C et al. (2011) Feasibility, diagnostic accuracy, and effectiveness of decentralised use of the Xpert MTB/RIF test for diagnosis of tuberculosis and multidrug resistance: a multicentre implementation study, *The Lancet*, Volume 377, Issue 9776, 1495 - 1505

²¹ Menzies NA, Cohen T, Lin H-H, Murray M, Salomon JA (2012) Population Health Impact and Cost-Effectiveness of Tuberculosis Diagnosis with Xpert MTB/RIF: A Dynamic Simulation and Economic Evaluation. *PLoS Med* 9(11): e1001347. doi:10.1371/journal.pmed.1001347

²² WHO (2013) GeneXpert Guide

It was after only the successful trial of the test in ideal settings that it was brought into consideration by the humanitarian sector. In this case, as in the health field more generally, this was by means of trials, with a focus on the generation of evidence of effectiveness. Humanitarian operations were the focus of iterations between development and implementation.

The scale-up and dissemination required a large-scale and concerted intervention on non-humanitarian actors, although this happened in part because of the advocacy of a range of actors including MSF. This last point highlights the fact that the involvement of the private sector is not an automatic driver of humanitarian innovation success. In this case, despite the successful development of the product, a large-scale financing intervention was needed in order to create affordable pricing structures. There is an interesting comparison to be made with the story of Plumpy'Nut and community-based feeding therapy. The less-cited addendum of that innovation story is that Nutriset, the commercial producers of Plumpy'Nut, were put under considerable pressure to relax their patent for peanut-based malnutrition treatments, and were accused of profiteering from humanitarian crises. Under pressure, they relaxed the patent structures, and the product became more widely available.

The second case study on diagnostics tells a rather different story. At the time of writing, there is a great deal of global concern about the urgency of improving Ebola diagnosis. The lack of decent and rapid diagnosis is having a profound effect in the unfolding epidemic. Numerous *search* efforts are underway to enable better detection and prevent transmission at the early stages. However, developing and testing new diagnostics in the middle of the largest ever outbreak of the disease has proved extremely challenging.

The disease presents unique constraints to diagnostic innovations. There is an obvious need for high accuracy in any test. False negatives can lead to disease transmitting individuals being allowed back into the community, while false positive can lead to healthy individuals contracting the disease while in kept in quarantined isolation with infected patients. In the worst case scenarios, patients can wait for up to five days while their blood is transported over hours or days to a laboratory. These individuals are held in isolation units with other suspected patients – so if they don't have Ebola when they go in, there is a high chance they will have it when they come out.

The difficulties have been compounded by conditions in the Ebola-affected countries. The three West African countries that are most affected by Ebola have very weak health systems, with few testing labs and facilities, and limited numbers of trained staff. Because of the growing caseload of suspected patients, there is a need to more than double the diagnostic capacity from 6,000 a week to over 12,000 a week, and also for laboratories to be located closer to the treatment centres.

The best existing test for Ebola employs a process called reverse transcription *polymerase chain reaction (PCR)*, a method developed in the 1980s that conferred a Nobel Prize in Medicine to its inventor. The PCR process isolates and amplifies the genetic material of the virus, allowing accurate analysis of even miniscule amounts that might be present in bodily fluids. However, this requires samples of test blood, trained personnel and a sophisticated computerized testing

machine, and each test cost \$100. The Ebola outbreak has led to *search and development* of new, quicker testing equipment. The new testing machines can now diagnose in one hour rather than the original six. The new machines retail at £39,000 and have already been purchased in bulk across many hospitals across the US, following an accelerated approval process by the US Food and Drug Administration. This saw a remarkable reduction in the time for approval, with the machine being passed in October 2014 after a few months of analysis, rather than years which is more typical. However these machines retail at \$39,000 and are more likely to be of benefit to developed countries in order to further strengthen domestic responses to Ebola. Indeed, none of these machines have to date made their way to West Africa.²³

The operational conditions for the Ebola response are such that a faster test result though important, is not the only important test of a new innovation. Because of the virulence of the virus, there are additional requirements for testing, specifically the need for protective gear for testers. Both WHO and CDC recommend should include impermeable gloves, footwear, eye and face protection, protective clothing and resistant masks. A new humanitarian product will need to deal with – at a minimum - the timing issue, the need for accuracy, the need for protection of testers, and the lack of testing capacity.

A number of different organisations, from the WHO, Wellcome Trust, USAID, US FDA and FIND (who were involved in the rapid TB test) have encouraged and incentivized the *search and development* of new rapid tests in the most-affected countries. Such incentives include provision of protocols and standards that new tests should meet. For example, the WHO and FIND have worked together established a *target product profile* for rapid simple tests that can be used in the control of Ebola, and have also generated an inventory of products currently available.²⁴ This product profile sets out everything from the diagnostic methods to specifying the conditions in which any new test must be deployable, and the skill requirements for implementing the tests. The collaboration has also developed guidance for the procurement of biochemical materials for use in the tests. This can be viewed as a vital strategic input into the search and development process. Some donors have also supported the development of new products. Wellcome Trust and DFID, through ELRHA, have funded the development of a new 15 minute test to be trialed in Guinea. USAID have funded an innovation window on Ebola, working with the design company IDEO, working on a range of issues from improved diagnostics to health-worker protection though cheap but effective suits.

This rapid investment has led to the emergence and flowering of a diversity new ideas and technologies for diagnostics. For example, there are some tests that work without the need for refrigeration, while some focus on improving accuracy without the use of the PCR method. Others seek to provide a mobile 'lab in a suitcase', while others take account of safety requirements. The sheer number of products that are appearing means that careful trials are urgently needed, along the lines of what was used in the TB case.

²³ Pollack, A (2014) Researchers Seek Crucial Tool http://www.nytimes.com/2014/11/05/business/ebola-researchers-rush-to-find-a-fast-diagnostic-test.html?_r=0

²⁴ WHO / FIND (2014) Target Product Profile for *Zaire ebolavirus* rapid, simple test to be used in the control of the Ebola outbreak in West Africa <http://www.who.int/medicines/publications/target-product-profile.pdf>

At the moment, however, the fact that the Ebola is being dealt with primarily through rapid response humanitarian operations means such trials are hard to implement. Unfolding responses are not especially conducive to rigorous testing of innovations. Where Ebola products have been trialed, it is often by involving healthy individuals not in the crisis conditions. As a result, there has been the parallel development of about eight parallel diagnostic products, with no common means of determining which works best and why. As Mark Perkins, the Chief Scientific Officer of FIND, remarked pointedly about diagnostic innovation in the Ebola response: "*it's the Wild Wild West in development*".²⁵

This account, although sobering, is useful because it illustrates how fragmented the disease innovation ecosystem becomes when it is reliant on ongoing humanitarian operations. The innovation ecosystem works better when it anticipates crises, and generated products and processes in advance, which can be tested and trialed for use in particular crises – as was the case with the TB test.

Although the new PCR machine was a remarkably rapid example of innovation moving from search to scale, this was only triggered by humanitarian concern, and has not led to a product that can be used in humanitarian settings. This reveals the downside of system that worked so well for TB tests: it does not always work well for the most vulnerable people. The most significant diagnostic improvements that have followed the humanitarian crisis of Ebola has been for the benefits of citizens of developed countries, and not those in the crisis context who have the most urgent needs.

For those suffering from or at risk of Ebola in the three most-affected West African countries, the innovation ecosystem simply delivered too little, too late. On a more positive note, however, it may well be that the diversity of Ebola tests now available will lead to trials and a successful product for use in future outbreaks.

Disease Prevention: Succeeding with Malaria, but Failing on Cholera

Disease prevention involves activities to limit the emergence and spread of communicable disease through appropriate measures in public health specifically, as well as in wider aspects of social and economic policy such as maintaining a healthy physical environment and ensuring good general living conditions. Such work faces obvious difficulties in emergency contexts, which by definition are characterized by catastrophic disruptions to human lives and livelihoods.

There are however numerous measures that have been developed so as to minimise the possibilities of a disease outbreak which can lead to a *disaster within a disaster*. Some of these preventative efforts are behavioural and social, while others might be highly medical in nature. As a result, innovations in emergency disease prevention cover a spectrum of disciplines and approaches, with some being more cultural and social, and others being more technically focused. Often, the most effective preventative mechanisms are those that integrate a range of disciplines.

One of the most significant innovations of recent years has been in malaria prevention. In post-

²⁵ Pollack, A (2014)

disaster settings, especially those that involved geophysical events such as floods, cyclones and earthquakes, there may be rapid change or a sharp increase in potential breeding sites for mosquitoes. Affected populations may also adapt to disasters in ways that increase their proximity to existing sites, for example through evacuation processes. Children are especially vulnerable in these situations. In many settings, displaced communities are given insecticide-treated bed nets, but these distributions assume that families have decent shelter facilities, which is often far from the case. In some settings, disaster-affected populations have been known to use malaria nets as doorways or dividing walls in temporary shelters, rather than for their intended use.

