



Legislation for promoting antimicrobial stewardship program in China

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On August 1 2012, China formally implemented the decree ‘Administrative regulations for clinical use of antibacterial agents’, which was issued by the Ministry of Health. This ruling defines all aspects of antibiotic use in hospitals, including antibiotic selection, procurement, prescription, use, monitoring, and legal responsibility, which was called as the ever-history strict regulation for antibiotic management in China. This event got widespread concern both in China and overseas, as this is the first formal standardised regulation regarding the administration of antibacterial drugs in the world issued by national healthcare authority. The major purpose of implementing this new regulation is to ensure that antimicrobial agents are rationally used within hospitals^[1,2].

In recent years, China has carried out an extensive healthcare system reform, which is expected ultimately to provide everyone with access to basic medical care. To achieve these aims, the existed running manner of profit-orientation in public hospitals should be completely abandoned and the administration of drugs, including antimicrobial agents, should be rationalised^[3]. Long-term antibiotic irrational use caused by the existed hospital running manner in China has generated severe antibiotic-resistant bacterial strains, although the healthcare authority released several technical files for promoting the rational use of antibiotics during the past 10 years, such as “principles for clinical use of antibiotics (2004)”, “national formulary (2008)” and “guides for hospital drug therapeutic committee (2002)” . Bacterial resistance now constitute a major problem in the healthcare system. Methicillin-resistant *Staphylococcus aureus*, extended-spectrum beta-lactamase-producing *Escherichia coli*, quinolone-resistant *Escherichia coli* and carbapenem-resistant *Pseudomonas aeruginosa* and *Acinetobacter baumannii* amounted to approximately 60 % in a national survey. The rational use of antimicrobial agents and the implementation of other methods to prevent bacterial resistance worsening have become

critical^[4,5].

The regulations recently introduced concerning antibiotic usage incorporate the internationally received antimicrobial stewardship program (ASP) , and include some administrative requirements tailored for the Chinese healthcare system^[1,6]. The regulations also include specific instructions for the leaders of medical institution who are responsible for the rational administration of antimicrobial agents, for establishing an effective antibacterial drug management system, and for forming a working group composed of infectious physicians, pharmacists, microbiologists and management personnel. Medical institutions must ensure that antibiotics are classified as non-restricted, restricted or special grades. Physicians and pharmacists need to receive specialised training in the prescribing of antibiotics before being granted varying levels of prescribing privileges depending on their professional title. The healthcare authority will set administrative goals for institutions; conduct reviews of antibacterial drug prescriptions; regularly publish information regarding the usage of antibacterial drugs in hospitals; commend physicians who closely follow the regulations; and impose penalties on medical staff who violate the regulations.

The regulations also encourage medical institutions to explore other strategies to improve the rational use of antibacterial drugs, such as antibiotic diversity use, active intervention for antibiotic use, clinical guide implementation and hospital infection control. At the same time, pharmaceutical companies should implement a standardized drug promotion procedure, and stop attempting to increase drug sales for economic incentives. Medical institutions need to regularly report the use of antibacterial drugs to the healthcare authority. In order to improve the administration of antibiotics, institutions which seriously and/or persistently violate the regulations will be imposed with appropriate penalties by the authority, such as degrading the hospital level and dismissing the leaders of the institutes involved. Medical staff who seriously violate the regulations may no longer be able to prescribe antibacterial drugs, have their professional qualification revoked, or may even be legally prosecuted if their actions have serious consequences.

To promote the implementation of these regulations, the Ministry of Health in China initiated a 3 year campaign in 2011 with a special task force in antibiotic management.. Through the strict implementation of these regulations and the introduction of legal penalties, the rational use of antibiotics in public medical institutions can be quickly and efficiently enforced^[7]. While these steps are suitable to reduce antibiotic use in the current Chinese healthcare system, the long-term management of these strategies requires further planning and a sustainable back-up system should be established, such as ASP professional, guidelines, ongoing staff training, illegal practice identifying procedure and so on Unfortunately, the antibiotic sales in social pharmacies are not within the legal jurisdiction of the regulation.

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