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Healthcare Providers' Accounts of Influences of Antibiotic-Related Reforms on their Behavior with Respect to the Use of Antibiotics for Children: A Qualitative Study in China

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Abstract

Purpose: High and inappropriate pediatric use of antibiotics by healthcare providers is a key driver of antibiotic resistance in China. The Chinese government initiated a programme of antibiotic-related reforms in 2011 after a wider healthcare reform in 2009. However, very few studies shed light on the influence of these reforms on providers' antibiotic-related behavior; only one qualitative study of providers' perspectives and experiences has been undertaken. Therefore, our qualitative study aims to explore the influence of the 2009 and 2011 reforms on providers' pediatric antibiotic use.

Methods: Qualitative interviews were conducted with 26 providers in Taiyuan city, a typical Chinese city in central China in 2016. Interviews were transcribed verbatim, translated from Chinese to English, and analyzed using framework analysis.

Results: Healthcare providers described how their behavior was influenced by the availability of diagnostic testing. They also pointed to financial considerations and pressures, as well as other healthcare institutions within China's healthcare system that influence their antibiotic-related behavior.

Conclusions: As far as we are aware, this is the first city-based qualitative study in China providing evidence of the influences of the 2009 and 2011 reforms on providers' antibiotic-related behavior. It points to issues around the enforcement of antibiotic-related reforms in community health institutions and retail pharmacies, and highlights the importance of understanding the reforms' influences on provider behavior within China's healthcare system as a whole.

Keywords: Diagnostic facilities; Financial considerations; Essential Drug List; Zero mark-up; China's healthcare system

Abbreviations: ABR: Antibiotic Resistance; OTC: Over-The-Counter; EDL: Essential Drug List; ZMU: Zero Mark-Up; CHIs: Community Health Institutions; GPs: General Practitioners; AST: Antimicrobial Sustainability Test; HICs: High Income Countries; LMICs: Low and Middle-Income Countries

Introduction

China has been seriously affected by antibiotic resistance (ABR) [1], which is driven by its high rates of antibiotic use [2-4]. Paediatric use of antibiotics by healthcare providers (hereafter ‘providers’) is recognized to be a particular challenge, with evidence of high pediatric prescription rates for child patients using hospital outpatient clinics and primary healthcare [5-8], as well as a widespread purchase of over-the-counter (OTC) antibiotics for children accessed from retail pharmacies [9], which is officially forbidden [10].

The Chinese government’s concern about the inappropriate use of antibiotics resulted in the Ministry of Health, now the National Health and Family Planning Commission, initiating a set of antibiotic-related reforms from 2011 [11,12]. These reforms mainly included the introduction of a three-year strategy ‘National Special Campaign of the Clinical Use of Antibiotics’ – to promote appropriate use of antibiotics from 2011 to 2013 [11]. One of key features of this strategy is the requirement that physicians adhere to guidelines regarding the prescribing of antibiotics; this should follow a careful check of patients’ clinical presentation and laboratory test results [13]. The strategy has been underwritten by the ‘Administrative Regulations for the Clinical Use of Antibiotics’, the strictest regulation in China so far in terms of antibiotic use [11,12].

The 2011 reform built on wider healthcare reforms introduced in 2009, which included policies removing financial incentives from drug prescriptions and designed also to promote the appropriate use of antibiotics [14-16]. Specifically, the government sought to increase access to safe and cost-effective medicines and, at the same time, reduce over-prescribing and use of expensive drugs [17]. The key measures to achieve these goals were the introduction of the Essential Drug List (EDL), supported by the zero mark-up (ZMU) policy. Reducing the high cost of prescription drugs was one of the five priorities of the 2009 reforms relating to prescription drugs [15,18], and the ZMU policy achieved this by removing the profit margin from drugs sold to prescribers. The EDL is a list of medicines that are most effective and safe, and can be

equitably accessed by the public at reasonable price [19]. The latest version, the National Essential Drug List (2012 edition), consists of three parts, including chemical and biological medicines, Chinese traditional formulated drugs, and traditional Chinese cut crude herbs; across these three groups, there are 43 types of antimicrobials [19]. The first stage of the implementation of the EDL and ZMU is at the primary level with the final goal of expanding these policies to the hospitals [18]. To date, the EDL and ZMU policies requiring all national essential drugs to be stocked and dispensed with zero mark-up (no mark-up between wholesale and retail price), have been widely implemented in primary care institutions [14,20]. These policies also encourage hospitals to make the procurement and provision of national essential drugs a priority and ensure that a minimum of the drugs used by hospitals are from the EDL. In addition, the ZMU policy was scheduled to be implemented in all urban public hospitals by 2017 [14,21,22]. Other parts of the 2009 reform, such as expanding the health insurance coverage, have also impacted on providers’ antibiotic-related behavior [15,16].

