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**Analysing the implementation of antibiotic stewardship policies
in China: a study of the Nationwide Special Rectification
Campaign on Hospital Antibiotic Use**

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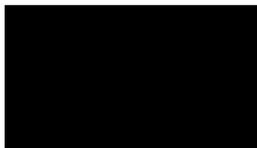
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Declaration

I, Lishi Li, confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

Signed

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Lishi Li

Abstract

China has been introducing antibiotic stewardship policies since the early 2000s to address the persistent and pervasive problem of irrational antibiotic use in hospitals. A recent set of antibiotic stewardship policies were set out between 2011 and 2013 in the Nationwide Special Rectification Campaign on Hospital Antibiotic Use (*The Campaign*).

Drawing on implementation theories, this thesis examines the implementation of *The Campaign* in respect of factors pertinent to both its context and process, and how these factors interacted. The thesis is based on qualitative data gathered using in-depth interviews and semi-structured interviews over two phases of fieldwork. Phase 1 analysed the perspectives of multiple actors at central (governmental organisations) and hospital levels (6 hospitals in urban Beijing, including a national tertiary hospital). Phase 2 – a case study focused on a single hospital – analysed the perspectives of actors from a typical secondary hospital in urban Shanghai.

It was found that top-down implementation – characterised by clear line of accountability, target approach, punitive measures and redundancy of policies – was evident at both the central and hospital levels. However, *The Campaign's* approach to focus on secondary and tertiary hospitals was strongly shaped by the organisation, delivery and financing of China's healthcare system and its relevant reforms. Implementation at the hospital level was heavily influenced by contextual factors at system (healthcare system), organisation (hospital and clinical settings) and individual levels (prescribers and patients). Rational prescribing practices were driven in part by *The Campaign's* interaction with some of those factors, but more crucially by frontline implementers' active adaptation in response to the local context and needs. In recognising the potential of the top-down approach, the findings also highlight the need to better involve frontline implementers, align wholistic healthcare reforms and understand the complexity of policy interactions in the implementation of antibiotic stewardship.

Dedication

For Helena and Bertrand

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List of Abbreviations

CARSS	China Antimicrobial Resistance Surveillance System
CAS	Centre for Antibacterial Surveillance
CERDU	Committee of Experts on Rational Drug Use
CFDA	China Food and Drug Administration
CHA	Chinese Hospital Association
CMA	Chinese Medical Association
CPA	Chinese Pharmacists Association
CPhA	Chinese Pharmaceutical Association
CSO	Civil Society Organisation
DDD	Defined Daily Dose
DID	Defined Daily Doses for 1000 Inhabitants Per Day
DTC	Drug and Therapeutic Committee
FRP	First Responsible Person
MoH	Ministry of Health
NCMS	New Cooperative Medical System
NHFPC	National Health and Family Planning Commission
NIHA	National Institute of Hospital Administration
TCM	Traditional Chinese Medicines
UEBMI	Urban Employee Basic Medical Insurance
URBMI	Urban Resident Basic Medical Insurance
WHO	World Health Organization

Chapter 1. Introduction

1.1 Introduction

This thesis presents an analysis of the implementation of antibiotic stewardship policies in China. To establish the rationale for, and the importance of this research, the introductory chapter first describes what antibiotics are, and establishes how problems in antibiotic use contribute to the problem of rising antibiotic resistance and how antibiotic stewardship policies can solve this problem by regulating antibiotic use in hospitals. Focusing on China, one of the biggest consumers of antibiotics, faced with huge challenges in rising antibiotic resistance, this chapter summarises existing knowledge of antibiotic use, resistance and policies in this country. With the research gaps identified, this chapter then describes the research aim, objectives and questions, and the study design used to address these questions. Finally, this chapter summarises the contents of each of the ensuing chapters.

1.2 Antibiotics, antibiotic resistance and antibiotic stewardship policies

The term “antibiotic”, which has been considered to be synonymous with “antibacterial” (Fleming, 1929; Waksman & Flynn, 1973; Blair *et al.*, 2015), refers to a vital class of pharmaceuticals that can inhibit or kill bacteria through specific interactions with bacterial molecular targets (Davies & Davies, 2010). In recent policy parlance, it is common for the term “antimicrobial” to be used with strong emphasis on “antibacterial” (MacDougall & Polk, 2005; Centres for Disease Control and Prevention, 2017), despite the fact that in a strict scientific sense, “antimicrobial” is a more inclusive term that encompasses chemical agents against microbes besides bacteria including viruses, fungi and parasites (Institute of Medicine of the National Academies 2010:428; World Health Organization 2016). Taking this into account, this thesis uses “antibiotic” as the predominant term to describe antibacterial; where “antimicrobial” is used in a policy context, it is considered to be equivalent to “antibiotic”, unless explained otherwise.

