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Women and children's real-world economic and drug indicators from 2015 to 2019

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ABSTRACT

Objectives: To obtain real-world data on rational drug use, pharmacoeconomic regarding women's and children's health and the benefits of Hainan free trade port (HFTP) health policies, we retrospectively investigated drug indicators, prescribing trend, and economic data.

Method: We retrospectively gathered the data from the database of the hospital information system and the quality indicators of pharmacy; we compared the monthly indicators from 2015 to 2019.

Results: In 2017, the HFTP maternal mortality ratio (MMR) was 24.46. In 2019, the HFTP infant mortality rate (‰) was 4.15, and the under-five mortality rate (‰) was 6.19. A total of 1,922,798 prescriptions included in the analysis, the defined daily dose of 2015–2019 ranged from 46.59 to 32.34. In 2019, the proportions of antibiotics prescribed in outpatient, emergency, and inpatient care were 14.19%, 16.68%, and 46.26%, respectively. The injection prescription percentage ranged from 13.08% to 8.08%. The proportion of medicine income to total hospital income of 2015–2019 ranged from 26.66% to 25.31%.

Conclusion: According to the analysis of women's and children's real-world drug data, economic investment and strict quality control of antimicrobial stewardship programs can lead to the rational use of drugs.

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Real-world study; pharmacoepidemiology; pharmacoeconomic analysis; rational drug use; antimicrobial stewardship program; antibiotic percent

Background

The whole world has seen dramatic reductions of 60% in under-five mortality rate (per 1000 live births) [1] from 93‰ in 1990 to 38‰ in 2019. In 2019, the Chinese infant mortality rate [2] (probability of dying between birth and age 1 per 1000 live births) was 6.76, the neonatal mortality rate (0–27 days) per 1000 live births (NMR, ‰) was 3.86, the under-five mortality rate (deaths per 1000 live births, ‰)) was 7.9. In 2019, the Hainan Free Trade Port (HFTP) [3] infant mortality rate (‰) was 4.15, and the under-five mortality rate (‰) was 6.19. In 2017, the Chinese national maternal mortality ratio [4] (MMR, maternal deaths per 100,000 live births) was 29; in 2017, HFTP [3] MMR was 24.46. Previous achievements in reproductive, maternal, new-born, child, and adolescent health (RMNCAH) have benefited from a number of factors [5], including the rapid change in socioeconomic determinants, the building of the maternal and child health system, and the maternal and child health information system, political will, the reformation of social health insurance, the launch of national RMNCAH programs and poverty alleviation. The World Health Organization (WHO) and the International Network of Rational Use of Drugs (INRUD) developed core drug use indicators [6] which includes indicators on prescribing, patients-care and health-care facilities, they were different from developed and developing countries.

In 2016, the World Economic Forum discussed the topic of antibiotics, childbirth, and maternal and infant mortality. These points to the dual nature of the problem. More children in Africa die from antibiotics deficiency than from antibiotic-resistant infections. Saving the lives of mothers and infants will require us to address the problem of access as well as excess, those who need lifesaving antibiotics must get them, and those who do not must not. World leaders also discussed antibiotic resistance at the G20 summit in China, and then at a high-level United Nations General Assembly meeting. Antibiotic use in very low-birth

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-weight (VLBW) infants decreased between 2010 and 2014 in Canada [7]. The annual antibiotic use rates (AURs) decreased from 0.29 in 2010 to 0.25 in 2014, which occurred in parallel with a reduction in the rate of late-onset sepsis from 19.0% in 2010 to 13.8% in 2014. However, among infants without culture-proven sepsis or without necrotizing enterocolitis (NEC), higher AURs were associated with adverse neonatal outcomes. Among the remaining 8824 infants without early-onset sepsis, late-onset sepsis, or NEC, a 10% increase in the AUR was associated with increased odds of the primary composite outcome, mortality, and stage 3 or higher retinopathy of prematurity. In 2018 in the USA [8], nearly 21,500 babies died, and the infant mortality rate (5.7 per 1000 livebirths) was much higher than other countries with similar levels of economic development (e.g., 3.8 per 1000 livebirths in the UK). In the USA, the second leading cause of these infant deaths is prematurity and related complications. In the USA – compared with term-born babies, those born before 37 weeks gestational age are more prone to infections, respiratory problems, and other complications in infancy, and can have long-term developmental disabilities (e.g., cerebral palsy), as well as behavioral and other health issues.