Understanding the influence of reform on providers’ behavior with respect to pediatric use of antibiotics is of great importance. However, although studies have suggested that the high rates of antibiotic use declined in China’s hospitals after the 2011 reform [23-25], there is little evidence on the reforms’ influences on providers’ antibiotic-related behavior, particularly the pediatric use of antibiotics [26-29]. Qualitative methods, which generate detailed data for our study, are increasingly used to capture provider perspectives and the perceived influences on their behavior [30,31]. However, only one qualitative study [29] conducted in a rural setting was located via our search of English-language (MEDLINE Ovid) and Chinese (Chinese National Knowledge Infrastructure) databases. The marked differences in socio-economic development across China – particularly differences in healthcare resources and health-related policies – mean rural-based studies may not capture influences on providers’ behavior in urban settings [32]. In addition, the study of Zhang et al. did not focus on the influence of the reforms, but explored more general factors related to village doctors’ antibiotic-prescribing decisions for children under 15 years old with upper respiratory tract infections [29]. Our qualitative study builds on the limited evidence. It explores providers’ perceptions of antibiotic-related reforms’ influences on their behavior with respect to antibiotic use for children in a city with a profile typical of mainland China.

Study Context and Methods

In China, hospitals are the cornerstone of the healthcare system [33]. While the primary care system, including community health institutions (CHIs) in urban areas, is weak, it is growing rapidly [14,32,34]. The CHIs can be further divided into community health centers and smaller community health stations. Most hospitals and CHIs have their own pharmacies and these hospital pharmacies still dominate China's pharmaceutical sales [14]. However, in recent years, retail pharmacies have become a rapidly growing sector, with an average 20% growth in annual pharmaceutical sales from 1978 to 2009 [9]. Retail pharmacies are expected to be staffed by pharmacists who are present during opening hours to provide pharmaceutical services [35]; however, it is not always the case and other staff, such as sales staff, can sell prescribed drugs in retail pharmacies [9,36,37]. Our qualitative study included providers in these different sectors. For the hospital sector, we included pediatricians working in outpatient departments along with hospital pharmacists; for the primary care sector, we included general practitioners (GPs) and community pharmacists working in CHIs; and for the retail pharmacy sector, we included retail pharmacists and sales staff working in retail pharmacies.

Our study, using semi-structured interviews, was piloted and conducted with providers in Taiyuan city, a medium-sized city in China with average wealth and health expenditure [38,39]. In line with other qualitative studies conducted in Asian countries with Confucian-

based cultures [40,41], both the study sites and participants of our study were enrolled via personal connections and social networks. This method, which has been confirmed by pilot work, was adapted to the cultural context of China, where the anonymous and formal methods associated with surveys based on random samples can reduce the study validity, for example through study participants giving what they perceive to be socially approved answers (social desirability bias) [42]. The study sites were accessed through senior-level staff, and in total three hospitals, six CHIs and five retail pharmacies were successfully enrolled. One potential study site (a CHI) refused. Study participants were then introduced by the senior-level staff, with additional participants suggested by those already recruited to the study.

Data Collection

The final sample consisted of 26 providers, including six pediatricians and four hospital pharmacists from three hospitals' pediatric outpatient department and pharmacy, six GPs and two community pharmacists from different CHIs and eight providers (including four retail pharmacists and four sales staff) in five retail pharmacies. The majority of participants were female (20/26) and aged 40 to 49 (14/26) (Table 1). No participants refused to take part or withdraw the study. The option of a further fieldwork period was not pursued as a consistent set of themes had been identified from these interviews.