Antibiotic resistance refers to the ability of bacteria to become less susceptible than their counterparts to a specific antibiotic; in a clinical context, this refers to the ability of infectious bacteria to survive exposures to clinically relevant concentrations of antibiotics that would kill otherwise sensitive organisms of the same strain (Institute of Medicine of the National Academies 2010:428). At the molecular level, antibiotic resistance is a natural phenomenon that unavoidably arises through Darwinian selection, where bacteria react to the selection pressure of antibiotics (World Health Organization, 2012). At the individual human level, the emergence and spread of antibiotic resistance is accelerated by inappropriate exposure to antibiotics absorbed from the external world (Holmes *et al.*, 2016).

In formal healthcare settings, antibiotics are prescribed by prescribers and taken by patients to treat bacterial infections. However, antibiotic use in hospitals, particularly “irrational” antibiotic use – defined as unnecessary or inappropriate use in respect of criteria such as clinical relevance, dosage and dosing schedule (World Health Organization, 1985, 2002) – has proved to be a significant driver of antibiotic resistance (Steinke & Davey, 2001; Goossens *et al.*, 2005; Costelloe *et al.*, 2010). This is an especially concerning problem, considering that the global consumption of antibiotics in human medicine increased by nearly 40% between 2000 and 2010 (Van Boeckel *et al.*, 2014), and irrational antibiotic use is observed to be a severe problem in both the developed and the developing world: based on available data, recent studies found that around 50% of antibiotics in Southeast Asia (Holloway, 2011) and around 30% of antibiotics in the United States (Fleming-Dutra *et al.*, 2016) were unnecessarily prescribed.

The significant extent of global antibiotic resistance and its negative impact on the health of the individuals and societies have been increasingly recognised. According to one of the most comprehensive reports to date, it was observed that bacteria that caused common healthcare-associated and community-acquired infections carried very high rates of resistance in all WHO regions: in particular, both the resistance to some of the “last-resort” antibiotics (including carbapenems and third generation cephalosporins) and to some of the most widely used antibiotics (exemplified by fluoroquinolones) was very widespread across the world (World Health Organization, 2014). Commensurately, antibiotic resistance leads to an increase in morbidity, mortality and costs of treatments worldwide, affecting both low- and middle-income countries, and high-income countries (Friedman, Temkin & Carmeli, 2016;

Laxminarayan *et al.*, 2016c). An estimated 23,000 people in the United States and 25,000 in Europe die each year from resistant pathogens, whilst an estimated 214,000 neonatal sepsis deaths are attributable to resistant pathogens each year (Laxminarayan, Matsoso, et al. 2016; Laxminarayan et al. 2013; in Laxminarayan, Sridhar, et al. 2016). The resulting economic impacts due to healthcare costs and productivity losses are estimated to be huge, with the overall crude economic burden estimated to be at least €1.5 billion euros in Europe in 2007, and \$55 billion in the USA in 2000 (Gandra, Barter & Laxminarayan, 2014; Smith & Coast, 2013). Furthermore, as the effective lifespan of antibiotics is negatively affected by antibiotic resistance, rising resistance can lead to an “antibiotic apocalypse” where no more effective antibiotics are available against some of the most resistant bacteria; this is due to the fact that the current antibiotic pipeline is not producing new antibiotics to counteract the increase in resistant bacteria sufficiently quickly (Smith & Coast, 2013).