Thanks to improved surveillance techniques, it is possible to better predict new malaria outbreaks, especially in settings where malaria is related to seasonal events such as floods. In these contexts, one option for effective prevention is to give treatment-level doses of drugs at regular intervals during the transmission season regardless of whether children in question have malaria symptoms or not. This approach, now known as Seasonal Malaria Chemoprevention (SMC), had been applied in a number of post-disaster settings but there was little rigorous evidence about whether it worked or not. This was an interesting example of an approach being in use without decent validation, and therefore being limited in its possible dissemination.²⁶

This changed in 2012, when researchers linked with the international Cochrane Collaboration to further evidence-based medicine conducted a review of the available evidence on SMC.²⁷ They focused on seven high quality studies in the West African countries of Burkina Faso, Gambia, Senegal, two in The Gambia and two in Mali - all countries where malaria transmission is highly seasonal. Across the countries, children aged between 3 months to 6 years were given up to 3 days of anti-malarial treatments on a regular basis during the seasonal peak period. In all of these countries, the preventative approach proved highly effective, preventing 75% of all malaria cases and 75% of severe cases, with minimal serious side effects.

The review team showed that the results were also relevant for other areas with similar malarial conditions - specifically where a minimum of 60% of annual cases occur in 4 consecutive months. SMC was found to be especially useful to protect the health of children at risk from severe malaria where there is limited access to care, such as in refugee camps, evacuation centres and other post-disaster settings.

In innovation terms SMC could be understood as having passed the search process, having been selected and developed, and implemented in some settings, but without much clarity of when and how it worked. The process of gathering and synthesising evidence helped to formalize the procedure through synthesis of test results from a variety of settings. Further implementation was greatly facilitated in late 2012, when the WHO made direct use of the Cochrane Systematic Review to draft a policy recommendation for SMC. The seven trials selected by the systematic review were cited in the recommendation papers. The WHO put the SMC recommendation as follows:

²⁶ WHO (2013) Seasonal Malaria Chemoprevention Website

²⁷ Cairns, M (2012) Estimating the potential public health impact of seasonal malaria chemoprevention in African children, Nature Communications 3, Article number: 881

“With the changing epidemiology of malaria, there is a progressive paradigm shift from a “one size fits all” approach, to the targeting of malaria control strategies to specific populations and/or locations for maximal effectiveness. In keeping with this approach, WHO is now recommending a new intervention against Plasmodium falciparum malaria: seasonal malaria chemoprevention (SMC). This intervention has been shown to be effective, cost-effective, safe, and feasible for the prevention of malaria among children less than 5 years of age in areas with highly seasonal malaria transmission.”²⁸

2012 also saw a large-scale humanitarian malaria prevention program, consisting of intermittent distributions of anti-malaria medicines, run by MSF in Mali and Chad. Anti-malaria medicines were administered to approximately 175,000 children between three months and five years of age in Koutiala District in southern Mali and in two areas of Moïssala District in Chad. This was the first time MSF had carried out a large-scale SMC program, and was one of the first large-scale applications in humanitarian sector as a whole.

In Mali, MSF teams observed a 65 percent drop in the number of malaria cases in the weeks following the distribution of treatment. Additionally, the number of malaria-associated hospitalizations fell from an average 247 per week to 84. In southern Chad, results were equally encouraging; in two health zones in Moïssala, the decrease in the number of malaria cases was between 72 percent and 86 percent, compared to cases recorded in the weeks prior to the first SMC distribution.²⁹

According to Dr. Estrella Lasry, a malaria specialist at MSF, further evidence of feasibility was essential for further scale-up: *“this prevention strategy could be an extraordinary public health tool, particularly for protecting children, who account for the vast majority of malaria deaths. We can draw on our projects in Chad and Mali to assess the feasibility of employing this strategy in other contexts.”*

The methodology has not proved to be a magic bullet, however. It is increasingly being requested in settings where there is year-round malaria, but SMC has not been found to be effective in such contexts, nor have there been equivalent preventative methods developed. In other settings there may be high levels of resistance to specific antimalarial drugs, making the treatment ineffective. Moreover, SMC itself can also contribute to a rise in drug-resistant malaria if it is implemented without close monitoring. As Lasry noted:

“the bottom line is that there is no optimal drug, highlighting the challenges of designing an appropriate prevention strategy for this context—yet leaving the sense that it’s essential to make some trade-offs and devise the best possible strategy with the limited tools at hand.”³⁰

Since this time, SMC has seen remarkably rapid approval across the humanitarian sector. The

²⁸ WHO (2013) Seasonal Malaria Chemoprevention: A Field Guide

http://apps.who.int/iris/bitstream/10665/85726/1/9789241504737_eng.pdf

²⁹ Lasry, E, et al (2012) Seasonal malaria chemoprevention: a new player in the malaria control arena, MSF Paper

³⁰ Lasry, E (2013) Seasonal Malaria Chemoprevention: Good News in a Year Marked by Malaria Emergencies, PLOS Blogs, 25th April 2013

2013 inter-agency handbook on malaria control in emergencies, published by a group of health-focused UN agencies and NGOs, citing SMC as “particularly useful during the post-acute phase or during chronic emergencies in sub-Saharan Africa, as it requires minimal specialist knowledge and can be administered by health staff.”³¹

This case study is one which shows the innovation ecosystem working remarkably well, with a rapid turnaround from application of approaches, evidence being generated, piloting in humanitarian settings, approval by WHO and subsequent incorporation into best practice guidelines. As with the development of TB, there was a major role for invention outside the sector, this time from developmental settings. As with TB tests the role of the WHO in approving the SMC protocol was essential. Implementation in humanitarian contexts, again here led by MSF, was critical for demonstrating SMC’s efficacy in emergency settings.

As with disease diagnostics, however, there are numerous counter-examples of innovation in prevention not working as might be hoped. Perhaps the most stark example in recent years, Ebola aside, was the 2010 cholera outbreak in Haiti. The first in that country’s recorded history, what has since become the worst country-specific epidemic in modern times has been traced to inadequate sewage facilities around a UN peacekeepers encampment. By the end of 2013, the outbreak resulted in over 8,500 deaths and 700,000 illnesses.³²

The outbreak highlighted major flaws in the basic delivery of humanitarian health assistance. Following the earthquake in January of 2010, Haiti was the focus of massive aid flows, and became the base of operations for almost 12,000 separate NGO operations. Despite Haiti being widely described as a watershed for technology innovations - including the development of new digital mapping technologies, mobile communications and population survey techniques – very few of these were successfully integrated into formal efforts to prevent and limit the outbreak.

This was not for want of trying however. A number of tools such as Ushahidi had been propelled to fame as a result of Haiti, and there were efforts to generate necessary information as the epidemic emerged and unfolded. A subsequent study led by Harvard University public health scholars found that social media approaches did indeed generate data that would have allowed for quick detection and response to the cholera outbreak.³³ The study found that social media platforms were faster than, and at least as accurate as official records in terms of detecting the start and early progress of the epidemic. Using an automated surveillance platform, HealthMap, the researchers found that informal reports were available online up to two weeks before official reports, which meant they could have been used to get earlier estimates of disease outbreaks and response planning. The tools were also cost-effective, fast and gave greater detail of population dynamics.

However, these tools were not seen as fitting in well to the traditional ‘chain of command’ approach that characterizes public health information. The Harvard team found that insufficient work was done by aid agencies to integrate data from new and innovative platforms

³¹ WHO et al (2013) Malaria control in humanitarian emergencies – An inter-agency field handbook. Second edition

³² UN (2014) UK Fact Sheet: Combating Cholera in Haiti

³³ Chunara, R et al (2012) Social and News Media Enable Estimation of Epidemiological Patterns Early in the 2010 Haitian Cholera Outbreak Am J Trop Med Hyg vol. 86 no. 1 39-45

with official data sources.³⁴ In effect, the tools that were available were not the focus of sufficient search, development or testing by aid agencies, and were not implemented in the ways that they might have been. As a result, the response was slower and less effective than it might have been.

The disease innovation ecosystem, which worked in very clear and tightly defined ways in relation to TB tests and SMC-based prevention, was more fractured in Haiti, just as with the Ebola response. What is interesting is that both of these cases demanded innovations to be developed in response to specific crisis situations, and with humanitarian agencies themselves playing a leading role in developing and implementing new approaches in real-time. This is clearly more difficult than more strategic innovation approaches, as were found in TB and malaria, which anticipated specific disease-related situations, and planned for the implementation of specific innovations. In such settings, humanitarian actors' are able to focus on working to test and prove the relevance of new approaches, and subsequently advocate for their wider dissemination. In the acute emergencies, however, the constraints of real-time responses may limit effective innovation. This highlights the fact that ecosystem is not actually set up in a strategic manner so as to meet the specific challenges of humanitarian responses.

It is important to note, of course, that the failures of aid in Haiti were about far more than imperfections or misalignments in the innovation ecosystem. The cholera outbreak was as much a failure of basic delivery, both by the aid community and the Haitian government, as a result of which, "*cholera is likely to become endemic in Haiti*"³⁵. Although there were many measures for sanitation that should have been implemented following the earthquake, many of these were not in place, allowing the rapid escalation of the cholera outbreak. Prevention measures such as chlorinated water distribution and waste management were scaled up far too slowly, and treatment measures such as oral rehydration were in short supply. Much of the prevention activities were concentrated in the urban centre of Port-au-Prince, allowing cholera to flourish in rural areas. Some experts have subsequently accused major aid organisations as fundraising for health efforts in a self-interested manner, without the capacity or know-how to carry out basic measures in public health in response to the outbreak. The failures of innovation must therefore be positioned and understood in the context of these broader problems.

