中国抗菌药物管理和细菌耐药现状报告 (2019)

Status Report on Antimicrobial Administration and Antimicrobial Resistance in China (2019)

国家卫生健康委员会 编

National Health Commission of the People's Republic of China

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序

当前，细菌耐药已经成为全球公共健康领域的重大挑战，也是各国政府和社会广泛关注的世界性问题。2011 年，WHO 提出“抵御耐药性——今天不采取行动，明天就无药可用”；2015 年世界卫生大会审议通过了控制细菌耐药全球行动计划，要求各成员国在未来 2 年时间内，制订本国的行动计划；在第 71 届联合国大会上，世界各国对微生物耐药问题进行了讨论，成为联合国大会有史以来讨论的第四个卫生议题。可见，加强抗菌药物科学管理、减缓细菌耐药，越来越成为全球共同关注的、非常紧迫的工作任务之一。

中国政府高度重视加强抗菌药物管理遏制细菌耐药工作。在应对细菌耐药联防联控工作机制下，制订发布了《遏制细菌耐药国家行动计划（2016—2020 年）》，成为全球最早发布和实施行动计划的国家之一。各部门按照行动计划，围绕抗菌药物的研发、生产、流通、使用、环境保护、宣传教育和国际合作等方面采取了一系列行动，取得了积极成效。抗菌药物管理的长效机制进一步强化，遏制细菌耐药的社会治理体系逐步形成，抗菌药物应用合理化水平不断提高，细菌耐药形势总体平稳向好。但是，作为世界上最大的发展中国家，遏制细菌耐药工作仍然面临一些困难，包括地域间、城乡间、机构间抗菌药物管理不平衡，制药企业研发抗菌药物动力不足，人民群众用药习惯急需改变等等。

习近平总书记在党的十九大报告中强调，人民健康是民族昌盛和国家富强的重要标志，要完善国民健康政策，为人民群众提供全方位全周期健康服务。《健康中国行动（2019—2030 年）》坚持预防为主，围绕疾病预防和健康促进两大核心，提出将开展 15 个重大专项行动，促进以治病为中心向以人民健康为

中心转变，努力使群众不生病、少生病。传统感染性疾病和新发再发传染病依然是影响人民健康的重要因素。加强感染性疾病预防、控制和诊治能力建设，维护和提高抗菌药物使用的安全性和有效性，遏制细菌耐药，是保障人民健康的重要责任，也是实现全球“同一个健康”的必由之路。让我们积极行动起来，坚持以人民为中心，坚持新发展理念，继续践行遏制细菌耐药国家行动计划，深化部门协作、动员社会参与、形成共同抵御细菌耐药的合力，为建设健康中国、决胜全面建成小康社会、夺取新时代中国特色社会主义伟大胜利作出新的更大贡献！

应对细菌耐药联防联控工作机制组长

国家卫生健康委副主任

Foreword

Antimicrobial resistance (AMR) has become one of the major public health challenges worldwide, raising wide concerns among all countries and the general public. In 2011, the World Health Organization (WHO) marked the World Health Day on the theme "Antimicrobial Resistance: No Action Today, No Cure Tomorrow". The 2015 World Health Assembly adopted a global action plan on AMR, urging all the member countries to develop their own national action plans to contain AMR within the coming two years. During the 71th Session of the United Nations General Assembly, counties formally discussed AMR, making it the fourth health issue ever discussed in the general assembly. Thus, strengthening the scientific management of antimicrobial drugs and alleviating AMR have become a global common concern and also an urgent task.

Improving antimicrobial use and containing AMR has long been a government priority in China. By adopting a broad and coordinated approach to addressing AMR and based on China's National Action Plan to Contain Antimicrobial Resistance (2016–2020), multiple ministries/commissions have carried out a series of activities in aspects including drug R&D, manufacturing, delivery, and use, environmental protection, education/awareness-raising, and international exchanges, with remarkable achievements. The long-effect mechanisms of antimicrobial stewardship have been strengthened, the social governance system to curb AMR has gradually been established, the rational use of antimicrobial drugs has been optimized, and the

general status of bacterial resistance has been improved. However, as the world's largest developing country, there are still some difficulties in curbing AMR: there are huge gaps in the management of antimicrobial drugs among regions, between urban and rural areas, and among institutions; pharmaceutical enterprises lack motivation to research and develop antimicrobial drugs; the quality of some drugs is not guaranteed; and people's medication habits are in urgent need of change.