In 2020 following the World Bank categorization, China was classified as an upper-middle-income economy based on gross national income per capita (GNI) [9]. According to the statistical bulletin [10] of national economic and social development of HFTP in 2019, there were approximately 9.45 million registered residents and 5.60 million urban residents. There were approximately 5,646 medical institutions 47,274 beds and 85,087 medical professionals. In 2019, the number of beds and doctors per 10,000 persons [3] was 53 and 25. Our medical center affiliated with Hainan Medical University consists of a maternal and child health hospital, a children's hospital and a maternity hospital. We have 800 registered beds and 1,500 employees and an annual total of 689 thousand outpatient and 23 thousand inpatient visits.

In 2016 public hospitals in 200 Chinese pilot cities abolished 15% of markups on medicine [11], which heralded as the biggest reform for China's modern health system. The Report on the Work of the Government (2017) introduced overall reforms in all public hospitals and abolished all markups on medicine; the pharmacies of Chinese public hospitals were non-profit. The National Health Commission of People's Republic of China (NHCPRC) [12] promulgated the Guidelines for Clinical Application of Antibacterial Drugs in 2015 and the National Action Plan to Contain Antimicrobial Resistance (2016–2020) in 2016. The baseline data of drug indicators, prescribing trends and pharmacoeconomic investment [13] with regard to women's and children's health may be impacted by the related regulations, so we compared the data of 2015–2019 from the database of the hospital information system (HIS).

Methods and materials

In August 2020, the NHCPRC released the Medical Quality Control Index of Pharmaceutical Administration (2020 Edition), which were implemented in various parts of China, we tried to compute the quantitative and qualitative indicators at the level of pharmacy. We calculated the real-world data [14,15] from the HIS and the ordinary quality data [16] of pharmacy. The data were based on the database of outpatient visits and hospitalized records [17]. We computed the monthly drug indicators from 2015 to 2019 and compared the means over 12-month periods.

Inclusion and exclusion criteria

Narcotic, poisonous substance, and radiopharmaceutical prescriptions are included in prescriptions. Agents in the J01 group of the ATC (Anatomical Therapeutic Chemical) classification system [18] included in antibiotic. Antidiarrheal drugs such as quinolone, gentamycin, nifuroxazide, and their combinations are included in antibiotics. Vaccines, menstruum, local anaesthetic, conjunctival, local sealant, and retrobulbar injection are excluded from injections. Anti-tuberculosis drugs, antifungal drugs, antiviral drugs, antiparasitic drugs, botanical antimicrobials, and antitumoral antibiotics are excluded from antibiotics.

According to safety, efficacy, bacterial resistance, and price, antimicrobial drugs are classified into three levels: 'nonrestricted use level', 'restricted use level' and 'specialized-use level'. Specialized antibiotics (specialized-use level) of our hospital included tigecycline, cefpirome, cefepime, aztreonam, cefotaxime sodium/sulbactam, meropenem, imipenem/cilastatin, panipenem/betamirone, biapenem, vancomycin, norvancomycin, teicoplanin, fusidic acid, linezolid, daptomycin, amphotericin B, itraconazole (injection), micafungin, and caspofungin.

Statistical method

IBM SPSS 17.0 for Windows was used to conduct the statistical analysis; the results were expressed as the mean ± standard deviation (M±SD). The Levene test was used for test homogeneity of variance; analysis of variance (ANOVA) was used to compare means of data. In terms of multiple comparisons, the Student-Newman – Keuls test was used for homogeneity of variance, and the Dunnett T3 test was used for heterogeneity of variance. The P value <0.05 was statistically significant.

Results

A total of 1,922,798 prescriptions were included in the analysis. The outpatient prescriptions from 2015 to 2019 are shown in Table 1 (F = 37.82, $P = 0.00$), and they increased from 23,815 to 44,457. The proportion of specialized antibiotic revenue to antibiotic revenue decreased from 22.39% to 13.65% (F = 6.691, $P = 0.00$). The defined daily dose (DDD) from 2015 to 2019 ranged from 46.59 to 32.34 (F = 22.62, $P = 0.00$). The DDD of specialized antibiotics from 2015 to 2019 (F = 6.51, $P = 0.00$) were 2.43, 2.07, 2.12, 1.61, and 1.40, respectively. Antimicrobial DDD [18] adjusted by weight [19] in paediatrics should be suggested and validated.

