

Crisis of antibacterial resistance and integrated problem solving

1. Definition

Bacteria are microscopic living organisms that can be seen through a microscope of a magnitude of about 1000x. There are hundreds of thousands of bacteria species existing in humans, animals and other life forms in the environment, some being beneficial (preventive), others destructive (pathogenic, hence called "germs"). Names are given to important strains, such as E. Coli, Salmonella, and pneumococcus. They are classified as microbes.

Bacterial infections can cause illnesses, depending on types of bacteria and parts of the body infected, such as abscess, pus, encephalitis, septicemia, urinary tract infection, lung infection, bone infection, septic arthritis, typhoid, and cholera.

Antibacterials/antibiotics are powerful medications that remove bacteria from the human or animal body. They are used to treat bacterial infections if the bacteria are susceptible to such medications.

Antibacterial resistance refers to the situation when bacteria can resist a microbial or an antibiotic. It does not mean that the person or animal resists (does not respond to) the treatment when using such a medication.

Resistant bacteria are bacteria that can withstand (resist) or are not killed by antibacterial drugs hitherto efficacious resulting in the inability of such medications to treat the bacterial infections concerned.

One Health is a universal concept of multidisciplinary collaborative approaches to healthcare of humans-animals-environment designed to integrate prevention and control of diseases and other health hazards as well as holistic health promotion, recognizing that the health of humans and animals as well as balanced environment are inter-connected.

For more details, see NHA 8/Main 1/Annex 1.

2. Significance of the problem, situation and trend

2.1 Significance of the problem and danger of antibacterial resistance

Antibacterial resistance is a major threat to public health. According to WHO, an increased incidence of antibacterial resistance cases will eventually lead to a global dilemma in which antibiotics/antibacterials will not work in the treatment of bacterial infection, affecting health and economy as a whole. The situation can be summarized as follows:

On health: 1) Bacterial infections hitherto treatable will become untreatable. 2) Ability to treat several other illnesses will be reduced, including cancer and other diseases that have seen greater promises of treatment, such as organ transplant (e.g. liver transplant and bone marrow transplant). These diseases or treatments can lead to a higher incidence of infection in patients who are likely to die from the infection without effective antibiotics. 3) Drugs used to treat infections caused by resistant bacteria are often dangerous and immensely more expensive than those originally used. This can lead to a shortage of funds for treatment. And 4) this results in a greater rate of mortality or longer illnesses. Each year it is found that there are about 88,000 Thai people with infections related to antibacterial resistance; of this number 38,000 die. According to the statistics of Ramathibodi Hospital, patients with infections caused

resistant bacteria are 10-20 times more likely to die than those with non-resistant bacterial infections.

On economy, antibacterial resistance makes it more difficult to treat infections, resulting in higher medication bills and longer hospital stays. Overall healthcare spending increases as a result, not to mention other expenditure that comes with the patients' inability to work and care by their closed ones. It is estimated that Thailand suffers an economic loss from antibacterial resistance both directly and indirectly to the amount of six billion and 40 billion baht respectively.

It can be seen that health personnel and the general public are still not aware of the severity of the antibacterial resistance problem. As we are all part of the problem, it is necessary to recruit cooperation from all sectors to manage the situation, ranging from creating awareness to reducing an unnecessary and unreasonable use of antibiotics. Over the years the Ministry of Public Health, as a lead agency, has been trying to develop Thailand's strategy on antimicrobial resistance (2016-2018), but the process lacked adequate participation from the sectors concerned. In this regard, the National Health Assembly provides a participatory approach leading to the formulation of a national policy on the integrated management of antibacterial resistance and continuous action designed to stop and reduce the severity of the problem.

2.2 Situation and trend

The situation and trend of antibacterial resistance affect all livings on Earth. There is a saying that "we can no longer treat the problem and its solution in a fragmented manner. The lives of humans, animals, plants, and other living beings are inseparably connected" (One Health). This was testified in Resolution 8 of the 6th National Health Assembly in 2013 on multidisciplinary collaboration for "One Health" of human-animal-environment: the severity of the problem felt in every region of the world.