Surveillance: Successful Mobile Early Warning, But Where's The Dissemination?

Surveillance is the systematic collection, analysis, and interpretation of deaths, injuries, and illnesses that enable public health agencies to track and identify any adverse health effects in the community. Activities in disease surveillance area involve the set up or strengthening of a range of mechanisms to ensure the early reporting of disease cases and the monitoring of disease trends, so as to facilitate prompt detection and response to outbreaks. During a disaster, it is important to conduct surveillance to determine the extent and scope of the health effects on the affected populations. It allows humanitarian agencies to assess the human health

³⁴ Ibid

³⁵ Farmer P, Almazor CP, Bahnsen ET, Barry D, Bazile J, et al. (2011) Meeting Cholera's Challenge to Haiti and the World: A Joint Statement on Cholera Prevention and Care. PLoS Negl Trop Dis 5(5): e1145.

impacts of a disaster and evaluate potential problems related to planning and prevention.

One ongoing and tested innovation in this area is the collaboration between the World Health Organization and the Philippines Department of Health in 2010, to develop a mobile-technology based early warning disease surveillance systems for post-disaster situations.³⁶ This approach, called SPEED, has subsequently been deployed in every major emergency to hit that country.

The Philippines is located in a region that is highly vulnerable to typhoons and earthquakes, and has been described as the most disaster-prone country in the world. Despite the devastating effects of calamities, there is no efficient and fast health information tool in the country to track and monitor the casualties of disasters, and their health status. During a particularly devastating series of typhoons in 2009, lack of reliable data and information systems compromised the affected communities in terms of prevention, health reporting and response. This situation saw a turning point in in 2009, in response to Typhoon Ketsana. This was the most devastating typhoon ever to hit the capital city of Manila and resulted in the largest ever leptospirosis outbreaks anywhere in the world.³⁷

Subsequently, the Global Outbreak Alert Response Network of the WHO identified the need for an effective monitoring system for early detection of unusual increases in major public health events during emergencies in Philippines. The World Health Organization, in collaboration with the Philippine Department of Health, USAID, AusAid and the government of Finland worked to create the Surveillance in Post Extreme Emergencies and Disasters (or SPEED) tool for infectious disease preparedness and response.³⁸

The basic principle of SPEED is the use of web-based software technology to receive data via SMS from all parts of the country. This data can be aggregated and used at different levels and different regions. The frontline component of the Philippines disaster response structures are local disaster evaluation areas, and health workers operating in these areas play a critical role in populating SPEED with data. SPEED reporting forms, loaded onto mobile phones and tables, enable the capture of essential information during consultations with members of affected communities. The system is set up to undertake surveillance and monitoring of 21 identified disease entities or health events that are common in emergencies or disasters.³⁹

The surveillance information gathered in the reporting form is the entered into the SPEED system using mobile SMS messaging. All the information is stored in the national SPEED server, allowing aggregated data to be viewed by and analysed by health managers, regional, and national decision-makers. The system allows online data validation and automatic generation of necessary reports. This enables the rapid transmission of a range of syndromic disease information from local evacuation centers to national levels of the health system. The system allows online data validation and automatic generation of necessary reports. Users can also create graphs, spread-sheets and maps to support early warning and decision-making about

³⁶Surveillance in Post Extreme Emergencies and Disasters (SPEED) (2014) Website:

http://www.wpro.who.int/philippines/areas/emergencies_disasters/speed/en/

³⁷ Amilasan AT, Ujiie M, Suzuki M, Salva E, Belo MCP, Koizumi N, et al. Outbreak of leptospirosis after flood, the Philippines, 2009. (2012) Emerg Infect Dis Volume 18, Number 1—January 2012

³⁸ SPEED Brochure (2011) SPEED Brochure, WHO and Philippines Department of Health - Health Emergency Management Staff

³⁹ Health Emergency Management Staff, DOH and WHO Philippines (2011) SPEED Operational Manual for Managers

possible disease outbreaks and feasible responses. The system also has a built-in capacity to alert users if certain diseases go beyond specific epidemic thresholds.

Since 2010, SPEED has been used in a number of disasters, including after Typhoons Quiel, Washin, Haiyan and Ruby. The largest single deployment was after Typhoon Haiyan in 2013, which led to serious concern about possible disease outbreaks. Aid resources were directed to the Department of Health to enhance emergency disease surveillance systems, including resources for deploying SPEED.

For the initial four months of the Haiyan response, SPEED was implemented in 411 health facilities in the affected areas. Over 300 staff were trained in the use of SPEED by the WHO, UNICEF, IMC and others; and over 340,000 consultations were reported, generating approximately 3000 SPEED early warning signals. Every single one of these signals led to responses to prevent possible outbreaks, ranging from specific health treatments, stockpiling of drugs and advocacy efforts.

In 2012, SPEED won a national award as one of the *"best examples of the highest level of innovation in the country's health marketplace."*⁴⁰ The award, funded by the Rockefeller Foundation, called SPEED *trailblazing* as one of the first early warning disease surveillance systems that has genuine nationwide coverage. As the Philippine government states:

*"...The aim of the system was to determine early and potential disease outbreaks and monitor disease trends. It has contributed immensely in reducing preventable deaths and diseases by enabling timely and appropriate response by local government officials..."*⁴¹

The counter-example for surveillance is not failed innovation process, but instead the lack of *dissemination* of the SPEED approach across countries. This does need to be qualified: SPEED *has* been scaled up nationally at the behest of the WHO and the government, and has been deployed in multiple emergencies, which is clearly an example of scaling. However, it has not been directly disseminated to any other countries. The independent review of SPEED conducted for Ausaid found that it was: *"very relevant to other countries and international agencies. While such a comprehensive effort would probably not be successful in countries with relatively low human and capital resources, there are many countries where it could be a viable model. Even in low-resource countries, the technique of SMS-based health reporting deserves consideration."*⁴²

What would have been needed for such dissemination? The humanitarian innovation ecosystem would need to have some means by which to take the protocols of SPEED and apply them to other equivalent settings, along with some of the critical lessons learned in the Philippines. The reality, however, is that the ecosystem has few incentives or capacities for doing such work without additional support. Expecting this may be a little like asking an emergency responder to help reform building standards codes. A small thought experiment is instructive here: had SPEED been developed solely by the humanitarian sector, one can easily

⁴⁰ St James Aquino, Y (2012) Disaster surveillance system wins award for health innovation, US Medical Tribune,

⁴¹ Ausaid (2013) Post-Disaster Surveillance in the Philippines: An External Review

⁴² *ibid*

imagine that SPEED would have been deployed once and then forgotten by the next emergency.

In the SPEED case, as with the previous positive ones, there was a central importance of actors outside the humanitarian sector – private sector, national governments, local governments, community-based organisations and national health providers – in helping to join the dots in the humanitarian innovation ecosystem. Were it not for these external actors, the system would not have been the success it has proved to be.

Outbreak control: Great for Polio, What about Ebola?

Outbreak control efforts ensure that new disease events are rapidly detected and managed through adequate preparedness (i.e. medical stockpiles, standard treatment protocols and staff training) and rapid responses (i.e. confirmation, investigation and implementation of control measures). Here the positive example is of the Syria polio response, and the use of an innovative new outbreak control mechanisms, in comparison to the relative weakness of the Ebola outbreak control effort.

An important innovation in outbreak control has been deployed successfully in Syria in the past two years, in response to the re-emergence of polio after the conflict that has wracked the country since 2012. Polio eradication is the focus of a global campaign launched by the WHO in 1988, led by a partnership between a number of national governments, WHO, UNICEF, CDC and the NGO Rotary International. Since 1988, thanks to the efforts of the campaign, the incidence of polio has been reduced by more than 99%. From being endemic in more than 125 endemic countries, today only four countries remain that have never stopped endemic transmission of polio: Afghanistan, India, Nigeria and Pakistan.⁴³

For many of the successful countries, the eradication approach was based on vaccine-based treatments for children, with the vaccine used in 2 rounds over a period of 4-6 weeks. This time gap between rounds was necessary because the initial vaccine combined three different variations of polio virus (known as trivalent and the large gap between doses minimised the potential of negative interference between these three virus types while in the gut of vaccinated children.

In 2005, a new single virus vaccine (known as monovalent) was found to be effective in many cases, without running the same risks of viral interference. Because of this new vaccine, the time between doses could be reduced to 1-2 weeks, and population immunity can be built up more rapidly. This is of particular importance when there are new outbreaks, in emergency settings where it is necessary to achieve a high level of immunity in a short time, or in situations where security and access means that the population is difficult to reach and immunization cannot take place in a predictable and regular fashion. This new approach was called the short interval additional dose approach, or SIAD for short.⁴⁴

The programmatic benefits of SIADs were first established in its successful application in Somalia in 2006. Somalia had managed to eradicate polio in 2002, but it became re-infected in

⁴³ Global Polio Eradication Initiative (2015) Website: <http://www.polioeradication.org/Polioandprevention.aspx>

⁴⁴ Global Polio Eradication Initiative (2010) The Short Interval Additional Dose (SIAD) - An intensified campaign approach to deliver monovalent Oral Polio Vaccine (mOPV) Implementation Guide

2005 by polio originating in Nigeria. The campaign was severely constrained by ongoing and entrenched conflict across the country, which was regularly ranked as the most dangerous and insecure country in the world.