As pointed out by CPC Central Committee General Secretary Xi Jinping in his report to the 19th CPC National Congress, a healthy population is a key metric of a prosperous nation and a strong country, and "we will improve the national health policy and ensure the delivery of comprehensive lifecycle health services for our people." The *Healthy China Action 2030* focuses on disease prevention and health promotion, and proposes to launch 15 major special actions to promote the transformation from treating diseases to people's health care and reduce the incidence of diseases. Today, the conventional infectious diseases and emerging/re-emerging infectious diseases are still key factors that affect people's health. Strengthening the capacity-building for prevention, control, and diagnosis & treatment of infectious diseases, maintaining and increasing the safety and effectiveness of antimicrobial drugs, and containing bacterial resistance are the government's key responsibilities to ensure people's health and also the only way to achieve the vision of One Health initiative worldwide. With the coordination among multiple sectors and the participation of the whole society and by adhering to the people-centered approach and the new development concept, we should actively implement the national action plan on antimicrobial resistance and maintain people's health, so as to build "Healthy China", secure a decisive victory in finishing the building of a moderately

prosperous society in all respects, and strive for the great success of socialism with Chinese characteristics for a new era.

Wang Hesheng

Director, Interagency Task Force on Prevention and Control of Antimicrobial resistance

Vice Minister of the National Health Commission of the People's Republic of China

编写说明

细菌耐药已经成为全球性的公共卫生问题，是全世界面临的共同挑战，引起各国和全社会的高度关注。为更加全面、客观地介绍中国抗菌药物管理和细菌耐药现状，提高抗菌药物科学化和精细化管理水平，延缓细菌耐药发生，维护人民群众健康，促进经济社会协调发展，在2016年度、2017年度和2018年度报告基础上，组织编写了《中国抗菌药物管理和细菌耐药现状报告（2019）》（以下简称《报告》）。

一、报告主要内容

《报告》分为4个部分，分别为现状与成效、国家行动计划相关进展、保障措施、问题、策略、附录。具体主要内容为：

第一部分　现状与成效

报告2018年中国抗菌药物临床使用现状、细菌耐药现状、其他重点关注病原体耐药情况、医院感染现状以及2011年以来各项指标的变化情况。

第二部分　国家行动计划工作进展

从抗菌药物相关研发与研究、抗菌药物审批和经营监管、抗菌药物临床应用管理、兽用抗菌药物管理、环境、宣传教育等各方面介绍国家行动计划进展情况。

第三部分　问题

结合监测数据，指出抗菌药物管理、细菌耐药控制、医院感染防控方面仍然存在的不足之处。

第四部分　策略

从卫生、农业、科研、产业化、环境、宣教等各方面提出未来工作计划。

二、报告数据范围和来源

1. 全国抗菌药物临床应用监测网、全国细菌耐药监测网、全国医院感染监测网等提供的相关数据信息。

2. 中国疾病预防控制中心提供的相关数据信息。为更全面反映抗微生物耐药形势，本年度的报告补充了关于淋球菌、艾滋病病毒、结核病和抗疟药物的耐药性数据。

（1）淋球菌耐药监测：中国淋球菌耐药监测通过中国疾病预防控制中心性病控制中心国家参比实验室、省级 / 区域中心实验室和性病门诊监测点三级系统开展工作，目前监测点已前后覆盖全国 16 个省（市、自治区），每年完成 1000 ~ 2000 株淋球菌临床菌株的收集及耐药检测。

（2）艾滋病病毒耐药监测：2004 年建立“艾滋病抗病毒治疗信息系统”，由全国各地抗病毒治疗机构信息管理人员将抗病毒治疗患者信息、治疗方案相关信息和（或）实验室检测结果录入系统。自从 2010 年起，开始为病毒学失败病例提供耐药检测，建议所有抗病毒治疗失败者进行耐药检测。