The rate of microbiological samples submitted for inspection in inpatients who encountered antibiotic therapy from 2015 to 2019 ranged from 65.90% to 83.35%, it achieved the goal which established by the NHCPRC in 2015, i.e., rate of microbiological sample submitted for inspection in inpatient encountered antibiotic therapy and specialized antibiotics were 50% and 80%, respectively.

The proportion of medicine income to total hospital income of 2015–2019 shown in Figure 1, and it ranged from 26.66% to 25.31%. The proportions of antibiotic revenue to medicine revenue from 2015 to 2019 were 37.53%, 29.80%, 26.41%, 20.87%, and 19.24%, respectively. The proportion of antibiotic revenue to Western medicine revenue (F = 27.29, $P = 0.00$) of 2015–2019 decreased from 26.69% to 14.78%.

The antibiotic prescription percentages from 2015 to 2019 were 35.17%, 28.92%, 33.25%, 30.67%, and 27.29%, respectively. In 2019, the proportions of antibiotics prescribed in outpatients, emergencies, and inpatients were 14.19%, 16.68%, and 46.26%, respectively, as shown in Table 2. The injection prescription percentages of 2015–2019 were 10.92%, 8.08%, 11.92%, 13.08%, and 11.21%, respectively. In 2019, the proportions of injections prescribed in outpatients and emergencies were 2.39% and 7.98%, respectively.

The proportion of antibiotics encountered in inpatient care shown in Figure 2 decreased from 59.12% to 46.26%. The proportions of specialized antibiotics encountered in inpatient care from 2015 to 2019 were 3.96%, 3.44%, 3.29%, 2.16%, and 1.34%, respectively. The proportions of antibiotic prevention encountered in cleaning (Class I) incision surgery from 2015 to 2019 was 3.64%, 6.62%, 13.03%, 9.45%, and 8.01%, respectively. According to the antibiotics goal established by the NHCPRC in 2015, the proportion of antibiotic prophylaxis in patients receiving type I incision operations/clean operations should be ≤30%.

Discussion

In 2019, the WHO [4] and partners released a consensus statement and a full-strategy paper on ending preventable maternal mortality (EPMM). The EPMM target for reducing the global MMR by 2030 was adopted as Sustainable Development Goal Target 3.1, i.e., to reduce global MMR to less than 70 per 100,000 live births by 2030 [5]. Although we are tertiary maternal and child health hospitals and teaching hospitals of Medical University, there are many factors affecting women's and children's health, and we limited to the discussion of pharmaceutical quality control, rational use of drugs, antimicrobial stewardship programs, and investment in pharmacoeconomic of HFTP policies from 2015 to 2019. In the future, we will collect more data on women's and children's health, we will discuss the further correlation and causality, the standard models between the economic and core drug indicator and NMR, MMR.

Table 1. Outpatient prescription and defined daily dose (DDD) of 2015–2019 ($N = 12$).

	2015	2016	2017	2018	2019
Outpatient prescription every month**	23815.83 ± 3320.84	27207.75 ± 3909.13	32658.25 ± 4206.40	32093.92 ± 3791.42	44457.42 ± 6246.92
Defined Daily Dose (DDD) **	43.85 ± 3.50	46.59 ± 4.03	36.17 ± 4.14	32.34 ± 5.39	39.18 ± 3.53
DDD of specialized antibiotic**	2.43 ± 0.68	2.07 ± 0.64	2.12 ± 0.52	1.61 ± 0.51	1.40 ± 0.41
Proportion of antibiotic revenue in outpatient and emergency to medicine revenue	30.15 ± 3.23	24.63 ± 3.82	23.13 ± 1.20	16.50 ± 2.65	16.66 ± 1.56
Proportion of specialized antibiotic revenue to antibiotic revenue**	22.39 ± 3.64	17.44 ± 4.20	17.47 ± 5.07	15.76 ± 5.41	13.65 ± 2.72
Rate of microbiological sample submitted for inspection in inpatient encountered antibiotic therapy	82.26 ± 4.98	82.02 ± 4.79	65.90 ± 3.43	70.92 ± 16.91	83.35 ± 2.38