Thanks to the work of a team of national volunteers and health workers who visited every household in every settlement multiple times, 1.8 million children under 5 were vaccinated. The WHO, in announcing the eradication of polio in Somalia, stated that it was enabled in large part because of the innovation of SIAD, which meant that infants in insecure areas could be immunized multiple times in a short time period.⁴⁵

The success in Somalia led to the SIAD approach being established as a core eradication strategy in those countries still subject to Polio outbreaks. However, while the strategy was persuasive from an operational perspective, the scientific basis was not well established. The Polio Research Committee approved a clinical trial in Egypt in 2010, and Pakistan in 2012, to assess the efficacy of SIAD. These trials have shown that population immunity could be more rapidly enhanced through SIAD.⁴⁶

The positive outcomes of these trials informed subsequent decisions to roll out SIAD in Syria, where the ongoing conflict saw a polio outbreak in October 2013, the first in the country for over 14 years. Eventually reaching dozens of cases, and spreading across the border to Iraq, the outbreak was referred to by the UN as the most challenging outbreak in the history of polio eradication. Access restrictions and a highly mobile population were compounded by the challenges of high insecurity inside Syria and damaged health infrastructures. The initial UNICEF-WHO strategy for responding to polio in Syria included SIAD as an innovative vaccine delivery approach that should be applied in Syria and the surrounding countries. The strategy highlighted the need for multiple doses in short time periods, the mobilization of community resources (as in Somalia), effective communication messages about the SIAD approach to share with communities, and negotiated access to hard-to-reach populations.⁴⁷ This was launched in December 2013 as the largest ever vaccination campaign in the Middle East, with plans to reach 25 million children across seven countries in the region, with more than 2 million inside Syria. At the time of finalizing this report, the WHO announced that there had been no new cases in Syria for a year, in large part because of the success of the SIAD strategy.

The response also saw a unique event in August 2014, where a number of operational health agencies convened a regional forum during the ongoing response to review innovative strategies for limiting the transmission of polio. This was led by WHO, and brought together officials across multiple agencies and countries, specifically to deal with the outbreak that had been declared a public health emergency of international concern. A key theme of the meeting deliberations was the use of existing innovations in mapping, surveillance, and control measures, with a particular focus on new medical and communication technologies.

The best counter-example to the success of SIAD is to be found in the Ebola response. Good outbreak control means an effective package of interventions, from case management surveillance, treatments, and social mobilization. All of these were apparent in the Syria polio

⁴⁵ WHO (2012) Somalia Polio Eradication Initiative Website <http://www.emro.who.int/polio/countries/somalia.html>

⁴⁶ Global Polio Eradication Initiative (2010) Evaluating SIAD, The Polio Pipeline, Winter 2010, Issue 5

⁴⁷ WHO-UNICEF (2013) WHO/UNICEF Strategic plan for polio outbreak response

effort. However, almost none of these were present in Ebola, meaning that Ebola outbreak control was always going to be weaker than for polio. However, there were particular failures inherent to the relative novelty of the disease and its emergence in urban settings for the first time that highlighted the challenge of innovation in outbreak control. The information [resented below is based on the state of play in the Ebola response at the time of writing (November 2014-Januray 2015).

The key focus of the Ebola outbreak control was on reducing human transmission, and focused on risk reduction messaging for affected country populations. This focused on factors such as reducing possible new infections from wildlife-to-human transmission, reduced human-to-human transmission through hygiene and protective equipment, containment measures such as safe and prompt burials of the dead, contact tracing and containment of sick individuals in quarantine. There was also a set of challenges around controlling outbreaks in healthcare settings through adequate precautions, from hygiene to protective gear. In many cases, however, these strategies promoted by the international community have not been targeted in a strategic fashion.

As an MSF briefing published in December 2014 noted, the outbreak control efforts by the international community were "*sluggish and patchy, falling dangerously short of expectations.*"⁴⁸ While there were multiple issues around staffing, facilities, and so on, a particular challenge highlighted was the widespread inadequacy of international actors to flexibly respond to changing circumstances with appropriate and relevant strategies. As a result, "*resources are being allocated to activities that are no longer appropriate to the situation*".⁴⁹ This finding can be seen as closely linked to the operational innovation capacity of the sector as a whole.

Disease management: technology for incremental change, facing resistance to radical improvements

Disease management involves the diagnosis and treatment of cases promptly with trained staff using effective treatment and standard protocols at all health facilities.

As already noted, in 2013 in Haiti, the response to the cholera outbreak of 2010 led to a number of technological innovations in the response. One in particular which did lead to a positive contribution to the disease response was led by the NGO Partners in Health and a number of local organisations, in collaboration with medical researchers. It involved the deployment of a mobile technology based health system for management of treatments for 50,000 participants in two communities. The system was deployed as part of a reactive oral cholera vaccination (OCV) campaign during the ongoing epidemic.⁵⁰

The core of the mobile health innovation was a tablet computer based information management

⁴⁸ MSF (2014) Ebola Response: Where Are We Now? MSF Briefing Paper

⁴⁹ *ibid*

⁵⁰ Teng, JE et al (2014) Using Mobile Health (mHealth) and geospatial mapping technology in a mass campaign for reactive oral cholera vaccination in rural Haiti. PLoS Negl Trop Dis. 2014 Jul 31;8(7)

system combined with geospatial mapping technology. With software developed for use on 7-inch tablets that could be easily deployed to the field, the operational teams pre-registered participants and distributed vaccine cards with unique barcodes to treatment-eligible residents during a census in February 2012.

First stored on the mobile devices, the data was uploaded nightly via Wi-fi to a web-hosted database. During the treatment campaign between April and June 2012, residents presented their cards at vaccination posts and their barcodes were scanned. Patient data from the census were pre-loaded on tablets to auto-populate the electronic form. Nightly analysis of the day's community coverage informed the following day's treatment strategy, and generated case-finding reports allowing identification of those who not yet vaccinated.

During 40 days of the programme, the team collected approximately 1.9 million pieces of data. A total of 45,417 people received at least one OCV dose; of those, 90.8% were documented to have received 2 doses.⁵¹

Although the platform required up-front financial investment and training, it reduced the need for paper registries and manual data entry, which would have been costly, time-consuming, and was known to increase error. Using Global Positioning System coordinates, the team was able to map treatment posts, and link these to population size, and subsequently vaccine coverage to understand the reach of the campaign.

A follow-on study showed that the use of mobile health technology in the OCV campaign allowed timely creation of an electronic registry with population-level census data, and a targeted treatment strategy in a dispersed population. It was concluded that the use of mobile health should be strongly considered in cholera treatment campaigns in future initiatives.⁵²

This particular innovation is noteworthy because it is a process innovation, which sought to enhance the effectiveness of an existing protocol. Such innovations can, it would appear, be effectively managed within the humanitarian innovation ecosystem.

What the system does do well is incremental innovations, which are no major challenge to practices or assumptions. However, more radical approaches to treatment are not always easily accepted. This of course needs to be understood in context: incremental and radical innovations are both necessary. But at the moment, there seems to be less support and scope for more radical, game-changing innovation efforts. Some of the barriers are professional or institutional. There are historical examples of radical innovations in treatment being resisted by the sector, often on the basis of existing medical knowledge and practice. For example, in the 1980s, the rise of TB cases in refugee camps was seen as problematic, but existing knowledge suggested that TB treatments should not be contemplated in such inherently unstable situations. As one researcher notes, "*it took several bold individuals and several controlled trials to establish beyond doubt that TB could be treated in refugee settings, even in rather unstable conditions. These previously controversial practices are now accepted*".⁵³

⁵¹ *ibid*

⁵² *ibid*

⁵³ Coninx, R (2007) Tuberculosis in complex emergencies, Bulletin of the World Health Organization, Volume 85, Number 8, August 2007, 569-648

Some three decades on, there is still some reticence for utilizing TB treatments in emergencies: treatment can take up to 6 months, and require meeting WHO criteria that is often impossible in post-disaster settings. The SPHERE project found that that poorly implemented TB programmes are widespread in humanitarian settings, and suggested that suboptimal programmes, which deliver fewer than 6 months of treatment, have the potential to do more harm than good.⁵⁴

A more recent example of the same phenomenon is the slow take up of the antiretroviral drugs in emergency settings. Up until relatively recently, populations affected by emergencies were seen as *"neglected in the provision of essential HIV/AIDS prevention, treatment and care services, in particular, in the delivery of life-saving antiretroviral drugs (ARVs) for prevention and treatment of HIV infections"*.⁵⁵

In particular, there were four key areas of challenges that needed to be overcome for facilitating delivery of ARVs in emergencies. The first set of issues was around communication, with regular channels typically disrupted by emergency events. For complex treatments such as ARVs, which involve elaborate appointments, prescriptions and medication schedules, and good communication between clinics and other facilities, the lack of effective communication channels is a major impediment. Access to care is also a major challenge, in settings where health facilities and pharmacies may be destroyed or impossible to access. The capacity of health systems, in terms of human resources and infrastructure, is also often diminished or limited by emergencies. This can lead to challenges in terms of being seen by health workers with sufficient knowledge of ARV treatments, and also more fundamental issues such as an inability to maintain complex patient records. Healthcare capacity is also under strain during emergencies, with more obvious and immediate health challenges taking priority for those managing overwhelming case loads. Fourth, there are issues around the disruption of supply chains of medications and other essential goods involved in patient care. This is especially challenging for medications like ARVs that require steady temperature control or refrigeration. Rational distribution of supplies is made problematic by unpredictable shifts in demand and limited communications.