2.2.1 Antibacterial resistance crisis at international level

Antibacterial resistance is a problem found everywhere in the world. Resistant bacteria can travel across a region, country and continent as they go with humans, animals, and objects that move around. Therefore, a global cooperation is needed to tackle the issue.

Despite more than 20 years of warning about the dangerous situation of the "antibacterial resistance crisis" both internationally and in Thailand, the awareness and progress of the prevention and management of the problem have not gone as far as it should. As a result, the situation has worsened. Many countries have come up with strict policies and measures, including USA, UK and Australia, not to mention such international agencies as WHO¹. There have been reports on global surveillance of antimicrobial resistance, leading to the World Health Assembly passing a resolution in 2014-2015 and adopting the global action plan on antimicrobial resistance.

2.2.2 Antibacterial resistance crisis in Thailand

According to National Antibacterial Resistance Surveillance Center, Department of Medical Sciences, the antibacterial resistance rate has continually been on the rise and become more severe². The surveillance, however, was mainly confined to hospitals. A number of studies on surveillance of visitors to East Asia, South Asia, and Southeast Asia, find that more than half experienced greater antibacterial resistance than before their visits. Some even reported that tourists developed antibacterial resistance from Thailand.

Such information indicates that resistant bacteria or strains come from food. For instance, vancomycin-resistant enterococci (VRE) (resistance to the last kind of

antibacterial drug used for this bacterium) is found in frozen food and in humans. A study in Kanchanaburi province finds that more than 60% of healthy people have several drug-resisting bacterial strains that create drug-destroying enzymes. It is hypothesized that this may have something to do with what they eat. The inspection of 200 chicken samples sold in the supermarkets finds that more than 50% of E. Coli bacteria have genes related to antibacterial resistance in several medications and about 18% of Salmonella germs are resistant to many drugs as well.

2.2.3 Use of antibiotics/antibacterials in Thailand

Thailand is known to have used a huge number of antibacterial drugs. According to a 2011 report, the manufacturing and importation of antibacterial drugs was valued as high as 11 billion baht, greater than the value of drugs used to treat chronic diseases on a regular basis for a long time. For instance, drugs for coronary artery disease, central nervous system, and cancer are valued at 9.2, 9.0, and 7.9 billion baht respectively.

Most Thai people, at every level, still lack awareness of the situation. 1) Bacteria have an incredible ability to develop themselves in such a way they can withstand (resist) all kinds of man-made antibacterial drugs. More importantly, 2) antibiotics/antibacterials are used in humans and animals/plants too often unnecessarily and ineffectually both in hospitals as well as in the community, resulting in a certain number of resistant bacteria being retained, and 3) the public does not have sufficient knowledge and understanding and does not pay adequate attention to the issue, especially in the prevention of bacterial infections and disseminations, leading to more illnesses and greater use of antibiotics/antibacterials. 4) People do not pay adequate attention to the control of the spread of drug-resistant bacteria.

3. Analysis of the problem and stakeholder roles

Important stakeholders are the public, academic and people sectors at all levels, including the government, community, professionals (e.g. physicians, veterinarians, nurses, and agricultural technicians), patients, farmers and the general public. They all need to come together to solve the problem under the principle of "One Health" of human-animal-environment to ensure effective action.

The analysis of the problem and its management are done 1) outside the hospital surrounding involving humans and animals/ plants/ environment and 2) within the hospital.

3.1 About antibacterial drugs

Terms used: The use of the terms can be incorrect, not readily understood, or incorrectly communicated. This can give rise to misunderstanding. Antibacterial drugs are often called "antibiotics", a word difficult for the public to grasp its significance. It has been incorrectly used for a long time but people do not think too much about it. They are also called "anti-inflammation" drugs, misleading people to think that they treat various inflammatory symptoms, including skin inflammation, eye inflammation, arthritis, and throat infections, all of which can be caused by a host of factors. It is important, therefore, that the term should be correctly used.

Type and pharmacopeia: Thailand sees a number of antibacterials commercially available on the market, each with different pharmacopeia. For example, 250-mg amoxicillin is manufactured by over 60 pharmacopeias under different trade names. Antibacterial drugs come in many forms, formulae and indications, while the quality is far from satisfactory. As a result, misapplications are possible, making the treatment ineffective, causing antibacterial resistance in the process. The situation

needs urgent review and addressing. The lead organization taking on the task is Food and Drug Administration for which greater support and follow-up are also needed.