The date of twelve months was computed, and the sample size of N was 12.
Defined daily dose (DDD) = cumulative DDDs/patients in the same period/day/100.
* $P < 0.05$, ** $P < 0.01$.
A total of 1,922,798 prescriptions included in the analysis. The outpatient prescriptions every month from 2015 to 2019 are shown in Table 1, they increased from 23,815 to 44,457. The defined daily dose (DDD) from 2015 to 2019 ranged from 46.59 to 32.34. The DDDs of specialized antibiotics from 2015–2019 were 2.43, 2.07, 2.12, 1.61, and 1.40, respectively. The proportion of specialized antibiotic revenue to antibiotic revenue decreased from 22.39% to 13.65%. The rate of microbiological samples submitted for inspection in inpatients who encountered antibiotic therapy from 2015–2019 ranged from 65.90% to 83.35%, they achieve antibiotics goals which established by the NHCPRC in 2015.

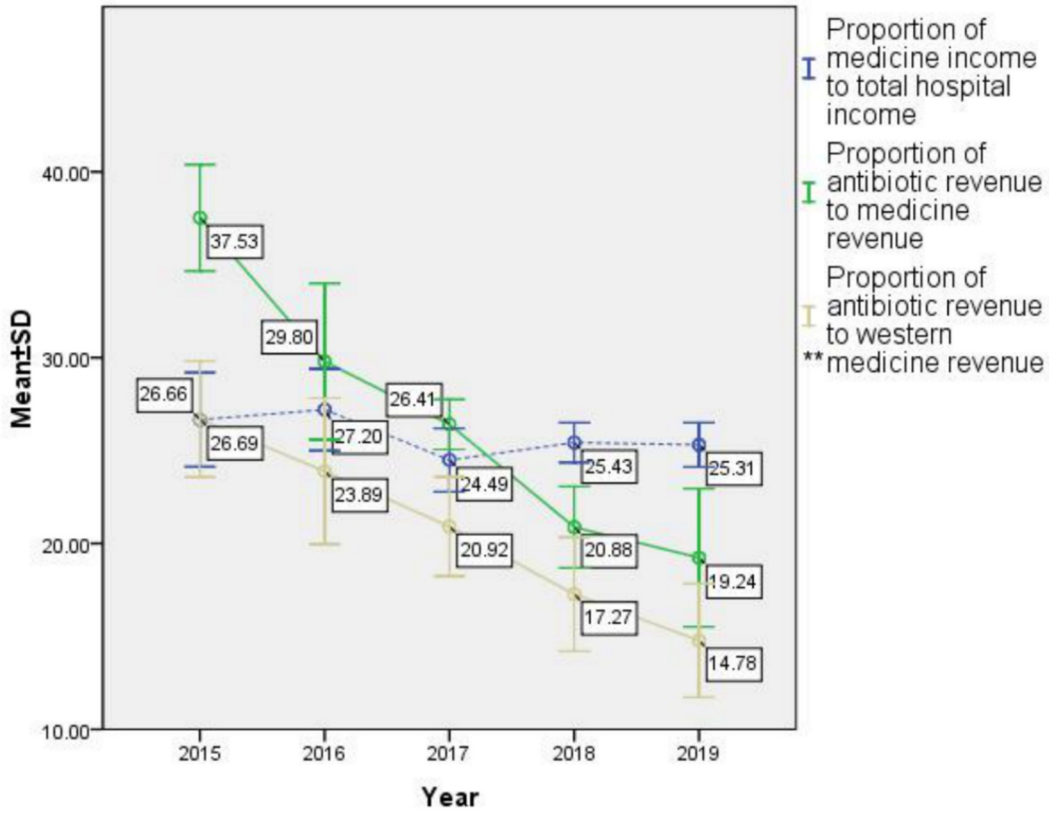

Figure 1. Pharmacoeconomic indicators of medicine (*N*=12).

The date of 12 months was computed, and the sample size of N was 12.

* *P*<0.05, **P<0.01

In 2016, public hospitals in 200 Chinese pilot cities abolished 15% of markups on pharmaceuticals. The proportionof medicine income to total hospital income of 2015-2019 was shown in Figure 1, it ranged from 26.66% to 25.31%. Theproportions of antibiotic revenue to medicine revenue from 2015 to 2019 were 37.53%, 29.80%, 26.41%, 20.87% and19.24%, respectively. The proportion of antibiotic revenue to western medicine revenue of 2015-2019 decreased from26.69% to 14.78%.

Table 2. WHO/INRUD core drug indicators of 2015–2019 ($N = 12$).