The shift started to happen around twelve years ago, with more organisations suggesting that there were means by which these challenges could be overcome. As with TB, the complex regimes associated with antiretroviral treatment was seen as impossible in emergency settings. Feasibility studies showed ARV delivery was possible and affordable in low-income settings. The price of the drugs, which fell some 99% between 1999 and 2007 thanks to ramping up of production in India and Brazil was also beneficial – and the result of active campaigning by international NGOs. But the treatment was still not delivered as a matter of course. The 2006 roundtable set out a consensus on a number of aspects of ARV delivery in emergencies, including minimum requirements for delivery, the services needed for such delivery to be effective, and the need to address particular groups, including pregnant mothers, survivors of sexual violence and exposed health workers. A special emphasis was placed on procurement systems for ARV drugs in emergencies, and management systems to prevent waste. The

⁵⁴ The Sphere Project (2004) *Humanitarian charter and minimum standards in disaster response*

⁵⁵ Inter-Agency Forum Consensus Statement (2006) *Delivering Antiretroviral Drugs In Emergencies: Neglected But Feasible*

meeting concluded that that provision of such service was “*an inalienable human right and a public health necessity*”.⁵⁶

The formal statement by the meeting framed the need for ARVs in emergencies in terms of the global challenge: that international targets for HIV-AIDS reduction would not be achieved if populations in emergency settings continue to be excluded from such treatments.

Almost ten years on from this statement, there are still major challenges to overcome in the delivery of ARVs in emergencies. According to one account, although there has been a rise in the numbers of people treated with ARVs in low and middle income countries, only a third of all patients who need treatments receive it, and many of those who don't live in countries that are most affected by natural and complex emergencies. Moreover, the toxicity and limited efficacy of ARVs has meant that they have been largely abandoned in developed countries.

Findings

Findings on the innovation ecosystem in humanitarian communicable disease responses

This section draws out some of the emerging findings on the nature and condition of the innovation ecosystem in infectious disease responses.

Resources – financial: Although there are significant financial resources for disease R&D outside the humanitarian sector, resources in the sector tends to be reactive and short-lived

There are significant financial resources available for R&D in infectious diseases, few of these are directly targeted at humanitarian work. The large majority of the available funds are not accessible by humanitarian organisations, but are instead made available for actors outside of the sector to develop of new diagnostics, protocols, drugs and treatments. There has been a veritable explosion in funding for health innovations in the past 15 years. Humanitarian disease innovations have certainly benefited from this, albeit in an indirect fashion. The work of initiatives external to the sector, such as GAVI, Meningitis Vaccine Project and FIND, have led to considerable improvements in disease-related products and processes, some of which the humanitarian sector has been able successfully to incorporate into their humanitarian health interventions. At later stages, the work of UNITAID in supporting and subsidizing new products has proved invaluable in terms of enhancing access to new health innovations. Although it is a very different market intervention, the role of Indian pharmaceutical firms in generating low-cost products such as meningitis vaccines to ARVs – has also been integral.

While humanitarian organisations may not be directly involved in such R&D processes, can play an important role in moving such processes through the ecosystem. So, in this case, the role of

⁵⁶ Inter-Agency Forum Consensus Statement (2006) Delivering Antiretroviral Drugs In Emergencies: Neglected But Feasible

MSF advocacy in highlighting the meningitis crisis in the 1990s was essential in generating concern and mobilising motivation and commitment. The WHO played a convening role, and also mobilised the relevant networks. PATH, although not strictly a humanitarian NGO, played a central role in developing the partnership which led to the new cheap vaccine. And the programme in Chad was implemented by a number of organisations, including MSF. This is a good example of the humanitarian system working in parallel with other systems, and innovation capacities and skills being mobilized in a dynamic fashion.

However, resources specifically to support humanitarians involved in the processes of raising levels of concern, identifying new solutions, testing them, or undertaking trials are not available in a consistent fashion. Many of the humanitarian organisations involved heavily in such work fund the effort through their own internal funds, or through specific mechanisms such as the Wellcome Trust. Within the humanitarian sector, there are source of finance such as the Global Innovation Fund, the Humanitarian Innovation Fund, as well as dedicated funds made available by donors such as DFID, Wellcome and others. R2HC, managed by ELHRA, is a means of supporting research – although there is not a focus on innovation per se. However, the funds available are seldom sufficient on their own to motivate the engagement of private sector actors up-front, nor are humanitarian actors necessarily especially well positioned for brokering such partnerships. As such, these funds have tended to support the more incremental innovations in process and technology that can be managed within humanitarian organisations themselves. Larger-scale funding for humanitarian disease innovations tends to spike after a specific emergency – such as cholera in Haiti or Ebola - and then fade away in quiet times, in common with funding for epidemic responses more generally.

As the Ebola case illustrates, there has been considerable mobilisation of resources for the Ebola response, covering everything from a rapid assessment protocol, funded by ELRHA; patient management systems being developed by LSHTM, and drug treatments being developed by a variety of global consortia. While this may of course seem sensible and obvious as a response to crises, it also means that much innovation work is reactive rather than anticipatory. While this is common in other sectors, there are specific reasons why the humanitarian sector needs to become more anticipatory, which relate to the difficulties faced by innovation when responses are underway.

Resources – knowledge: Operational humanitarian knowledge is essential at all stages of the innovation process but it is not always well supported or integrated into innovation management efforts

Bringing new solutions into emergency settings requires humanitarian medical knowledge and expertise throughout the process – from raising concern, mobilizing commitment, searching for establishing partnership for new product development, developing clinical and management protocols, undertaking tests and trials, advocating for access and managing adoption.

However, there is insufficient support to the collection and mobilizing of this knowledge in ways that advance evidence-based humanitarian practice. This is perhaps best illustrated by the fact that concern is almost always driven by emerging crises and resulting challenges, with little ongoing capacity to analyse and respond to such needs between or across emergencies.

This is consistent with the lack of strategic research and weakness of evidence-based practices in the sector more generally. Research funding tends to be narrowly defined around specific technical gaps or challenges that can be delivered by the humanitarian system or highly responsive to a sudden explosive event associated with high levels of mortality. Again, as noted below, this is not unique to the humanitarian sector.

For the large part, the resources made available for furthering knowledge of infectious disease responses in humanitarian crises are for the enhancing the delivery of specific known treatments and protocols. Therefore, when there is funding for research it tends to be for the evaluation of programs to demonstrate their effectiveness. One could argue that such evaluations are less for learning, to improve what is done, and more for accountability, to demonstrate to donors and funders that resources were used effectively. While the two are not necessarily at odds with each other, the reality is that in humanitarian responses, the accountability requirement tends to overwhelm the learning element. This means, for example, that certain practices may be continued because of the accountability requirements, even if they are not particularly effective.

There is a general lack of operational research capacity that limits the testing of new ideas, although some also see new ideas as limited by the lack of imagination and creativity in the sector – and by the very low risk appetite. Many new ideas tend to come from the wider health innovation ecosystem, globally or nationally, and usually through the medium of specific individuals rather than institutionalized mechanisms. Where this is done well in other settings, this is because of *translational research* into the applicability of innovations – but this is not very well understood or applied in humanitarian contexts.

There is no reason why this should not be strengthened through targeted investments by donors. As Box 1 indicates, there is a good understanding of gaps in evidence, which may also serve a proxy for understanding where evidence-based innovations should be prioritized.

Box 1: Critical gaps in Humanitarian disease evidence base (LSHTM/ODI)

- The lack of standardised medical protocols and quality procedures in some areas, and the dominance of unproven or ineffective approaches in other areas
- The gaps in delivery approaches around particular disease, with hepatitis A&E, HIV-AIDS and measles singled out in particular
- The lack of specific measurement methods and indicators for rapid outbreaks (e.g. Ebola, cholera)
- The lack of evidence on how to best design and manage urban health responses
- The lack of approaches for dealing with highly mobile and fluid populations and the health challenges
- Lack of understanding of how best to respond to regional crises – including the West African Ebola crisis, and the regional polio outbreaks around Syria
- Lack of approaches for enhancing cultural / social sensitivity around programmes, especially around trust and acceptance

The work of the R2HC, a stable-mate programme of HIF managed by ELHRA, has started to make a contribution to addressing these gaps, but the programme is relatively small scale, and in the early stages. One promising development has been the mobilization of a specialized call

for research in response to the Ebola crisis, a number of which have focused on research around new and innovative approaches to analysis, modeling and managing community relations.