Hence, rationalising antibiotic use in hospitals is a crucial aspect to controlling antibiotic resistance and avoiding its detrimental consequences. This is mainly achieved through the implementation of antibiotic stewardship policies. At the hospital level, antibiotic stewardship policies are a set of coordinated interventions designed to improve rational antibiotic use with the goal of optimising antibiotic use to achieve the best clinical outcomes while minimising adverse events and limiting selective pressures that drive the emergence of resistance and reducing excessive costs attributable to suboptimal antibiotic use (Society for Healthcare Epidemiology of America, Infectious Diseases Society of America & Society, 2012). Besides stipulating treatment guidelines for specific clinical conditions and a formulary of pharmaceuticals available for prescription, antibiotic stewardship policies also introduce interventions of two broad categories: restrictive interventions (such as formulary restriction based on levels of professional authority) seeks to control prescribing behaviours, and persuasive interventions (such as training and education) seeks to improve prescribing behaviours (Davey et al. 2015:191). The implementation of these policies involves a multidisciplinary team comprising prescribers, pharmacists, microbiologists, epidemiologists and infectious disease specialists (Lee *et al.*, 2013), overseen by a management team that work closely with other administrative structures pertinent to pharmaceutical use and infection control, such as the drugs and therapeutics committee and infection control committee (Davey et al. 2015:192). To track the impact of the policies, a wide range of measures can be used to measure various aspects of antibiotic use in hospitals (Morris, 2014). For examples, antibiotic consumption can be

measured by the defined daily doses (DDDs) controlled for the population at risk of receiving antimicrobials over a specific period of time (Monnet, 2007), and frequency of antibiotic use can be measured by proportion of encounters with antibiotic prescriptions (World Health Organization, 2002). To further support these policies at the regional and national levels, it is crucial to develop and strengthen two broader policy domains pertinent to antibiotic stewardship. Surveillance of antibiotic use and resistance provides the basis for formulating, monitoring and evaluating interventions and strategies, and infection prevention and control helps reducing the spread of resistant bacteria and likelihood of infections within healthcare settings (Dar *et al.*, 2015; Jinks *et al.*, 2016; Farrar & Davies, 2016).

Despite the fact that the effectiveness of antibiotic stewardship policies for improving antibiotic use in hospitals is strongly established and widely supported by extensive evidence base (Davey *et al.*, 2013; Karanika *et al.*, 2016; Schuts *et al.*, 2016; Chandy *et al.*, 2014), antibiotic stewardship policies are not a requirement in all hospitals; thus, ensuring implementation of these policies is crucial (Plachouras & Hopkins, 2017). Outcomes of high-level policy discussions and reviews both suggest that at the local level, policy implementation requires approaches tailored to the local context, such as resources available, organisational characteristics and cultural elements (Wellcome Trust, 2016; Plachouras & Hopkins, 2017). At the national level, enforceable targets, coordinated actions and the strengthening of health and public health systems are crucial (Laxminarayan *et al.*, 2016a; Jinks *et al.*, 2016).

1.3 Antibiotic stewardship policies in China

As a major driver of increasingly high levels of antibiotic resistance observed in recent years (Zhang *et al.*, 2006; Wang *et al.*, 2010; Xiao *et al.*, 2011; Zhao *et al.*, 2012; Li *et al.*, 2014a), irrational antibiotic use has been an extensive and significant problem in China (Reynolds & McKee, 2009; Xiao *et al.*, 2013a). Different types of irrational use of medicines in China have been widely documented and summarised, exemplified by polypharmacy, overprescribing of antibiotics, over use of injections and wrong usage of antibiotics (Mao *et al.*, 2015). Behaviours related to irrational antibiotic use in China, as shown by extensive studies, are driven by a number of influential contextual factors at the system, hospital and individual levels, such as hospitals' economic incentives to profit from prescribing, prescribers' and patients' lack of

knowledge (Mao *et al.*, 2015; Reynolds & Mckee, 2011), and deteriorating prescriber-patient relationship (Hesketh, Wu & Mao, 2012; He, 2014).