	2015	2016	2017	2018	2019	WHO Optimal Value [20,21]	Africa Standard [47, 48]
Antibiotic prescription percentage	35.17 ± 3.35	28.92 ± 4.89	33.25 ± 7.99	30.67 ± 6.10	27.29 ± 6.24	13.4–24.1	45.9
Proportion of antibiotic prescribed in outpatient	24.90 ± 1.84*	20.31 ± 2.45*	17.38 ± 0.90*	14.08 ± 1.65	14.19 ± 1.34	-	-
Proportion of antibiotic prescribed in emergency	27.54 ± 3.68	32.45 ± 3.00*	28.14 ± 2.69	17.77 ± 5.19	16.68 ± 1.51	-	-
Proportion of antibiotic encountered in inpatient	59.12 ± 4.66*	60.65 ± 2.82*	58.10 ± 3.45*	48.37 ± 11.41	46.26 ± 2.22	-	-
Injection prescription percentage	10.92 ± 2.15	8.08 ± 1.93	11.92 ± 6.07	13.08 ± 5.12	11.21 ± 2.43	20.0–26.8	28.4
Proportion of injection prescribed in outpatient	5.56 ± 0.93*	3.80 ± 0.95	7.45 ± 3.86*	2.71 ± 0.66	2.39 ± 0.41	-	-
Proportion of injection prescribed in emergency	16.81 ± 3.22	11.80 ± 2.70	17.58 ± 4.28	9.78 ± 1.71	7.98 ± 2.03	–	-

WHO: World Health Organization; INRUD: International Network of Rational Use of Drugs; - uninvestigated.

The date of twelve months was computed, and the sample size of N was 12.

*$P < 0.05$, **$P < 0.01$.

WHO/INRUD core drug indicators include indicators on prescribing, patients-care and health care facilities. The antibiotic prescription percentages from 2015 to 2019 were 35.17%, 28.92%, 33.25%, 30.67%, and 27.29%, respectively. In 2019, the proportions of antibiotics prescribed in outpatients, emergencies, and inpatients were 14.19%, 16.68%, and 46.26%, respectively. The injection prescription percentages of 2015–2019 were 10.92%, 8.08%, 11.92%, 13.08%, and 11.21%, respectively. In 2019, the proportions of injections prescribed in outpatients and emergencies were 2.39% and 7.98%, respectively.