Routines: The routines and processes of humanitarian disease innovation is highly specialised, based on the particular needs of medical practices

As the flow diagram below illustrates, there are a number of features of humanitarian disease innovation processes that are specific to the sector. At the beginning of many of the processes looked at here, there is a degree of advocacy and outreach – initially this is be political in nature, and seek to convince others of the inadequacy of existing responses, or the possibilities of novel responses. This works to shift from levels of concern to building motivation and commitment for change. At this stage, there may be a process of internal invention process, especially for changes that are incremental in nature, which can be undertaken within humanitarian organisations themselves. However, there may equally be advocacy of external actors, such as private sector bodies, donors, and so on, to develop appropriate solutions. In some cases this outreach is less political and more technical, involving the search for possible solutions, and matching these to identified needs.

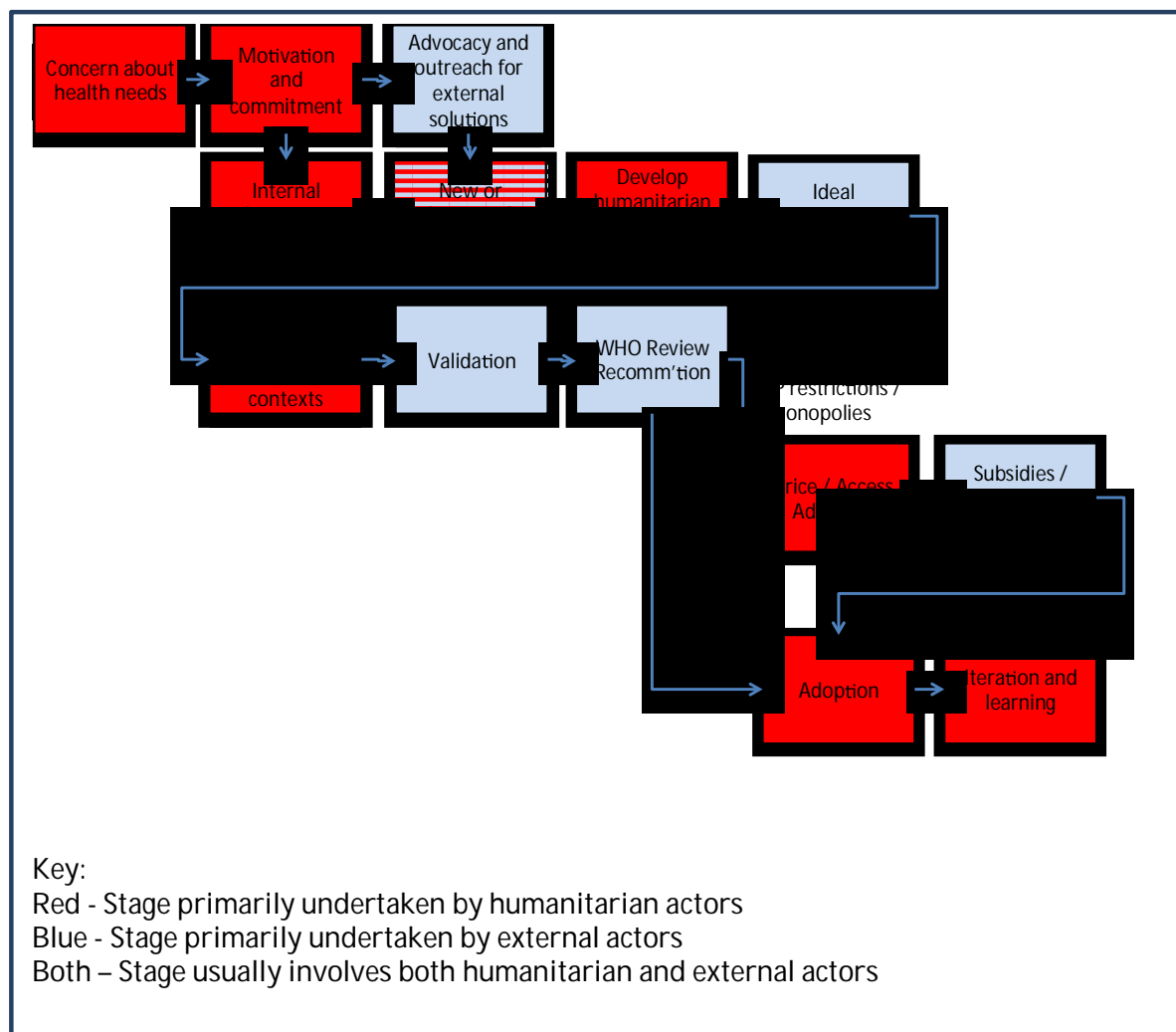


Figure 3: The humanitarian disease innovation process

Unlike a number of other sectors, perhaps most notably shelter, there does not appear to be a wealth of external solution providers clamouring to get new disease-related solutions into the sector. The reasons for relate more to the economics of medical innovation as any other factor, and - as the shelter sector illustrates well -there is no guarantee that a wealth of external ideas will actually generate solutions that are appropriate to humanitarian settings.

Having identified new or improved solutions, there is a need for this to then be reviewed from a perspective of both clinical and operational feasibility, and to develop appropriate protocols. This can often mean meeting existing standards of care that have been developed for specific diseases – and there is not always a guarantee that new solutions will pass this hurdle.

Following this, there is a strong emphasis on multiple trial stages of possible new solutions, usually undertaken in ideal and field operations, and for external validation of the same. This means that, as well as the political drivers of innovation, there is a strong need for evidence, especially in the middle of the innovation process.

After evidence is generated, and validated, there is then the ubiquitous stage of WHO assessment, which typically brings together multiple actors and experts to review the evidence and make a recommendation. Usually, when the evidence points strongly toward a particular approach, this recommendation process ends up being affirmative, but there may also be multiple iterations at this stage.

Depending on the nature of the solution, the recommendation may lead directly to dissemination and adoption of a given approach. However, depending on the IP regime that applies and the degree of monopolistic power around a given product, there may need to be further advocacy around prices or access based on humanitarian needs. This may lead to adjustments by IP holders directly to enable greater access, or there may be adjustments within markets, such as subsidies by governments or intergovernmental players, or the entry of new actors. In some cases, restrictions here can be a major brake on the innovation process.

The dissemination and adoption process is also not altogether straightforward – and there is a situation in the humanitarian sector where even effective, proven innovations do not become widespread. This is due to various issues around organisational culture and donor norms, but also around the capacity of implementing organisations to deliver new and perhaps sophisticated treatments.

Relationships: The humanitarian disease innovation ecosystem veers between being an innovation 'relay race' – where actors come together in dynamic ways, and innovation 'labyrinths' in which new ideas get hopelessly lost

The successful case studies looked at here can perhaps best described as a kind of *innovation relay race*, with different actors starting the race, taking the baton at particular stages and helping to progress things to the next stage. This is not a planned process on the whole, although there are some examples where the stages come together with a remarkable sense of serendipity. Nor could it always be said that the same actors are running the same race: not every actor involved in the humanitarian innovation process places equal weight on

humanitarian principles, for example. That said, there are clearly a number of roles that actors inside the sector, and those outside, play on a repeated basis.

- WHO is the standard setting organization, and is also the approver and flag bearer for new innovations. It has a crucial role in supporting innovations at a national and local level within emergencies.
- MSF in particular and NGOs more generally often find themselves in the position of raising the alarm on innovation: highlighting concerns and advocating for change, and working to push particular innovations through from one end of the process to the other.
- Academics and research institutes are clearly central in generating objective evidence, designing and running trials, and testing new approaches. These actors also have an important role in evaluation and learning around the effectiveness of existing approaches, and advocating for change in untested or ineffective methods. Operational organisations play an important complementary role in terms of enabling research access, and facilitating such evidence-gathering processes. Some – especially MSF – play a regular role in leading them, supported by researchers and academics.
- Private sector organisations are vital sources of technology and ideas, of R&D expertise and product development. They can help to identify new ways of solving problems, and have the incentives and know-how to crack specific challenges. They can be a tremendous force for good in innovation ecosystem, but they can also be fiercely protective of intellectual property in ways that run counter to the humanitarian imperative. Among the international aid community, the health NGO PATH is perhaps the most important player focused on supporting and enabling operational R&D for new disease innovations, many of which end up being of relevance for humanitarian operations
- Large scale delivery organisations, especially UN and NGO implementers such as UNICEF, WFP, UNHCR, MSF, Save the Children, Oxfam and others have a considerable influence on whether a particular innovation gets taken up, adopted and effectively disseminated across the network of partners. The credibility and normative role of the UN has a bearing on how open other actors will be to new approaches, and can also help to shift donor attitudes toward funding programmes based on new approaches.
- Donors fund existing operational programmes responses, provide tangible and symbolic support to new innovation processes, subsidise humanitarian purchasing of innovative products and solutions, and work together to fix ongoing market failures in the delivery of specific commodities or solutions. They also play a more strategic role, undertaking reviews of gaps and outstanding issues (both directly and indirectly through partners), and using these to direct attention and resources to specific innovation challenges.