	Sex		Age			position
	Male	Female	30-39	40-49	50-	
Paediatricians	2	4	3	3	0	Physician-in-charge
GPs	3	3	1	2	3	GP
Hospital pharmacists	1	3	2	2	0	One chief pharmacist;
						one deputy chief pharmacist;
						two pharmacists-in-charge
Community pharmacists	0	2	0	2	0	One deputy chief pharmacist;
						one pharmacist-in-charge
Retail pharmacists	0	4	0	4	0	pharmacist
Retail pharmacy staff	0	4	3	1	0	Retail pharmacy: sales staff

Table 1: Participant profile.

Interviews were undertaken using interview guides (Appendix A) informed by evidence from earlier studies and revised in the light of pilot work. One-to-one interviews were conducted (from April to July 2016) face-

to-face by TZ in Chinese at participants' work places with no other providers present. The interviews were recorded by either audio-recorder or notes, according to participant preferences, with the duration ranging from 15 minutes to 90 minutes. After each interview, field

notes were used to record additional information, such as the settings and the researcher's feelings.

Ethics Statement

Ethical approval was granted by the Research Governance Committee of Department of Health Sciences, University of York. All ethics-related documents were translated into Chinese. No incentives were offered to participants and informed consent was obtained from all participants.

Data Management and Analysis

Audio-recorded interviews were transcribed verbatim and then translated from Chinese to English by TZ; translations were discussed with HG and PW for ambiguities of meaning (e.g. Chinese concepts without an English equivalent) prior to data analysis.

Data were analyzed using framework analysis, a qualitative data analysis method increasingly used in health research, which progresses through a set of stages [43,44]. Transcripts were read and re-read, and then views and experiences that recurred within and across the transcripts were noted and collated into themes by TZ to build an overarching framework. The draft framework was discussed and refined by the study team. Each transcript was then indexed using the themes in the framework by TZ. The themes and subthemes were then discussed and refined by the study team. Participants are identified below by provider group (pediatrician, GP, hospital pharmacist, community pharmacist (based in CHIs), retail pharmacist and retail pharmacy staff) and study participant number.

Results

The antibiotic-related reforms were noted by most participants as an influence on their antibiotic-related behavior. These influences clustered into broad themes, including

- a) provider facilities (discussed by 23 providers),
- b) financial considerations (16)
- c) the influence of other healthcare institutions (16).

Provider Facilities

Most providers noted the important role of provider facilities, particularly the laboratory-based blood tests, in their decisions related to the use of antibiotics for children. For example, in response to questions about

how to diagnose diseases and make antibiotic prescribing decisions for children, providers noted:

'We will mainly base decisions [to prescribe antibiotics for ill children] on the blood test result. If the result indicates that the ill child's disease is a bacterial infection, we will use antibiotics.'[GP2]

'This....one thing is the blood test. If the [result] of the blood test indicates that the disease is a bacterial infection, I will consider [prescribing antibiotics]. This is the most important one.'[Pediatrician 2]

'For the use of antibiotics, we will either base [the decision] on our clinical experience or the results of antimicrobial sustainability test (AST).'[Hospital pharmacist 3]

Providers' accounts also indicated that blood-testing facilities were widely available in hospitals and CHIs, enabling providers to obtain results quickly.

'The blood test is fast. [It takes] half an hour to [get the result], generally. For the mycoplasma test... the result will be available in the afternoon if you do it in the morning, and you will get the result tomorrow if you do it in today's afternoon.'[Pediatrician 2]

While some providers regarded the results of laboratory test as the most important factor in their clinical decision-making, the limitations of diagnostic facilities were also widely pointed out. These included the limited availability of test facilities in community health stations and their relatively low accuracy; moreover, there was a delay on obtaining results for some types of tests, which led providers to base their antibiotic prescribing decisions only on their clinical experience.

'I will ask them to do the blood test [in the hospital near us if parents demand antibiotics for their ill child]. For community health centers, they can do the blood test in their centre; however, our community health station cannot do the blood test.'[GP1]

'As the results of sputum culture and AST cannot be obtained as quickly when patients come to the hospital – for AST, the results can only be obtained after three days – the use of antibiotics in the first three days is all based on the physician's experiences.'[Hospital pharmacist 3]

The shortage of other relevant healthcare-related resources, such as inpatient beds, was also mentioned by

providers as factors influencing their antibiotic prescribing behavior.