Places selling antibacterial drugs: There are many kinds and levels of antibacterial drugs, the situation requiring various levels of expertise and knowledge to deal with. It is only appropriate that they should be grouped under the prescription drug category, which only medical doctors or pharmacists who really know the subject matter should be allowed to prescribe. Alas, they are commercially available through many channels, without proper control, whether at hospitals, clinics, drugstores, retail stores or even groceries, and at weekend markets³. They are sold or dispensed in general drugstores by people who are not medical doctors or pharmacists. It is only right that every sector concerned, including the people sector, should help in the re-organization of the system and be on the lookout. In this matter, Food and Drug Administration will act as coordinator. It has started a project called "little FDA" operating as an important driving force at the community level.

Thailand's surveillance system regarding the antibacterial drug distribution and use does not include components that allow the sectors concerned to assess and analyze the situation in a systematic manner and, therefore, does not reflect reality in a timely manner. It relies in the most part on sporadic analysis and study. Thus, there is no clear rule on the control of antibacterial distribution from upstream (importation point) to downstream, i.e. end users.

3.2 Antibacterial users

Many medical doctors, pharmacists, other health professionals, farmers and the general public tend to use antibacterial drugs too often unnecessarily and unreasonably.

Prescribers of antibacterial drugs in humans: Prescription entails a good knowledge and understanding regarding illnesses caused by bacterial infection and the type of bacteria involved. This is to ensure a reasonable selection and use of antibacterials and may involve laboratory testing; in some cases, this must be done by specialists only. However, in reality, 1) outside hospitals, antibacterials are found to be commercially available in clinics, drugstores, and groceries, while the prescription is done by people without adequate knowledge and understanding of the matter. In addition, there is no system to monitor or supervise the antibacterial use against whether or not the situation warrants it. 2) In the hospital environment, many hospitals do not have a clear policy about the systemic management approach (called "Antibiotic Stewardship Program". They do not have in place manuals dealing with such issues as appropriate antibacterial use, resistant bacteria surveillance, organizational communication, diagnosis of susceptibility of bacteria to drugs, and infection control management. Most importantly, 3) there is a shortage of well-versed health personnel, especially doctors specializing in bacterial infection.

The general public: Most people do not have a correct knowledge and understanding about antibacterial drugs. They call these drugs antiseptic or anti-inflammation drugs and can buy them whether for oral or external use (self-administered, for agricultural use or for pets) without real or proper understanding. Many use a multi-drug package (commonly called " Ya-chut") which includes antibacterial components without knowing what those drugs are for, without proper instructions or caution. Equipped with little knowledge and understanding about a reasonable use of antibacterial drugs, illnesses or proper dosage, they even ask the doctors to prescribe "anti-inflammation", "antibiotic" or "antiseptic" drugs when no such need exists.

Advertisement through various media can reach people everywhere in the country, also promoting antibacterial drug sale through health personnel and bypassing ethical principles about drug sale promotion. Such practice has an effect on the behavior of unnecessary drug use and prescription.

Animal Husbandry, fishing and agriculture: The use of antibacterial drugs in husbandry, fishing and farming, including production of beautiful animals, pets, and show animals, has an effect on health and environment. In the past antibacterial drugs were also used to accelerate animal growth; the practice was banned in 2015. However, antibacterial drugs are still mixed in animal feeds or in the water for the animals to drink, in an attempt to prevent or treat animal diseases. Some strong antibacterial drugs (azithromycin and rifampicin) are also used in fighting cocks. Antibacterial use is also known in the entire orange plantation. In all this, people are not aware of the extent to which antibacterial drugs are used in agriculture or what residues are left behind in various forms. Consequently, everyone is exposed to antibacterial drugs, resistant bacteria or their genes, or a combination of the three, even though they may never have taken the drugs before.

4. Current policy and measures

4.1 Policy undertaken to solve antibacterial resistance problem at various levels

At national level: Measures already put in place include the 2011 National Drug Policy and National Drug System Development Strategy 2012-2016, covering the management of antibacterial resistance as part of a reasonable drug use, as well as National Strategy for the Preparation, Prevention and Problem-solving of Emerging Communicable Diseases 2013-2016.