Despite the lack of official or comprehensive data, multiple studies have corroborated that the levels of antibiotic use in hospitals in China is likely to be higher than that of developed countries both at the primary care level (Hui *et al.*, 1997; Dong, Yan & Wang, 2008; Li *et al.*, 2012; Wang *et al.*, 2014a) and at higher levels of hospitals (Li *et al.*, 2013; Sun *et al.*, 2015a). A very wide range of estimates for the proportion of encounters with antibiotic prescriptions have been reported in past studies, mostly ranging between 30% to 80%, with the aggregated average standing at around 50% across all three levels of healthcare in China (Yin *et al.*, 2013). Whilst it is difficult to state a convincing number from these studies, a recent study conducted a direct benchmark comparison on antibiotic use between China and Sweden based on data from 2012 (Sun *et al.*, 2015a). Drawing on data from 35 hospitals sampled from the official surveillance network for antibiotic use in China and 7 university hospitals in Sweden, the study found that the proportions of encounters with antibiotic prescriptions in Chinese hospitals (10% for outpatient and 50% for inpatient) remained much higher than in Swedish hospitals (1.1% for outpatient and 34% for inpatient). However, signs of significant progress towards reducing antibiotic use were observed in China, as inpatient antibiotic consumption in Chinese hospitals decreased dramatically from 910 DDD/1000 inpatient days in 2008 to 473 DDD/1000 inpatient days in 2012, in comparison to 588 DDD/1000 inpatient days in Swedish hospitals (Sun *et al.*, 2015a). This is supported by observations in other studies based on national data on pharmaceutical sales, which showed that antibiotic use had been steadily decreasing since around 2011 (Geng, 2014; Xu & Gan, 2012; Zhu & Cheng, 2012; Sun *et al.*, 2015a; Tao *et al.*, 2013; Gan, 2012).

Several studies speculated that the observed decrease in antibiotic use in hospitals starting around 2011 was strongly linked to the implementation of a new set of antibiotic stewardship policies in China in the form of the *Nationwide Special Rectification Campaign on Antibiotic Use in Hospitals* (*The Campaign* for short) between 2011 and 2013 (Sun *et al.*, 2015a; Tao *et al.*, 2013; Gan, 2012; Xu & Gan, 2012). Preceded by a series of policies set out by the Ministry of Health of China (now National Health and Family Planning Commission) since the early 2000s, *The Campaign* represented the government's first major intensive effort to strengthen the enforcement of existing policies (Ministry of Health, 2011, 2012b; National Health and

Family Planning Commission, 2013), which covered all policy domains of antibiotic stewardship at both the hospital and the national levels, including introducing treatment guidelines and interventions to change prescribing behaviours, (Ministry of Health, 2004), setting up regional and national surveillance networks (Ministry of Health, 2005, 2006, 2009b), and strengthening the control of hospital-associated infections (Ministry of Health, 2000, 2004). At the same time, *The Campaign* especially emphasised a target approach to monitoring and managing antibiotic use in hospitals (Ministry of Health, 2008b, 2009a). Existing research and documents have provided a broad overview of *The Campaign*: the national policy context of *The Campaign* has been described by the policy documents and useful reviews (Cui *et al.*, 2017; Xiao & Li, 2015), and the impact of *The Campaign* has been studied by a number of evaluations or alluded to by studies of trends and patterns of antibiotic use. Although a clear causal link between *The Campaign* and reductions in antibiotic use is not yet established (further evidence on this will be presented in Chapter 3, Literature Review), these studies collectively paint a picture of a nationally driven stewardship intervention being seemingly effective at delivering its desired impact. However, the mechanisms through which the purported impact could plausibly take place—especially, with respect to the process of implementation and the necessitating changes in prescribing behaviour—remains very poorly understood. In particular, there have been only two published studies of the implementation of antibiotic stewardship policies in China, and neither adequately analysed the entire healthcare structure and context in which actors at the country and the hospital levels operated (Wang *et al.*, 2016; Jin *et al.*, 2011). Thus, there was a strong need to conduct a full analysis of the implementation of antibiotic stewardship policies in China, especially *The Campaign*, in order to understand the roles of central level and hospital level actors and factors.

1.4 Research questions and methodology

In light of the need to understand the implementation of antibiotic stewardship policies in general, and the research gap concerning China in particular, the overall aim of this research was to explore and analyse the implementation of *The Campaign* in China from 2011 to 2013 at the central and the hospital levels.

Drawing on implementation theory, which lent critical concepts – through top-down and bottom-up approaches to understanding policy implementation at different

levels – for understanding the contextual factors influencing implementation, and the factors crucial to the process of implementation, the three overall research objectives and the specific research questions for each objective were generated as below:

Objective 1: to understand the national policy context of antibiotic stewardship policies in China

- a. What reasons led to actions on antibiotic use in hospitals?
- b. Who were the key actors at the central level?
- c. What were the antibiotic stewardship policies to date?
- d. How did *The Campaign* relate to these policies?

Objective 2: to understand the healthcare system context in which implementation of *The Campaign* took place

- a. What did the system level context comprise?
- b. What did the hospital level context comprise?
- c. What did the individual level context comprise?

