



The global need for effective antibiotics—A summary of plenary presentations[☆]

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ABSTRACT

To highlight the global need for effective antibiotics and explore possible concerted actions for change, cross-cutting plenary sessions served to frame the program of the conference. These sessions contained presentations on the present state of antibacterial resistance and the availability, the use and misuse of antibiotics. A number of possible actions were discussed, such as rational use of and access to antibiotics from various perspectives. The roles of vaccines and diagnostics were touched upon and followed by in depth discussions on supply-side bottlenecks with their scientific, regulatory and financial challenges. The value chain for research and development (R&D) of antibiotics has to be reengineered if we are to realize the development of much needed new antibiotics. This challenge will require a multitude of actions, some of which are related to changing the financial realities of antibiotics and interventions by global and regional institutions.

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1. Background

1.1. Setting the scene: the global picture of antibiotic resistance

The antibiotic era in clinical medicine was launched more than 70 years ago with the introduction of sulfonamides. However, the major breakthrough was the mass production of penicillin during the Second World War. Professor Otto Cars, chairman of Action on Antibiotic Resistance (ReAct), Sweden, underlined that the stunning success of penicillin which meant a drastic increase in survival from bacterial infections, clearly changed the world (Fletcher, 1984). However, there were already early warning signs of what was to come. As early as 1942, René Dubos predicted that bacterial resistance should be expected. “Rather than counter bacterial resistance with even more potent weapons”, he argued that we should, “seek instead more peaceful coexistence with pathogens” (Moberg, 1996). When Alexander Fleming (Fleming, 1945) received the Nobel Prize in 1945, he noted, “it is not difficult to make microbes resistant to penicillin”.

Resistance develops by spontaneous mutations or through horizontal transfer of resistance genes. In large bacterial populations

(e.g., the gut flora) small subpopulations of resistant bacteria will be selected and amplified by antibiotic treatment that kills susceptible bacteria. The selection process has been ongoing since the beginning of the antibiotic era and has contributed to an increasing gene pool of resistance in the commensal flora, in hospitals, in the community and in the general environment. Through indiscriminate use, ignorance and complacency, this valuable resource has been squandered and the consequences are now becoming increasingly apparent. Presently, at least 25,000 patients in Europe die per year because their bacterial infections are not treatable with available antibiotics (ECDC/EMEA, 2009). It is a fact that many advanced treatments that we today take for granted (e.g., cancer chemotherapy, care for preterm babies, transplantation and major surgery) cannot take place without the support of effective antibiotics.

The situation in developing and low-income areas is worrisome. Poverty, overcrowding, extremely poor housing, malnutrition, contaminated food and the lack of clean water create a basis for transmission of pathogens. In addition, healthcare systems are weak or non-existing in these environments, and antibiotics are often sold and used without medical consultation. As always, poor people suffer most in all respects, as so amply pointed out by Professor Zulfiqar Bhutta, Aga Khan University, Pakistan. Infections in infants, such as diarrhea and pneumonia, are the cause of 40% of the death toll in this age group in underprivileged areas. Diarrhea that is caused by Shigella, salmonella and cholera takes the lead and the resistance to antibiotics (such as ciprofloxacin) increases rapidly in those pathogens. Resistance data is not complete for the

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whole world, but the available information is cause for alarm and action. The increase of antimicrobial resistance worldwide is then an imperative challenge for those who want to improve health and quality of life for the inhabitants in all parts of the world. This will negatively influence the possibilities to attain the health-related Millennium Development Goals (MDGs).

1.2. Reflections from a global perspective

Dr. Guenaël Rodier, WHO Regional Office for Europe, emphasized that although there is a serious deficiency of global data on antimicrobial resistance, available information shows an alarming increase in resistance affecting all infectious agents. To take multidrug resistant tuberculosis (TB) as an example, globally 440,000 cases are estimated to have occurred in 2008 while a mere 7% of these were actually notified in the official WHO statistics. The malpractice of antibiotics can be characterized as overuse, underuse and wrong-use! Antimicrobial resistance spreads through health care associated infections, usually associated with weak healthcare systems. Dr. Rodier further noted the absence of global momentum, both in the action to improve rational use of antibiotics and infection control and in the development of new antibiotics. However, the main strategic components should be surveillance, prevention, containment, research and innovation. A coordinated global response is sorely needed in which “nobody is exempt from the problem or from playing a part in the solution”.