In addition, there are a large number of committees and sub-committees set up by agencies concerned to manage antibacterial resistance in various dimensions⁴. However, all the efforts have not yet developed toward a clear policy; as a result, management integration is yet to be made into a national policy. There is no agency to integrate the policy and day-to-day activities of various agencies in a systemic fashion. The organizations in the most part do not work in a concerted manner. There is no coordinating center for information gathering on the situation, analysis and management on the basis of which a good early warning system can be developed. There is no real monitoring at the national level, especially the monitoring of a big problem of "management of awareness, knowledge and understanding of the people sector". The work in this area is not systematic enough and not sufficient.

At hospital level: Some action has been taken. For example, the presence of hospital accreditation⁵ has made it possible to set up a system to prevent and control bacterial infection and antibacterial use in hospitals. Yet, a glaring factor found in almost all hospitals is the lack of medical doctors with a true knowledge and understanding of bacteria, bacterial infection, reasonable use of antibacterial drugs, and prevention of the spread of antibacterial resistance.

4.2 Legal measures

There is much work done separately. Agencies responsible for legal enforcement come under a number of ministries, regarding control and promotion aspects. Here are some examples:

Drug control measures: The Drug Act B.E. 2510 (1967) and its amendment enforced by Food and Drug Administration (FDA) look after the registration of pharmacopoeias and categorization of drugs. They have something to do with the

control of drug distribution and consideration regarding which drugs need prescription, which drugs must be sold in what kind of establishment, control of manufacturing plants and importing companies, measures to control drugstores, and control of drug advertisement.

Also, the Drug Act B.E. 2510 (1967) lists certain items (including antibacterial drugs) to be exempted from control, thus having no measures to control them. On the other hand, if those items come under other laws, the control may not be as strict as under the Drug Act.

For instance, the Ministry of Public Health Announcement on items exempted from being listed as drugs includes the following: 1) products with antibacterial drugs of streptomycin type (15% by weight) or oxytetracycline (1.5% by weight) intended for agricultural use to kill plant diseases⁶ and 2) some antibacterial drugs with pre-mixtures to stimulate and promote animal growth for agricultural purposes. The latter should be brought back under the Drug Act B.E. 2510⁷, but they are still allowed to use as pre-mixtures in animal feeds to prevent the spread of the germs.

Measures to control antibacterial use in hospitals: The Department of Health Service Support, Ministry of Public Health, is the agency that enforces the Sanatorium Act B.E. 2541 (1998) dealing with the registration of private hospitals and clinics. However, there is no regulation whatsoever about the dispensation of drugs. Consequently, there are no measures to control the dispensation of antibacterial drugs. The Healthcare Accreditation Institute (HA), well aware of the importance of its role, has begun to draft assessment criteria of hospital quality to cover the policy and practice regarding antibacterial resistance. The problem remains, however, as not many private hospitals are not under this system; nor does the accreditation govern clinics and polyclinics.

Besides, the control of unnecessary antibacterial use and the promotion of reasonable use have not yet been seriously implemented. There are no real measures in place even though many types of antibacterial drugs on the National Essential Drug List are required to come under strict supervision of specialists. In practice, this cannot be enforced for *lack of medical doctors specializing in communicable diseases and antibacterial fields*. It is still not accepted that the knowledge and specialization of bacterial infection is something that requires a specialized study and clear understanding of the subject. Besides, there is a lack of bacteria testing including the reading and effective use of the results that take into account the relationship with epidemiological information, an essential factor leading to a reasonable antibacterial use.

Control measures for drug use in animals in animal hospitals: There is no clear system on the control of antibacterial use in animal hospitals. The *Animal Sanatorium Act B.E. 2533 (1990)* and its amendments do not have clear provisions on the control of prescription of antibacterial drugs in animals, the management of infection or its spread in hospitals. Indeed, the transfer of resistant bacteria or genes is found from animals to humans and vice versa.

Control of drug use in agricultural sector: *The Control of Animal Feed Quality Act B.E. 2558 (2013)* has in place some measures that prohibit mixing antimicrobial drugs of every kind in animal feeds intended to accelerate growth or increase effective use of animal feeds⁸. Still, the law enforcement and information of the data system, as well as rules and regulations, need to be improved, not to mention possible use of other laws.