Objective 3: to explore and analyse the implementation process of *The Campaign*

- a. How was *The Campaign* implemented at the central level?
- b. How was *The Campaign* implemented at the hospital level?

In order to address these questions and understand “fundamental and searching questions about the nature of social phenomena” (Pope & Mays, 2006), the research adopted a qualitative approach. This fieldwork of the research came in 2 phases. In phase 1 it explored the perception and experience of policy implementation from the perspectives of policy actors including central officials, and managers, prescribers and patients from hospitals in urban Beijing. In phase 2 it analysed in detail the interaction between context and implementation process at the hospital level using a theory-driven case study (Yin, 2009), took place at a secondary hospital in Shanghai and included key actors including managers, manager-prescribers, prescribers and patients. In-depth interviews and semi-structured interviews were the main data collection methods.

Thematic analysis of data was conducted for each subgroup within each phase of fieldwork, before all the themes from all the subgroups were reorganised and integrated based on a theoretical framework constructed using implementation theory,

which sought to describe and analyse policy implementation in respect of context and process, and their interactions at the two levels represented by the nested subgroups.

1.5 Contents of the thesis

This thesis will begin by a discussion of relevant theories on policy implementation in Chapter 2 (Theoretical Background), which contribute to the construction of a theoretical framework that lays the conceptual foundation for the study design and data analysis. This theoretical framework distinguishes context and process at different levels – macro and micro levels – of policy implementation and highlights their interactions.

This will be followed by a review of empirical studies in Chapter 3 (Literature Review). Two structured literature reviews were conducted to examine the empirical studies relevant to the overall research topic: the first review examined the impact of *The Campaign*, and the second examined implementation of antibiotic stewardship policies in various country contexts and of health policies in China. This review of the literature will establish the evidence base for on the impact of *The Campaign* and situate further research to understand its implementation. It will also identify the common themes in policy implementation from the findings of the studies, discuss the extent to which implementation theories are applied in the existing literature, and explain how this research will strengthen existing research through the use of empirical qualitative data from a comprehensive range of policy actors and the application of the theoretical framework used in the analysis.

The healthcare system background of China will be set out in Chapter 4 (Healthcare System Background). Three key aspects of China's healthcare system – governance and administration, organisation and delivery, and financing and provider incentives – will be described. How these arrangements could influence not only policy implementation, but also antibiotic use in hospitals will be explained. An overview of antibiotic use in hospitals in China will be provided, and how different levels of contextual factors pertinent to the healthcare system influence antibiotic use and prescribing will be explained.

A detailed description and analysis of the national policy background will be set out in Chapter 5 (National Policy Context), in which the rationale for antibiotic

stewardship policies in China, their development over a decade, and how the perceived lack of success in implementation led to *The Campaign*, will be explained.

The study design and methods for collecting empirical data in this research will be discussed in Chapter 6 (Study Design and Methodology). This chapter will explain the rationale for the use of qualitative research to understand implementation of *The Campaign* and describe the overall study design that encompassed two phases of fieldwork: phase 1 explored the perspectives of multiple actors at central and hospital levels in Beijing; phase 2 examined policy implementation at a secondary hospital in Shanghai using a case study design. A conceptual map of the study, which explains how the theoretical framework informs the study design, will be presented. This is followed by detailed descriptions of the selection of study sites, data collection methods and process, and methods of data analysis in the two phases of fieldwork. In describing the data analysis, an extended conceptual map will be presented to demonstrate how the conceptual framework is used to structure the result chapters. Ethical issues and commentary on the methodology used in this research will be discussed at the end of this chapter.

Results of the research will be reported in Chapters 7 (Policy Implementation at the Central Level), 8 (Policy Implementation at the Hospital Level, Part I: Analysis of the Perspectives of Multiple Actors from Hospitals in Beijing) and 9 (Policy Implementation at the Hospital Level, Part II: A Case Study of a Secondary Hospital in Shanghai). Chapters 7 and 8 reported results from phase 1 fieldwork in Beijing, and Chapter 9 from phase 2 fieldwork – a case study – in Shanghai. In analysing the interactions between context and process of the implementation of *The Campaign* at both central and hospital levels, these chapters will draw on the extended conceptual map presented in Chapter 6 (Study Design and Method).