2. Policy challenges to optimizing the use of antibiotics

2.1. Reaching for global access and affordability

The currently biggest problem in low-income countries is the lack of knowledge and presence of misconceptions among the people. Dr. Eva Ombaka, senior consultant and former director of the Ecumenical Pharmaceutical Network, observed that there are some overlooked resources that can be used much more. For example, cell phones are widely available in these environments and there is some limited access to and use of the Internet, especially by the youth. These means can be much more and innovatively used, including using cell phones to pass correct/urgent information to isolated areas. A possible downside is that sick people may source and use unreliable health information from the Internet. A second aspect is the purchase and use of drugs from a “drug shop”, where drugs, including antibiotics, are generally freely available. However, the service providers are often not professionally trained and the drugs are of questionable quality-substandard or counterfeit! It remains that the public at large needs to be informed about use of drugs and mobilized to demand and practice better health behavior. For example, prescription drugs should be administered only on prescription, and the right of *any* medical doctor or other health worker to prescribe *any* existing drug should be questioned. Alliances will be necessary to bring about change.

2.2. Rational use: where less is more

Professor Roger Finch, University of Nottingham, UK stated that, for many types of major global infection, there is clearly a therapeutic failure because available treatments are not effective enough. Among these infections are TB, MRSA infections, hepatitis B and C, HIV and most diseases that exist in tropical areas. Better and faster diagnostics would be of great help in selecting most appropriate treatment and in reducing empirical prescribing. To improve disease management electronic support could be employed to improve the quality of prescribing and facilitating linkage of data from diagnostic tests, drug use and outcomes. The drugs presently available should be treated with great caution to preserve their

value and thus extend their useful life. Regulatory Authorities have a key role to play in ensuring that generic/off-label drugs have indications appropriate to current clinical needs. Concerted and sustained international collaboration is necessary to effect these changes.

2.3. Perspectives on rational use and access

Dr. Ramanan Laxminarayan, Director of the Global Antibiotic Resistance Partnership, USA, presented an economist's perspective on the actual challenges and found bacterial disease persisting as a major killer. The consumption of antibiotics increases globally in that there is, in addition to much restricted availability because of poverty, an increasing middle class of people who have economic means to buy what they think they need. Dr. Niyada Kiatying-Angsulee, Chulalongkorn University, Thailand emphasized perspectives on regional “network of network” from South East Asia involving the establishment of a national alliance, an institute surveillance system and the promotion of rational antibiotic use. Dr. Dana Hanson, World Medical Association, USA, discussed the commitment of physicians as expressed by the World Medical Association to progress based on professional skill and solidarity.

3. Global priority-setting for research and development to manage antibiotic resistance

3.1. Introduction

The session was opened by Professor Zulfiqar Bhutta who stressed the need for an action-based agenda that would take innovation to where it is needed most. The roles of vaccines, diagnostics and antibiotics in relation to bacterial resistance were discussed by Dr. John Clemens, International Vaccine Institute, South Korea, Professor Rosanna Peeling, London School of Hygiene and Tropical Medicine, UK and Dr. Andreas Hedding, ReAct, Sweden. They addressed the state of the current pipeline, identified gaps and included a forward-looking discussion about prioritization of these technologies and their respective and combined potential values.

It has become increasingly clear that antibiotic resistance is a multi-dimensional, complex problem, the roots of which span over many scientific areas and sectors of society. There will not be one magic bullet solution to resolve antibiotic resistance, but rather a variety of counter measures and actions targeting different aspects of the problem. Although antibiotics are by far not the ultimate solution to the problem of bacterial infections, they will be a mainstay in their management. Thus, the question is not whether we need new antibiotics – because we do – but by which mechanisms they should be developed to ensure that any new health technology or product is addressing a global need and that aspects of access and affordability are considered in the process. In addressing antibiotic resistance the targeting several areas is essential:

- Improved rational use (which in principle equals more restrictive use in both human and non-human sectors).
- Improved infection control/hospital hygiene.
- Development of novel antibiotics and complementary technologies (i.e., vaccines and new and/or improved diagnostic methods).

3.2. Pneumococcal vaccines

Strategies to manage antibiotic resistance require combined efforts using several available resources in the health system. Prevention of disease can be achieved through a number of measures, where vaccination stands out as a highly cost-effective intervention. *Streptococcus pneumoniae* is one significant pathogen in which

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