Import control: *The Export and Import of Goods Act B.E. 2522 (1979)* controls the import of drugs and pharmaceuticals. It is jointly enforced by FDA and the Ministry

of Commerce. What is lacking is the process that could lead to an effective control ranging from the import and registration of pharmacopeia and pharmaceuticals, to supply, distribution to use of drugs.

4.3 Monitoring and surveillance of antibacterial resistance and use of antibacterial drugs

National Antimicrobial Resistance Surveillance Center, Thailand (NARST) , Department of Medical Sciences, Ministry of Public Health, collects information on bacteria in humans only, especially those sent from certain hospitals. What is missing is the lack of monitoring in the community and animal hospitals, as well as mechanisms to manage epidemiological information in a useful manner and effective communication to decision makers, health personnel, farmers, the business sector, and the public.

Center for Surveillance of Resistant Bacteria in Animals and Husbandry Products which is still at the early stage of establishment will be more visible in 2016. The surveillance part designed for the farming sector covers three areas: husbandry, fishing, and plantation. The report indicates a lower trend of antibacterial resistance. Yet, reports from a number of research studies and various sources show a host of other existing problems, including the residue of antibacterial drugs and resistant bacteria and genes in meat products available in the market⁹.

For all this, there is yet no system for the monitoring and surveillance of antibacterial resistance in the community and the environment in which a greater trend is seen in the use of antibacterial drugs in such areas as plantation, animal breeding, animal shows, and sericulture.

4.4 Surveillance and control of the spread of antibacterial resistance in hospitals

Backed up by the information of the National Antibacterial Resistance Surveillance Center, it is well known that the rate of drug resistance of pathological bacteria has been on the rise. However, most hospitals are still without an appropriate system that could prevent the occurrence and spread of resistant bacteria.

4.5 Strengthening the civil society sector

To a certain extent, efforts have been made by various agencies and organizations to educate the public to create the right attitude toward infection, protection against infection and antibacterial drug use. The practice, however, tends to be piecemeal and is neither comprehensive nor systematic enough. The situation warrants a budgetary support and collaboration from all sectors.

5.1 Guidelines for problem solving

5.1 Raise the issue as national agenda for problem solving with a view to putting in place a central mechanism designed to integrate the actions of various ministries, agencies, organizations and partners so that they can really collaborate with each other and receive appropriate support on a regular basis, including creating a central information center at national level.

This is a continuation of the effort to develop a national policy and strategy on problem management, on monitoring and surveillance of antibacterial resistance and antibacterial use, on surveillance and control of the spread of antibacterial resistance, and, very importantly, on the strengthening of the civil society sector. Nevertheless, over the last several decades most attempts have not been very successful or sustainable enough, while the problems have worsened all along. It needs a strong mechanism at national level and support from the national administration, with the Ministry of Public Health and Ministry of Agriculture and Cooperatives acting as joint lead agencies. The proposal

is to be submitted to the cabinet, through the National Health Commission, for consideration. This will enable all sectors, especially the ministries concerned and civil society sector, to plan together to solve such problems of diverse dimensions in an integrative manner and implement their work successfully, provide them with appropriate budgetary support, monitor their work on a regular basis so that they move along the same direction, and mutually support each other on the basis of the "One Health" principle.

5.2 Develop a central database system to manage the problem of antibacterial resistance: It is necessary to develop a central database system to collect data from the surveillance of antibacterial resistance in humans, animals, and husbandry products, including the monitoring and reporting of antibacterial use at every level, starting from import to distribution to use. This will make it possible to monitor and control the distribution of antibacterial drugs in its entirety, utilize the information in the database, and disclose it to the public for early warning purposes. In this way, the general public, personnel, and supervising agencies will become more aware of the problem and together help to manage it.

5.3 Support R&D, generate and manage the body of knowledge: It is important to come up with necessary research topics for Thailand in this matter, to process, analyze and synthesize the matter to generate the real body of knowledge. For example, a manual for reasonable dispensation of drugs must be based on earlier preliminary diagnosis and regulations on what ailments need no antibacterial (e.g. the common cold caused by a virus), on the standard practice of elimination or control of drug-resistant bacteria in hospitals and control of their spread to the environment, on reference materials, and on the body of knowledge and examination of data sources or consultation sources on drug use for the public.