The thesis will conclude with Chapter 10. The research will be summarised in relation to the aims and objectives. A critique of the methodology will be provided, in which the limitations of the study design and methods, and the measures taken to mitigate these limitations in the 2 phases of fieldwork will be discussed. The contribution of the thesis to knowledge will then be presented. This will be followed by a detailed discussion of the findings of this thesis and their implications for policies and future research.

Chapter 2. Theoretical Background

2.1 Introduction

As outlined in Chapter 1 (Introduction), this thesis concerns the implementation of antibiotic stewardship policies in China. This chapter establishes relevant theoretical frameworks to guide the analysis of policy implementation, and situates this research in relation to existing empirical studies which address similar or related issues.

Theories of policy implementation are examined: their development, perspectives and explanatory power are summarised and discussed. The development of implementation research saw the formation of different views on policy implementation; three main streams of theoretical approaches to understanding the implementation process have emerged: top-down, bottom-up and hybrid approaches. In discussing the implementation process, these approaches also address the concept of implementation context, particularly its role in influencing policy implementation.

The application of these theoretical ideas in empirical studies, or the lack thereof, is examined in respect of three research topics highly relevant to this research, namely implementation of antibiotic stewardship policies around the world, implementation of other health policies in China, and implementation of antibiotic stewardship policies in China. Common themes emerging from the findings of these studies are summarised.

The critical exposition of theoretical concepts and review of empirical studies highlight research gaps in the study of antibiotic stewardship policies both in empirical evidence on policy implementation and in application of implementation theory, and informs the generation of research questions and selection of theoretical perspectives for this research.

2.2 Overview of the study of policy implementation

This section discusses the study of policy implementation by describing its origin, subsequent development, and applications. A major theme of implementation studies concerns two seemingly opposing schools of thought: the top-down approach and the bottom-up approach. These approaches view policy implementation differently,

leading to different interpretations of the concept of implementation process. Both approaches recognise the importance of implementation context: discussion of implementation context is inherent to any kind of theoretical treatment of implementation process.

Origin and development of the study of policy implementation

The study of policy implementation as a distinct subject was formalised in the 1970s. Following the emergence of early works on implementation exemplified by Selznick's *TVA and the Grass Roots* (1949), formalisation of the field is represented by Pressman and Wildavsky's seminal study *Implementation: How Great Expectations in Washington are Dashed in Oakland* (1973), which pioneers the explicit use of "implementation" as an analytical term in reviewing and analysing the "implementation deficits" of federally funded job-creation schemes (Goggin, 1990; O'Toole, 2000; Schofield, 2001).

Central to driving the theoretical development of implementation research are the views and assumptions about the "processual" nature of policy implementation in relation to overall policy process that bridges "policy" and "action" (Schofield 2001).

Early research views policy implementation as a step separated from policy formation, comprising a distinct hierarchy of rational and linear processes (Schofield, 2001; Barrett, 2004). These intermediary administrative processes are considered to have a decisive role in translating formulated policies to policy goals and outcomes (Easton, 1965; Derthick, 1972; Ryan, 1995; Hill & Hupe, 2002). Although early research in the field aims to theorise these notions by examining the complexity of administration (Schofield, 2001) and develop causal relationship between policy implementation and outcome (Barrett, 2004), they tend to be explorative and inductive studies with "very few theoretical variables in focus" (Winter, 2006).

The central assumptions of this early research are examined and scrutinised in later research, where scholars have different opinions on the "relationship between implementation and other elements of the policy process" (Ryan, 1995). Consequently, three different approaches to understanding policy implementation emerge as scholars developed theoretical frameworks that could guide empirical analysis (Winter, 2006). For scholars who see policy implementation as a "top-down" process, policy

formulation is clearly separated from policy implementation. For scholars who emphasise the active role of the recipients in policy implementation and their power in formulating de facto policies on the ground, policy implementation is a “bottom-up” process, so that no distinctions can be drawn between policy formulation and implementation (Ryan, 1995). The divisions between these two perspectives, and their relative merits and limitations are described and discussed in greater detail in the next sub-sections.

The two contrasting perspectives of implementation are eventually reconciled using a “hybrid” approach, which views policy formulation and implementation as a continuum (Majone & Wildavsky, 1978). Marking a transition towards “more comparative and theoretical-deductive oriented” approaches (Saetren 2014, quoting Lester et al. 1987; Goggin et al. 1990; Hill & Hupe 2002), the hybrid approach seeks to validate the explanatory power of theoretical frameworks from previous works and develop more unified frameworks (Winter, 2006; Schofield, 2001).