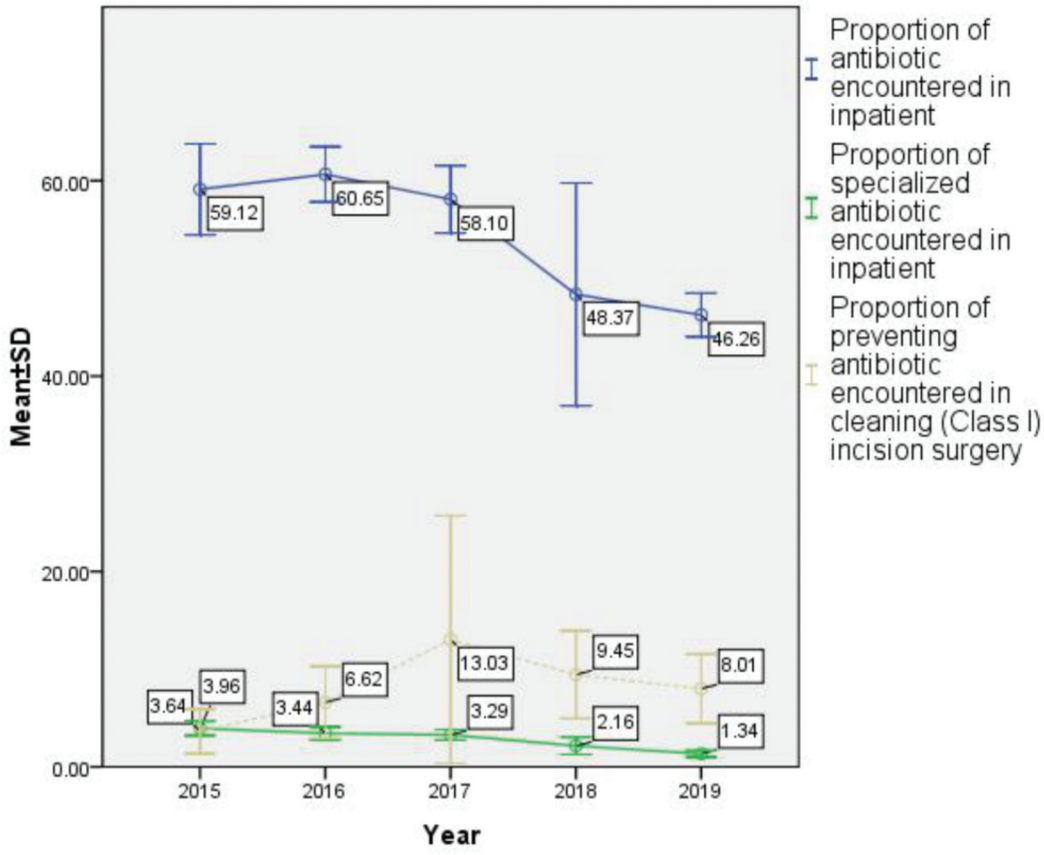

Figure 2. Indicators of specialized and preventive antibiotics (*N*=12).

The date of 12 months was computed, and the sample size of N was 12.

The standard of specialized antibiotics was in the Inclusion and Exclusion Criteria.

* $P<0.05$, **$P<0.01$

The proportion of antibiotics encountered in inpatient care shown in Figure 2 decreased from 59.12% to 46.26%. The proportions of specialized antibiotics encountered in inpatient care from 2015 to 2019 were 3.96%, 3.44%, 3.29%, 2.16% and 1.34%, respectively. The proportions of antibiotic prevention encountered in cleaning (Class I) incision surgery from 2015-2019 was 3.64%, 6.62%, 13.03%, 9.45% and 8.01%, respectively. The indicators achieve the antibiotics goals which established by the NHCPRC in 2015, i.e., the proportion of antibiotic prophylaxis in patients receiving type I incision operations/clean operations should be ≤30%.

Real-world pharmacoeconomic quality control indicator

The Real-World Study (RWS) to evaluate drugs in children was critical for the safety and efficacy [22] of drugs. Without this type of research [23], the medication used in children would be limited to data from adult studies or off-label use for indications [15]. Most studies in the pregnancy focus on a single or selected outcomes, while the pregnancy must balance the benefit of treatment against possible adverse effects [24]. Evidence-based medicine and RWS [15,20,25] through data mining and standardized quality control could avoid the repetitive experimental design.

Regarding the real-world pharmacoeconomic models [21], the Work of the Government (2019) states that government subsidies for resident's medical insurance would raise an average of 30 CNY per person, half of which used for serious disease. We had reduced the deductible line for serious disease, raised the reimbursement rate from 50% to 60%. The Boao Lecheng Pilot Zone of International Medical Tourism locate in HFTP, they launched a special type of drug insurance. Insurance covers 70 anticancer drugs from around the globe for the treatment of 35 common cancers, including 49 drugs that have yet to be approved for sale in the Chinese mainland market. The annual premium for Hainan residents was only 29 CNY per person, while insurance covers up to 1 million CNY in drug costs.

The prevalence of drug prescriptions and the potential safety in a real-world cohort of Dutch patients with cirrhosis was based on the Outpatient Pharmacy Database and the Hospitalization Database of the PHARMO Database [26]; potentially unsafe drugs used by 60.0% of patients during the entire follow-up. Most

patients used one drug (35.7% of patients), but 24.3% used multiple drugs (range 2–8). About 63.3% of potentially unsafe drugs dispensed more than once (median 2). General practitioners prescribed 62.6% of potentially unsafe drugs, specialists prescribed 33.3%, and the prescriber was either another health-care professional or was unknown in 4.2% of prescriptions. Hong Kong's overall volume of antibiotic use increased between 2000 and 2015 [27], antibiotics were dispensed in 29.2% of all hospital admissions in public hospitals, and the annual proportions of hospital admissions with antibiotics dispensed increased from 27.87% in 2000 to 31.39% in 2015.

Chinese antimicrobial stewardship programs

The WHO has designated antimicrobial resistance (AMR) as a major health priority and developed action plans. The establishment of antimicrobial stewardship programs (ASPs) [28] advocated as a key intervention to reduce antibiotic consumption and multidrug-resistant (MDR) bacteria. Resolution WHA68.7 (2015) adopted the global action plan on antimicrobial resistance [29,30], laid out five strategic objectives: to improve the awareness and understanding of antimicrobial resistance; to strengthen knowledge through surveillance and research; to reduce the incidence of infections; to optimize the use of antimicrobial agents [28]; and to develop an economic model for sustainable investment and to note the progress made by establishing the Global Antimicrobial Resistance Surveillance System (GLASS).