'Inappropriate prescriptions are relatively common due to the inadequate health resources. For the pediatric department, patients will crowd into the whole department in the winter. Therefore, for antibiotics like cephalosporin, the regulated use, which should be used two or three times per day by intravenous infusion, cannot be achieved?' [Hospital pharmacist 1].

Financial Considerations

None of providers referred to financial pressures and incentives as influences on the use of antibiotics in hospitals, even though the ZMU policy has not been implemented in the hospital in Taiyuan city during the fieldwork period. Conversely, providers from all the different groups noted that financial concerns were a major factor in shaping providers' antibiotic-related behavior in retail pharmacies.

'Well, I think the commercial interests do not have impacts on the hospital. Our hospital will only earn 15% of the drug retail price as a profit. ...Moreover, a new policy [ZMU policy] which stops the hospital from earning money by selling drugs has been introduced in many provinces, and it will be implemented in Shanxi province soon' [Hospital pharmacist 1]

'The [retail] pharmacies are run for [profits]. After all, they are heavily influenced by the market, so they will put making a profit in the first place.' [Pediatrician 2]

'The profit [is the main influence on the sale of antibiotics in retail pharmacies]. They, particularly the small scale pharmacies, [sell drugs] as they think it can make a profit. The sale of antibiotics can also make a profit, although the profit might not be very high.' [Retail pharmacy staff 3]

For CHIs, although some CHI-based providers noted that EDL and ZMU policies had been fully followed in their workplace and financial factors were no longer an influence on their use of antibiotics, the majority acknowledged that financial considerations would influence providers' antibiotic-related behavior in CHIs, particularly for those working at community health stations.

'All drugs we use here belong to the EDL; we can only use drugs from this list. ... We don't earn profit from it [selling

drugs], and the retail price of drugs is equal to the procure price.' [GP1]

'They [community health stations] should sell drugs mainly based on the EDL, but actually, they are mainly based on the amount sold and profit [when selling drugs].' [Community pharmacist in CHI2]

Influence of other Healthcare Institutions

Most providers pointed to an appreciation of how antibiotic use was the outcome of interactions between healthcare institutions. First, they noted that, overall, the set of policies issued since 2009 reform was better enforced in higher-level healthcare institutions, such as hospitals.

'The [enforcement of] antibiotic use regulation is [becoming more stringent] step by step, so the use of antibiotics [in the hospital] might be more regulated than the lower level [of healthcare institutions]. Yes, the higher the level of the medical institution is, such as the secondary A or tertiary A hospitals, the more regulated the use of antibiotics will be.' [Hospital pharmacist 3]

This more tightly-regulated sector is still the main healthcare provider in China and was preferred over CHIs by parents who additionally had access to OTC antibiotics from retail pharmacies. In consequence, hospital-based providers suffered from the pressures of high workload and limited time, which influenced their communication with parents during the consultation and, in turn, their antibiotic-related care of children. Providers in CHIs also noted how this hierarchical relationship influenced how they managed demands from parents for antibiotics for their child. This systems-level perspective ran across the interviews.

'Many patients will go directly to the hospital rather than visit a CHI first. Yes, I think the majority of our patients are like that [who will go to the hospital directly]. ... In the busiest period, we can see 50-60 children in one morning. So it will take 3-4 minutes to see one ill child. Yes, as you see 60 children within 4 hours, it takes 4 minutes for each child.' [Pediatrician 6]

'For some parents who insist and require us to use antibiotics for their ill child, as we seldom use antibiotics here, I will say like 'you need to do a test if you strongly require the use of antibiotics'. ...So in this situation, we actually transfer this type of patients to the hospital.' [GP1]

'As you come here and ask me to diagnose your child's disease, I will make my decision on your child about whether antibiotics are needed; but if you insist on demanding antibiotics, you can choose to go to the higher level hospital.' [GP2]

Providers also considered that the more tightly-regulated use of antibiotics in hospitals had worsened the antibiotic use in retail pharmacies. For example, some interviewees noted that pediatricians would ask patients to purchase unnecessary antibiotics from retail pharmacies, as prescriptions issued within the hospital were restricted by regulations. For these interviewees, including some pediatricians and hospital pharmacies, retail pharmacies were regarded as a solution when faced with parents who made strong demands for antibiotics.