The “top-down” and “bottom-up” debate

Heavily influenced by “the question of how to separate implementation from policy formation” (Hill & Hupe, 2002) as described in the previous sub-section, the top-down versus bottom-up debate is one of the dominant themes in the development implementation research. The following subsections focus on the two opposing approaches to understanding implementation, highlighting their differences and tensions.

a. Top-down approaches

Top-down approaches to understanding policy implementation focus on official, formal policies that typically have legal mandate from the central government (O’Toole, 1989), with a view to optimise the intended policy outcomes. Therefore, the perspective of analysis is largely pertinent to the government policy level, as policy is considered to be formulated “at the top” (Ryan, 1995). This view, as described in the previous sub-section, assumes that implementation is a separate and linear translation process between the Centre and “those who will implement the policy” (Schofield, 2001; Ryan, 1995). These assumptions are “a direct by-product of the rational, perfect public administration model” (Schofield, 2001). The concept of “control” – particularly “central control” – is emphasised in this perspective (Winter, 2006).

Despite “control” being a key concept, early implementation research rather focuses on the lack thereof, in the form of implementation problems, barriers, and failures (Schofield, 2001). For example, in addressing the extent of control required for successful implementation, Pressman and Wildavsky (1973) spend much of their analysis of a federally mandated programme at local level arguing that implementation very often involves multiple actors and is therefore dependent on numerous organisational and administrative linkages; based on probabilistically-based arguments, it is claimed that the cumulative deficits in each of these steps could ultimately create a large “implementation deficit” (Hill & Hupe, 2002). Whilst the pessimistic tone (Rothstein, 1998) per se is not necessarily a problem, early implementation research suffers weaknesses that require addressing. In particular, the assumptions about the negative impact of multi-actor involvement on the presumably ideal scenario of linear implementation, and the subsequent effectiveness of policy implementation is overly simplistic, leading to problematic exaggeration of the probabilities of failure (Bowen, 1982). In reality, policy implementation is likely to involve multiple actors, including state actors (actors in the government), and non-state actors (actors outside government) exemplified by civil society organisations (organisations which fall between the state and the individual or household) (Buse, Mays & Walt, 2012). However, multi-actor implementation could be a crucial factor of success rather than failure (O’Toole, 1986). Using the same probabilistically-based framework, it can be demonstrated convincingly that persistent and coordinated collaboration amongst different actors could improve the effectiveness of securing necessary clearances and reducing superfluous hurdles for policy implementation (Bowen, 1982).

Rather than stall on the impossibility of perfect control, the ensuing research seeks to elaborate assumptions, capture more dimensions of complexities of policy implementation, and address weaknesses of previous research by proposing explicit theoretical frameworks.

Influential top-down models of policy implementation with more iterated intermediary processes and multiple variables representing various influencing factors were developed, exemplified by the frameworks developed by Van meter and Van Horn (1975) and Sabatier and Mazmanian (1980). These frameworks still maintain a clear distinction between policy formulation and implementation. However, they recognise that policy formulation could affect policy implementation. Involvement of policy actors in the formulation phase may influence their compliance in implementation

(Van Meter & Van Horn 1975: p459), which could contribute to a “feedback process” that concerns the reformulation of policy based on experience of the implementation process (Sabatier, 1986). These frameworks also identify a range of variables linked to implementation processes, addressing influential factors such as content of policy, administrative mechanisms, policy actors and implementers involved, availability of resources, and the wider economic, social and political environment (Sabatier & Mazmanian 1980:544).

Another approach to achieve in-depth analysis of imperfect control is first to come up with ideal conditions that enable “perfect implementation” before examining the extent to which each condition could be met in the real world. Similar to “the way in which economists employed the model of perfect competition”, this approach imagines the best possible combination of “external elements” such as resource availability and political acceptability and “internal elements” concerning administration that could produce “perfect implementation” (Hood 1976:6). The work of Hogwood and Gunn (1985) is a prime example of this approach. In their framework, “external” and “internal” elements to policy implementation are considered in the form of ten “preconditions” for “perfect implementation”. These preconditions (Hogwood & Gunn 1984: 199-206) are as follows:

- The circumstances external to the implementing agency do not impose crippling constraints;
- That adequate time and sufficient resources are made available to the programme;
- That the required combination of resources is actually available;
- That the policy to be implemented is based upon a valid theory of cause and effect;
- That the relationship between cause and effect is direct and that there are few, if any, intervening links;
- That dependency relationships are minimal;
- That there is understanding of, and agreement on, objectives;
- That tasks are fully specified in correct sequence;
- That there is perfect communication and co-ordination;
- That those in authority can demand and obtain perfect compliance.