In 2019, the Global Antimicrobial Resistance, Prescribing and Efficacy Among Neonates and Children (GARPEC) network conducted antibiotic prescribing surveys, and it was the first global study [31] to describe the paediatric patterns of WHO's Access, Watch and Reserve classification, encompassing antibiotic prescriptions for 23,572 patients from 56 countries. The Denver Health Medical Centre developed a methodology [32] to evaluate antibiotic usage across inpatient and ambulatory care sites in an integrated healthcare system. A total of 10.9% of the patients received antibiotics. Of all antibiotics prescribed, 54.1% were from ambulatory care, 38.0% were from the hospital and 7.8% were perioperative. Emergency departments/urgent care centres, adult outpatient clinics, and noncritical inpatient wards accounted for 26.4%, 23.8%, and 23.9% of antibiotic use, respectively. Only 9.2% of all antibiotics are administered in critical care units.

There are several operational national surveillance networks for the monitoring of bacterial resistance, both of which are well known in China [33]: CARSS (China Antimicrobial Resistance Surveillance System, http://carss.cn/) and CHINET (China Antimicrobial Surveillance Network, http://www.chinets.com). In 2016, 1,273 hospitals from Chinese all provinces participated in the CARSS, including tertiary hospitals (75%) and secondary hospitals (25%). In 2016, a total of 2,727,605 bacterial strains were included for analysis. CHINET currently includes 34 hospitals and 30 tier 3 hospitals, of which 5 are children's hospitals and 4 tier 2 hospitals, which represent 25 provinces covering 960 million people in China. Antimicrobial susceptibility data for more than one million clinical isolates were collected and put into the CHINET database.

The Status Report on Antimicrobial Administration and Antimicrobial Resistance in China (2019) [34] was issued by the NHCPRC. In 2018, the proportion of antibiotics encountered in inpatients was 36.4%, the proportion of antibiotics prescribed in outpatient care was 8.9%, and the DDD of 2018 was 49.7. In Pakistan, the core drug use indicators in two tertiary care hospitals in Bahawalpur [6] showed that 51.5% of prescriptions had an antibiotic prescribed. Core drug use indicator studies from developed and developing countries were different [35,36], such as the antibiotic percent of Saudi Arabia [37] (32.2%), Sweden (10.4%), Kuwait (39.1%), Bahrain (26.2%), Egypt (39.2%), Brazil (37%), Swaziland (54.2%); and the injection percent of Saudi Arabia (2%), Sweden (0%), Kuwait (9.1%), Bahrain (8.3%), Egypt (9.9%), Brazil (11%), Swaziland (38%).

Conclusion

Based on the analysis of HFTP women and children's real-world data, our medical centre achieved the national goals. Our core drug indicators and economic investment have improved over time, and strict antimicrobial stewardship programs are the main reason that led to the rational use of drugs. Many factors affect women's and children's health, pharmaceutical quality control, rational use of drugs, antimicrobial stewardship programs and economic investment were in part responsible for the low maternal and infant mortality rate in HFTP.

List of abbreviations

AMR	antimicrobial resistance
ANOVA	Analysis of variance
ASP	antimicrobial stewardship program
ATC	Anatomical Therapeutic Chemical
CARSS	China Antimicrobial Resistance Surveillance System
CHINET	China Antimicrobial Surveillance Network
DDD	defined daily dose
EPMM	ending preventable maternal mortality
GNI	gross national income per capita
HFTP	Hainan Free Trade Port
INRUD	International Network for Rational Use of Drugs
MMR	maternal mortality ratio, maternal deaths per 100,000 live births

NHCPRC National Health Commission of the People's Republic of China
NMR neonatal mortality rate, neonatal deaths (0–27 days) per 1000 live birth
TCM traditional Chinese Medicine

Disclosure statement

No potential conflict of interest was reported by the author(s).

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Availability of data and material

The datasets are available from the corresponding author.

Consent for publication

The manuscript represents valid work, and the manuscripts are enclosed in the submission. The results/data/figures in this manuscript haven't published elsewhere; they aren't under consideration by another publisher.

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