5.4 Create awareness and disseminate knowledge to society at large and the people concerned. This is another success factor in the management of antibacterial resistance. A strong participation of the people sector will be an effective mechanism for problem management. Measures to be used include the following:

5.4.1 General social campaigns to create awareness and behavior modification together with proactive action: Some important approaches include a launch of campaigns and support for health promotion and disease prevention. For example, public communication will use creative media, while more educational tools will be developed involving, for instance, the use of applications, info-graphics or early warning, availability of data for the general public, and wide dissemination of the lesson learned and success stories.

5.4.2 The right of the public to be informed of the situation of antibacterial resistance in food and the environment: This will ensure that the public is aware of the problem and situation and can use available information on making decision on food and drug consumption.

5.4.3 Strengthening the people sector and collaboration with the consumers to stimulate the farming and business sectors, e.g., animal feeds companies and pharmaceutical plants, to help and manage the problem.

5.4.4 Creating local cooperation networks: For instance, local administrative organizations, people organization, and government sectors can support the creation of social dialogue with the help of the academic sector and law enforcement authorities.

5.5 Put in place a system of surveillance of antibacterial resistance and antibacterial use at national level: Efforts must be made to develop a system of surveillance of antibacterial resistance and antibacterial use more comprehensively to

include testing and screening, monitoring of drug-resistant bacteria and genes in humans, animals and husbandry products, monitoring and reporting of antibacterial drug use at every level from import to manufacturing, to distribution and use.

5.6 Legal measures or regulations: More measures and regulations are needed as follows:

5.6.1 With regard to drugs for humans and animals: More action is needed in the regulations of registration of pharmacopeias, review of pharmacopeia registration, and categorization of drugs, with consequent effects on the control of antibacterial drug distribution. Consideration will be made on such issues as what antibacterial drugs should be removed from drugstores, control of advertisement of prescription drugs, control of measures for import and distribution of drugs and their monitoring, control of sale of antibacterial drugs in drugstores and other shops, and measures to supervise and control drug use in healthcare establishments, i.e. hospitals and all kinds clinics.

5.6.2 With regard to agriculture and animal husbandry: Efforts must be made to raise control so as to limit the antibacterial use in agriculture and persuade farmers to do sustainable farming. In addition, review should be made to consider revoking the Ministry of Public Health Announcement in which two antibacterial drugs are exempted as non-drugs.

5.7 Prevention and control of the spread of antibacterial resistance in hospitals (for humans and animals) and animal husbandry:

5.7.1 With regard to hospitals for humans: It is necessary that the personnel working in this area should have an adequate knowledge of the subject. Yet, what is found lacking is policy support and resources. Besides, the physical structure of the hospitals is not yet appropriate. Therefore, there needs to be a policy that supports improvement of the hospital structure, a policy on patient admission, manpower and resource support necessary for the work to be adequately carried out, and measures to enhance the knowledge and skills of doctors to be able to prescribe antibacterial drugs appropriately, to provide more training to doctors specializing in infection prevention, and to control the spread of antibacterial resistance.

5.7.2 With regard to animal hospitals: As there is not enough information on antibacterial use in animals raised in hospitals, action must be taken to collect and review data, conduct more studies on the real situation, and develop a system to control and supervise drug use in animal hospitals.

5.8 Stricter supervision to ensure international compliance with standard practice for food and farm health, as the control criteria for food produced for domestic consumption are lower than those for food produced for export purposes. In fact, domestic food production must be free from drug-resistant bacteria, just like export food products. More incentives should be given to business operators. Support should be given to sellers to guarantee that their products are free from antibacterial drugs or drug-resistant bacteria. A sense of social responsibility should be inculcated to raise awareness and develop various management forms for all farms, big and small, for safe food production in a comprehensive manner.

6. Issue for consideration by the National Health Assembly

Requesting the National Health Assembly to consider Document NHA 8/ Draft Resolution 1 "Crisis of antibacterial resistance and integrated problem solving"

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