（3）结核病耐药监测：全国结核病耐药性监测以分层整群抽样的方法随机抽取了全国 72 个县（区）作为监测点（共有 72 个监测点），覆盖全国 31 个省（自治区、市）。每个监测点连续纳入一年中所有就诊的病原学（实验室细菌学

检查或者分子生物学检查）阳性肺结核患者，选取其痰标本进行涂片、培养、菌种鉴定和药敏试验进行耐药监测工作。

（4）抗疟药物（青蒿素）耐药性监测：2007年以来，我国在世界卫生组织湄公河疟疾项目支持下，在云南边境地区开展了双氢青蒿素哌喹片（一线治疗药）治疗恶性疟的效果评价监测研究。所有监测对象的选择、监测方案以及疗效判定标准均按WHO体内药物治疗效果监测方法实施。

3. 相关部委提供的数据信息。

三、有关说明

1. 关于相关分析的方法

全国抗菌药物临床应用监测网：入网监测医疗机构登录“全国抗菌药物临床应用监测网”，通过网络将相关数据信息按监测技术要求上传或录入至监测数据上报系统中。监测系统采取回顾性随机抽样调查的方法对监测范围内医疗机构的病历和处方进行统计分析，得到相关的抗菌药物使用率等相关指标；并通过采集监测范围内医疗机构抗菌药物使用量，统计计算出医疗机构、各省级单位乃至全国的抗菌药物种类及品种的消耗量（累积DDDs）和使用强度[DDDs/（100人·天）]。

全国细菌耐药监测网数据分析方法：收集所有成员单位全年的数据，去除重复分离的菌株，应用Whonet 5.6软件进行统计分析。数据分析在统计和分析方法上与往年基本保持一致。在去除重复菌株的规则上，通过系统自动审核及人工审核，对部分不合格的数据进行了剔除，以减少由于个别成员单位的错误数据所致的误差。

全国医院感染监测网数据分析方法：各医院根据统一的调查方法，采用横断面调查的方式，调查某一日医院内所有住院患者的医院感染情况，医院感染判定标准按照中国2001年颁布的《医院感染诊断标准（试行）》执行。所有监

测数据录入 WEB 数据处理系统（oa.yygr.cn），由专人进行审核，对审核合格医院的数据进行汇总。

2. 报告中所有涉及金额的数据均是人民币

《报告》的数据收集工作得到了全国抗菌药物临床应用监测网、全国细菌耐药监测网、全国医院感染监测网、中国疾病预防控制中心的鼎力配合，编写工作得到了有关部委、各监测网、编写专家组的大力支持，在此表示感谢！由于编写人员水平有限，加之编写时间紧、任务重，报告中所反映的结果亦受上报数据质量影响，难免存在缺点和偏差，恳请广大同仁批评指正，以便今后不断改进。

编　者

2019 年 8 月

Introduction

Antimicrobial resistance (AMR) has become a public health issue of global concern. To offer comprehensive and objective knowledge on the antimicrobial administration and AMR in China, improve the scientific and refined management of antimicrobials, postpone the occurrence of AMR, safeguard the people's health, and promote the coordinated development of socioeconomy in China, we organized the development of the *Status Report on Antimicrobial Administration and Antimicrobial Resistance in China – 2019* (hereinafter referred to as *"Report"*) based on the 2016, 2017 and 2018 editions.

I. Main Contents

The *Report* comprises four parts: current situations and achivements, progresses in national action plans, supporting and guaranteeing measures, problems, and strategies.

1. Current situations and achievements. This part includes the status quo of clinical application of antimicrobials, antimicrobial resistance, resistance of other major pathogens, and nosocomial infection in 2018 as well as the changes of these indicators since 2011 in China.

2. Progresses in the national action plan. This part covers the progresses of the national action plans in terms of antibacterial drug R&D, licensing and supervision of antibacterial drugs, administration of clinical application of antibacterial drugs,

administration of the use of antimicrobial drugs in veterinary practice, environment, and education/awareness raising.