Of course, there are many stages in the development of innovations in infectious disease responses, and the above is an account of how things work when innovations work well. When

things do not work so well, the roles of different actors are less like a relay race and more like a labyrinth: a confusing maze of dead ends and wrong turns that is both confused and confusing, and within which potential innovations get hopelessly lost. The labyrinth is characterised by competition and turf battles, and far too little genuine collaboration. Indeed, the lack of collaboration and openness between actors in the humanitarian health space was bemoaned by a number of interviewees as a major limiting factor in innovations.

Rules: The protocols and ethics of medical innovation place exceptional demands on, and driving motivations for, innovation processes

Innovations in medical areas are subject to some of the most complex and challenging protocols of any field. As well as obvious aspects such as medical ethics, and standards set by national governments, the WHO, and specific agencies, there are numerous process requirements that are associated with even routine changes to specific medical protocols. For example, when meningitis outbreaks in Niger were analysed to improve the vaccination programmes, it took 17 years worth of data and sustained, in-depth, analysis to challenge the WHO protocols from one vaccination to two.

There is also a need for evidence and trials and for solid epidemiological data to support the decision to try new approaches. The Ebola case illustrates all of these issues well. Initial expert calls to trial experimental drugs in response to the crisis proved to be incredibly divisive, with many actors calling such approaches as pragmatic, while others suggested that it seriously contravened medical ethics, and constituted potential abuse of disaster-affected communities. More recently, the use of experimental drugs by some NGOs, and the related death rates amongst patients, have led to staff walkouts, donor investigations and closures of facilities. This raised issues around consent for such efforts – whether it is possible, or whether asking for it is justifiable.

Because of the nature of medical practices and the professional, operational and ethical limits within which it must operate, innovations in disease response are arguably less amenable to improvisation and experimentation than other humanitarian sectors. Even the simplest of new ideas or approaches must undergo significant testing, research and development. This focus on medical ethics stands in stark contrast to the almost legitimized lack of regulation of the humanitarian sector as a whole.

Results: Results are essential for approval and dissemination, but can also limit the space for innovation

As noted above and earlier, there is a need for medical standards for evidence to be met when making the case for innovation. This means, for instance, detailed assessments/indicator-based analysis based on impact on mortality, morbidity, efficiency, cost-effectiveness. While this can be a barrier for many organisations attempting innovation but paradoxically current practices may not be subject to the same standards.

Results are essential for moving possible solutions through the development cycle. However, despite the resources required for such trials, there is no way of knowing what is being trialled

or tested, with no common database or information sharing platform of tests and trials underway.

Results are also essential to move solutions into widespread use, and require data and evidence to be published in peer reviewed journals and validated by independent assessment. These results usually need to be approved by WHO as the major standards setting agency in international health. Such approval is usually a precursor to widespread use by operational agencies. However, some solutions may be applied by specific organisations before such approval – in particular, MSF and UNICEF often play a trailblazing role.

Even when results are substantially in favour of new approaches, and innovations have been approved for use, new approaches can be deployed alongside earlier practices, even if the latter are known to be less effective. This highlights the operational conservatism in the sector, and the constraints of emergency settings.

It also raises the issue of lack of user/patient feedback and rights, and related advocacy efforts. In general, patient feedback on existing approaches, and patient roles in developing new innovations, is limited by the culture and modus operandi of the sector.

Findings about the system

The innovation systems model (figure 3 below) developed in support of the wider project to which this study belongs defines innovation as passing through several phases:

- Concern in the sector: as the result of, e.g., frequent severe events;
- People trying new ideas: as concern drives more people to look to address particular problems;
- Plausible inventions: as more people bring plausible formal or informal inventions from a variety of sources;
- Possible solutions in development: as plausible solutions are identified and effort is made to develop them;
- Solutions in widespread use: as practical solutions are made and widely propagated.

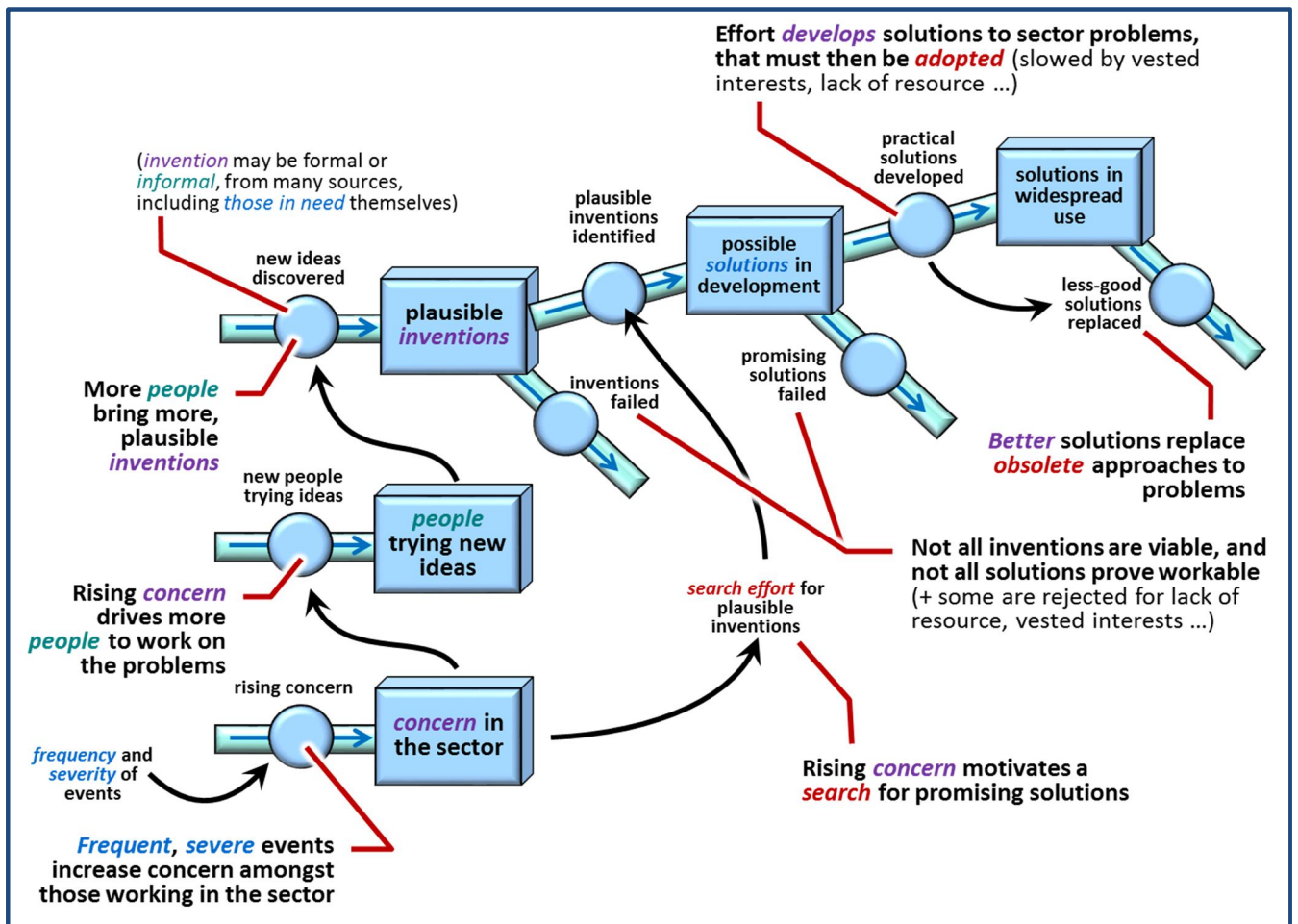
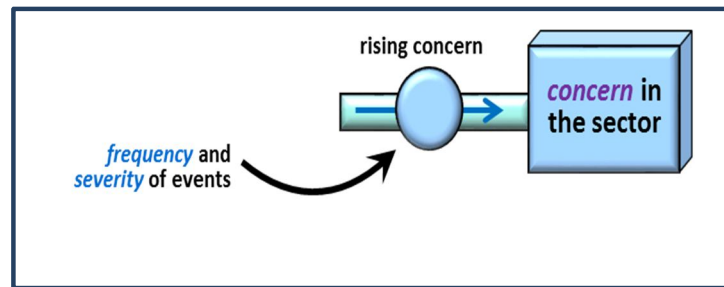


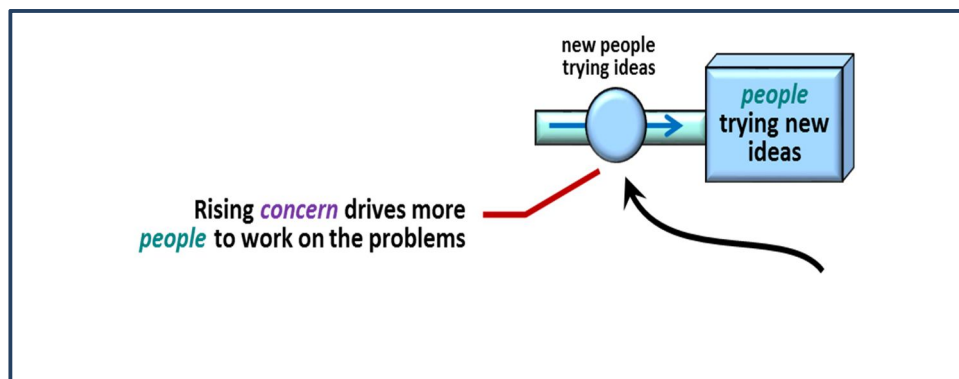
Figure 4: Humanitarian Innovation Ecosystem project - Systems Model

The following presents the main characteristics of the emergency disease innovation ecosystem at each of these stages. It also identifies factors that enable or inhibit the continuation of the innovation process along the system model.