'On one hand, these physicians understand antibiotics should not be used for particular diseases and they are afraid of the checks and punishment from the hospital; on the other hand, they still feel it is too risky to not prescribe antibiotics even though antibiotics are not needed. Therefore, they choose to prescribe antibiotics and ask patients to buy them out of the hospital, so the hospital cannot find out about their inappropriate antibiotic prescribing behavior.' [Hospital pharmacist 1]

'Professionally I may consider that it [antibiotics] is unnecessary for their child, but if you [parents] really want it [antibiotics], you [parents] can find other ways to get it.' [Pediatrician 5]

As policies issued under the 2009 and 2011 reforms were not mainly focused on retail pharmacies, the enforcement of this set of policies in retail pharmacies was not explicitly discussed by providers. However, study participants in all provider groups pointed to the poor enforcement of other regulations in retail pharmacies as a factor influencing providers' antibiotic-related behavior, such as the illegal selling of OTC antibiotics. Further, most providers in retail pharmacies regarded hospitals and CHIs as the primary source of inappropriate antibiotic-related behavior. As most consumers did not have medical-related knowledge, they would strictly follow doctors' prescriptions when purchasing antibiotics in retail pharmacies.

'Uh...anyway, the abuse of antibiotics has become very common in China now as the enforcement of regulations in this area [retail pharmacies] is ... [less stringent].' [Retail pharmacy staff 1]

'Therefore, the doctor is the key. As most families only have one child, parents usually bring their child to the hospital [when they are unwell], and most of them will comply with the doctors' suggestions. They will purchase drugs strictly based on the prescriptions no matter what kinds of drugs are prescribed by doctors.' [Retail pharmacist 1]

'I think the major factors [influencing the sale of antibiotics in the retail pharmacies] are [antibiotics prescribed from] hospitals and requirements [from consumers].' [Retail pharmacy staff 2]

Discussion

As far as we are aware, this is the first city-based qualitative study in China exploring providers' perceptions of the influences of the 2009 and 2011 reforms on their antibiotic-related behavior. Similar to other qualitative studies [45-47], our study has limitations related to its small sample size. Additionally, it is cross-sectional and therefore cannot compare providers' views pre and post reforms, but relies on comparisons that providers made about practices prior to and following the reforms. However, its qualitative design provides insight into provider perspectives. The research team has an interdisciplinary background with one female Chinese researcher and two UK researchers (male and female) from different research areas. This facilitated the validity of the study through data interpretation by researcher familiar with Chinese cultural values, who, additionally, was able to clarify any language or culture-related ambiguities; moreover, the use of personal contact recruitment methods reduced potential social desirability bias in a Confusion-based country [48].

As the important role of laboratory-based blood tests in making antibiotic-prescribing decisions was highlighted in the three-year strategy, most providers in our study noted provider facilities as an influence on their antibiotic-related behavior. However, they also pointed to concerns about the lack of diagnostic facilities which made it difficult to adhere to these policies and could work against their appropriate use of antibiotics, concerns which were particularly evident at primary care level. This fits with findings from the qualitative study of Zhang et al. conducted after the reforms, which indicated a lack of diagnostic tests in village clinics of rural China and its influences on doctors' inappropriate antibiotic-related behavior [29]. Moreover, the limitations of quality-assured diagnostic facilities at primary care level have been reported by a nationwide survey in China [49]; this problem was also highlighted as a challenge among

low and middle-income countries (LMICs) resulting in delayed or inaccurate diagnosis and therefore ineffective treatment, which related to gaps, such as basic equipment and laboratory supplies [50].

Our study identified that financial considerations were another factor influencing providers' use of antibiotics. However, only a few participants pointed to the influence of finance-related policies (the EDL and ZMU policies), even though this set of policies is one of five priorities of 2009 reform [33]. Moreover, a key aim of this set of policies is to reduce financial incentives from prescribing unnecessary drugs at primary care level, with the expectation that the policies will be implemented in other healthcare institutions, such as tertiary hospitals [49,51]. However, providers' accounts suggested that financial considerations in different healthcare institutions were not in line with the policies' focus, with evidence that making profits from antibiotic prescriptions was still regarded as a factor related to the use of antibiotics in CHIs. These findings are similar to studies undertaken in various provinces in China, which noted that the EDL and ZMU policies had no effect on the inappropriate use of antibiotics among primary care institutions [52-54], even in the period after the introduction of 2011 reform [51,55,56].