3. Problems. It introduces shortcomings in the areas of antimicrobial administration, control of AMR, and prevention and control of nosocomial infection.

4. Strategies. It introduces the working plan in terms of health, agriculture, scientific research, industrialization, environment, and education/awareness raising.

II. Data sources

Data were collected mainly from the Center of Antibacterial Surveillance, the China Antimicrobial Resistance Surveillance System (CARSS), the National Nosocomial Infection Surveillance System, the Chinese Center for Disease Control and Prevention, and other networks. Other information was offered by relevant ministries/commissions.

In order to reflect the situation of antimicrobial resistance more comprehensively, this year's report supplements data on drug resistance of gonococcus, HIV, tuberculosis and malaria.

1. The surveillance of gonococcal resistance in China is carried out through the three-level system of the National Reference Laboratory of the Center for Disease Control and Prevention of China, Provincial/Regional Center Laboratory and Sexual Disease Outpatient Surveillance Point. At present, the surveillance points cover 16 provinces (or autonomous regions and municipalities) in China, and collect and detect 1000-2000 clinical strains of Neisseria Gonorrhoeae each year.

2. In 2004, the "AIDS Anti-Viral Therapy Information System" was established by the Chinese Center for Disease Control and Prevention. The information managers of anti-viral treatment institutions across the country is in charge of inputing the

information of anti-viral treatment patients, treatment programs and/or laboratory test results into the system. Since 2010, drug resistance testing has been provided for virological treatment failure cases, and it is recommended that all failed antiviral therapies be tested for drug resistance.

3. The national tuberculosis drug resistance surveillance system used stratified cluster sampling method to randomly select 72 counties (districts) as surveillance points, covering 31 provinces (or autonomous regions and municipalities) in China. All pathogenic positive cases are included, and sputum samples are collected for smear, culture, bacterial strain identification and drug susceptibility test.

4. Since 2007, with the support of the Mekong Malaria Project of the WHO, China has carried out a surveillance project on the efficacy of dihydroartemisinin piperaquine tablets (first-line therapeutic agents) in the treatment of malignant malaria in Yunnan province. The surveillance is implemented according to the WHO in vivo drug treatment effect monitoring method.

III. Analysis methods

1. Methodology of analysis

Data from the Center of Antibacterial Surveillance All the registered medical institutions login in the Center of Antibacterial Surveillance and upload or enter the relevant data into the surveillance data reporting system according to the surveillance technical requirements. The system conducts statistical analysis on the medical records and prescriptions of medical institutions in its surveillance scope by retrospective survey of random samples and gets indicators (e.g. the utilization rate of antimicrobial agents); by collecting the consumption of antimicrobial agents in medical institutions, the system also performs statistical computation for the category

of antimicrobial agents and the consumption (accumulated DDDs) and use density (or, DDDs/ 100 bed-days) of each category in a medical institute, district, city, province, or the whole country.

Data from China Antimicrobial Resistance Surveillance System The system collects the annual data of all member units, removing duplicated strains and using Whonet 5.6 to perform statistical analysis. The statistical analyses were consistent with those in previous years, with only exception of the adjustment of the rule for removing duplicated strains. Some unqualified data were removed through both automatic and manual review to minimize the errors caused by the wrong data of individual member units.

Data from the National Nosocomial Infection Surveillance System The medical institutions participating in the investigation employed the same cross-sectional survey method to investigate the nosocomial infections of all inpatients in a certain day. The nosocomial infection was determined in accordance with the *Diagnostic Criteria for Nosocomial Infections (Trial)* issued in 2001. All monitoring data were recorded in the WEB data processing system (oa.yygr.cn) and reviewed by specially-assigned persons.

2. All the sum of money involved in the report are presented as CNY (Renminbi).

We thank the Center of Antibacterial Surveillance, the China Antimicrobial Resistance Surveillance System, the National Nosocomial Infection Surveillance System and other networks for their support and help during data collection. Also, many ministries and commissions, surveillance networks, and experts provided valuable inputs during the development of this Report. However, we are solely responsible for any errors and omissions in this Report and any feedback from our readers is warmly welcomed.