Concern

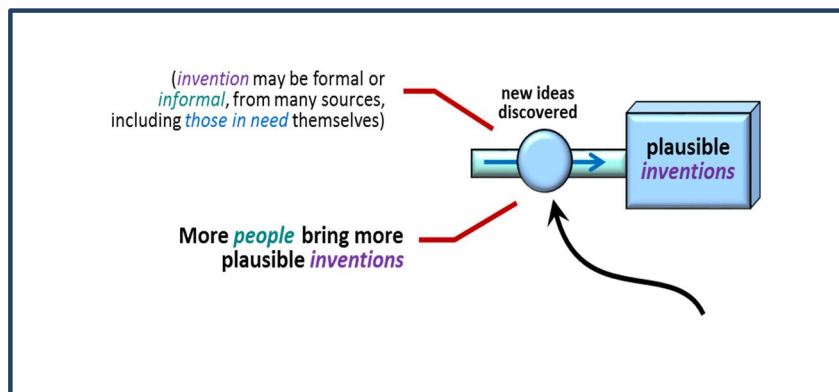
Concern is typically event-driven and shaped by new disease emergencies. This leads to a very scattergun approach, which increases after particular crises, but does not stay in the memory of policy makers or practitioners. Concern amongst humanitarian actors is seldom sufficient to trigger processes of innovation. Instead, where these happen, it is because the same problem is faced by other actors who have more capacity or resources to act.



Trying new ideas

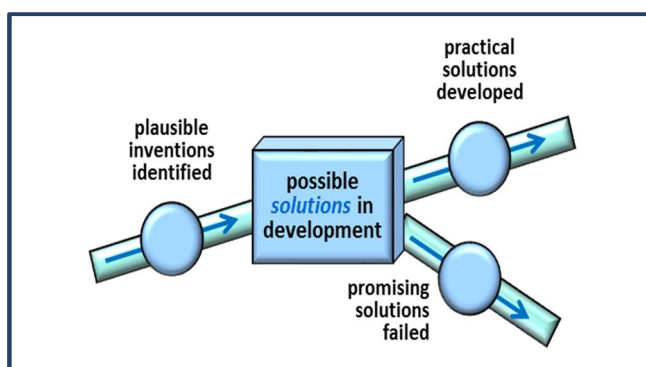
There are few actors in the humanitarian health space who consistently try to experiment with new ideas. There are a number of inhibitors to new ideas, specifically around the ethics of experimentation, and the need for good evidence before a new approach can be trialed. However, the general lack of evidence, for new or established practices, suggests that the real barrier is less about ethics and more about operational conservatism.

One obvious example is MSF, who have played an important role in a number of the innovation processes looked at here. Interestingly, a lot of MSF's role in trying new ideas has not been to invent whole new approaches, but rather to scan the horizon for new approaches and undertake translational research on their efficacy in emergency settings. This can be seen as a valid means by which to overcome the ethical barriers to innovation.



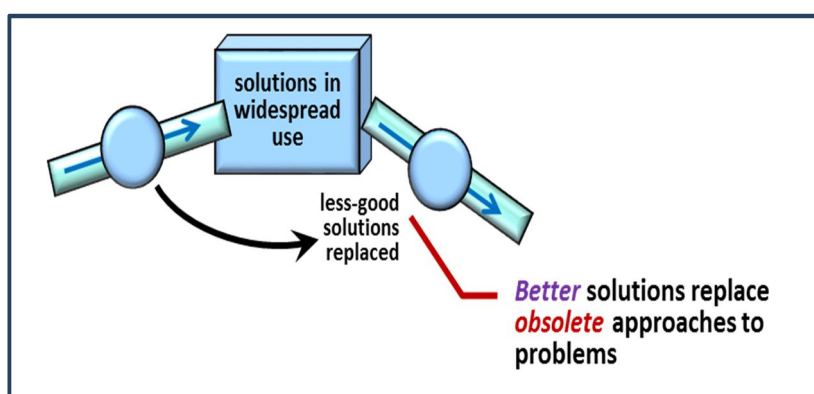
Plausible Inventions

For a disease related innovation to be viewed as a plausible approach, a key requirement is demonstration trials and some degree of pragmatic adaptation to emergency contexts. There needs to be some means by which the invention is shown to be of some relevance for emergency or similar settings, some means by which the idea can be demonstrated to be adaptable to the context of emergencies. Lack of such adaptation can mean that innovations that are plausible are never accepted as such, and do not therefore get formally applied in settings away from where they first emerged.



Possible Solutions in Development

There is a range of possible solutions in development at any one time, and a key requirement for these is the generation of evidence about their utility. This requires some investment in systematic evaluation against standards or protocols for disease management. This evidence almost always needs to be reviewed by the WHO before being approved for recommendation.



Solutions in Widespread use

Across emergency disease responses, there have been some very interesting examples of scale up and adoption, once the evidence is available. However, there is no mechanism in the sector to halt the use of the old protocols, with few approaches taken off the recommended list. As a result, old and new approaches co-exist, and whether a particular approach is used is more about the institutional history and capacity of a given humanitarian actor, and less about the efficacy of particular approaches.

Conclusions and Recommendations

This investigation into the innovation ecosystem in humanitarian health suggests that such a perspective is not especially widespread in the sector. Instead, as with the rest of the humanitarian sector, the focus has been on specific innovations processes and how they have managed to move through from invention into diffusion.

Although the humanitarian health innovation ecosystem is not *directly* comparable to national ecosystems, being more akin to the innovation ecosystem of a specific industry. But it is possible to draw comparisons between the two, and observe a number of features that are common to both. Both are often rudimentary and fragmented, both are largely based on capacities and investments of external actors, both must operate with limited and narrow capacities, both face limited connections between research, operations and delivery, and both are largely shaped by specific dominant actors. The most significant previous study of humanitarian health innovation suggests that much innovation largely based on a *trickle down* model of innovation from other contexts.

More specifically:

- The various elements in the innovation ecosystem remain disconnected, impeding the progress of innovation in the sector;
- The impediments may be as much about institutional barriers to change as the lack of resources or capacity;
- Humanitarian health has relatively little dedicated research and development capacity, and does not draw systematically upon the capacities for health innovation available outside the sector in the wider global health arena;
- Areas such as intellectual property management and regulation, production and operation standards, other social research are also very limited;
- There are scattered R&D-linked activities in different areas: the ecosystem can be characterised as a series of operational and policy networks working across a broken innovation *value chain*.

This said, there are times when the ecosystem can work very well, in tandem with external ecosystems and actors, in order to transform practices. A number of examples looked at here do exactly that. This then raises the question of what is missing from the humanitarian disease

innovation ecosystem. Based on the analysis here, the following elements seem to be especially important:

- A lack of a consistent platform for voicing concerns about humanitarian innovation needs, or an audience that wants to hear these concerns;
- A lack of sustained financing for humanitarian disease innovation processes, at all stages of the process;
- A lack of methods, protocols and systems for undertaking trials and a lack of information management and knowledge sharing systems;
- A lack of means or platforms for developing and supporting partnerships for innovation, and a lack of horizon scanning / search and discovery efforts to track the humanitarian relevance of new innovations in the wider global health space;
- A lack of keystone actors and networks that work to orchestrate and support the ecosystem and hold it together.

On the basis of the above, five recommendations are made below for how the disease innovation ecosystem might be strengthened.

- More support to *stronger innovation leadership*, enabling operational organisations to actively work to overcome political barriers to innovation through advocacy and influence work.
- More sustained resources for undertaking design in emergency settings, product horizon scanning, developing R&D partnerships, and evaluating approaches. A greater emphasis on translational research seeking to bring *parallel experiments* from global health into the humanitarian sector, and more emphasis on simulations to assess viability of new ideas.
- More support for undertaking early stage trials of viable methodologies in disaster settings or equivalent contexts. This will also involve establishing a common *clearinghouse* for ongoing trials and experiments.
- There needs to be more investment in inter-disciplinary partnerships and networks which work across the innovation cycle, bringing together a range of actors to solve each stage of the challenge in the most effective way. Ideally, these would be developed as neutral platforms where innovation can happen beyond the politics of the sector. Examples of joint ventures between competing firms might be a good example to follow.
- Support for a keystone/network role is urgently needed to ensure the *ecosystem* adds value at each stage, and to ensure that the parts are greater than the sum of the whole. One ambitious of doing this might be through establishing a *Global Alliance for Humanitarian Disease Innovation*– an international public-private partnership akin to platforms such as GAVI. This will help elevate humanitarian disease innovation to a global public good.

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