In the studies of high income countries (HICs), the high workload and limited time have been identified as factors that influenced providers' antibiotic-related behavior for children in primary care [57,58]. These factors were also noted by providers in our study; however, they appeared to combine in different ways among providers working in different parts of China's healthcare system, pointing to the interactions between different healthcare institutions. Along with previous findings related to provider facilities and financial considerations, our study further identified the structure of China's current healthcare system as an overarching factor shaping the reforms' influences on providers' use of antibiotics for children.

The overutilization of hospitals for all forms of healthcare provision is a long-standing problem in China; even after the 2009 healthcare reform, hospitals remain the main healthcare provider [32], with higher levels of trust and resources than primary care institutions [14,49,59]. High patient demand and the resulting pressure on the hospital pediatricians evident in our study required them to maintain high levels of patient throughput, a factor that appeared to increase pressures on them to prescribe antibiotics.

Compared to the hospitals, China's primary care system is weak and faces multiple challenges, including underutilization by the public and under-resourcing [14,49]. Studies note that patients were not switching from hospitals to primary care system after the first few years of 2009 reform [14]. Consistent with this picture, providers in our study who worked at CHIs did not report the workload pressures described by the hospital pediatricians. Moreover, despite increased government subsidies at primary care level since the 2009 reforms, staff in the CHIs is still facing problems of low incomes compared with hospitals [49], which meant that, in our study, financial concerns were more evident in CHI-based providers' antibiotic-prescribing decisions. In addition, although the importance of the EDL and ZMU policies was underlined by 2009 reform, there is no national pharmaceutical policy framework in China, which has been found to undermine their enforcement [14]. These problems in the healthcare system as a whole have made it difficult for China to realize the aims of 2009 and 2011 reforms.

The retail pharmacies are a relatively independent sector in China's healthcare system, which are supervised by China Food and Drug Administration and were not the focus of the antibiotic-related reforms [32]. Similar to studies investigating the antibiotic distribution in China's retail pharmacies [9,36,60], we found that antibiotics were inappropriately used in retail pharmacies due to poor enforcement of regulations and financial incentives. In addition, while our data are derived from a small-scale study, they suggest that the more regulated use of antibiotics in hospitals and CHIs as a consequence of the reforms has had some perverse effects. In particular, it may have resulted in retail pharmacies, with poorer enforcement of antibiotic-related regulations, becoming a more significant source of unnecessary antibiotics. For example, consumers could purchase unnecessary antibiotics prescribed by doctors from the retail pharmacies, or, as none of retailers in our study mentioned the need for a prescription, they could get over-the-counter antibiotics from retail pharmacies when doctors refused their antibiotic demands. This points to the importance of interactions between healthcare institutions with, in this instance, policies to promote appropriate antibiotic use having the effect of transferring the inappropriate use of antibiotics from institutions which have introduced more stringent enforcement systems to those with poor enforcement.

Conclusion and Implications

Our study adds important evidence on providers' perceptions of the reforms' influences on their behavior with respect to the use of antibiotics for children. Undertaken five years after the most recent antibiotic-related reform, the 2011 reform, this study has highlighted provider facilities, financial considerations and other influences from healthcare institutions as being important determinants of antibiotic prescribing behavior for children.

Our study points to the importance of strengthening the relatively weaker parts of China's healthcare system. Strengthening the primary care sector through an increase of government investment and subsidy is in line with the Chinese government's emphasis on primary care as a key aspect of its national plan [61]. Because of the lack of effective antibiotic-related regulations on the retail pharmacies, further policies and reforms focusing on the retail pharmacy sector are also clearly required. Additionally, antibiotic-related policies and reforms should take the China's current healthcare system as a whole into consideration, which was identified as an overarching factor shaping the reforms' influences on providers' pediatric use of antibiotics.

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