Intended for an audience at the government policy level, this model assumes a strong and democratically elected government dedicated to public objectives, and that

challenges to implementation arise because many of those “upon whom action depends” are not elected and they could be driven by private interests different from the government’s, “at least in the case of civil servants and the staff of health services, nationalised industries etc” (Hogwood & Gunn 1984:207).

The assumed alignment between central authority and local implementers, therefore, requires further examination. A key concept that elaborates this relationship is “accountability”. Whilst the term has multiple extended meanings based on the basic concept of one being “called to account” by an authority for one’s actions (Mulgan, 2000), a useful definition that captures core elements of the concept – “external scrutiny”, “justification”, “sanctions” and “control” (Mulgan 2000:557) – considers accountability to be “a relationship between an actor and a forum, in which the actor has an obligation to explain his or her conduct, the forum can pose questions and pass judgement, and the actor may face consequences” (Bovens, 2007). Two forms of accountability can be further identified. Whilst political accountability refers to the actions of elected officials being held to account by the electorate, and managerial accountability refers to delegated individuals being held to account by those in higher authorities against predetermined criteria pertinent to the responsibilities of interest (Day & Klein, 1987). Therefore, managerial accountability, as opposed to political accountability, provides more suitable dimensions to examine the technicalities of aligning central and local actors within lines of authority.

In considering the mechanisms through which managerial accountability can be strengthened – particularly programme accountability concerning outcomes of actors’ activities (Leat, 1988) – attention is drawn to the “targets approach”, exemplified by the example of the New Labour UK Government, which monitored the delivery and performance of public services in the UK using standards stipulated by the government (Hood, 2006, 2007). Three archetypes of this approach are summarised: target systems (aspirational standards expressed as numeric threshold), ranking systems (measurement of comparable units against one another) and intelligence systems (collection of background information and data that are not part of the previous systems) (Hood, 2007). Improved alignment and accountability in the “target approach” is achieved mainly through its punitive tendency. On the one hand, failure of implementers of public services to reach stipulated standards or attempts to abuse the system may lead to their sacking (Hood, 2006), a point that was made long ago by Voltaire in his observation of the management approach of the British naval

administration in *Candide, ou l'Optimisme* (1759): “Mais dans ce pays-ci, il est bon de tuer de temps en temps un amiral pour encourager les autres” (or “But in this country, it is sometimes good to kill an admiral to encourage others”). On the other hand, empirical research suggests that the ‘target approach’ creates greater tendency to punish failure than reward success in terms of generating electoral support for the government incumbents (Hood & Dixon, 2010). As a result, this approach has been shown to lead to better achievement of policy goals (Bevan & Hood, 2006a; Hood & Dixon, 2010) and deter gaming behaviours (Hood, 2006; Bevan & Hood, 2006b).

In addition to the target approach, it is noted that the deployment of multiple approaches to enhance alignment and accountability, such as setting up multiple mechanisms of inspection, and using professional bodies to improve regulation, can be reasonable rather than excessive (Allen *et al.*, 2016). Scott (2000:52-53) considers “redundancy”, in which “overlapping (and ostensibly superfluous) accountability mechanisms reduce the centrality of any one of them”, are the necessary results of both deliberate designs and contingency in response to changes in the system. In this sense, applying a combination of accountability mechanisms is a way to ensure alignment of central authority and local implementers in policy implementation. For instance, multiple regulatory measures for pharmaceuticals, such as through legal institution (Jayasuriya, 1985), official accreditation (Ensor & Weinzierl, 2007) and service monitoring by insurance payers (Maynard & Bloor, 2003) often exist in parallel with specific stewardship policies.

In the aforementioned top-down frameworks, the theoretical treatment of the implementation context is integral to that of policy implementation. Whether capturing variables in policy implementation or considering “perfect” conditions for implementation, the implementation context has been consistently conceptualised as macro level factors external to the implementation process and beyond the control of relevant policy actors, which can influence the implementation process and the behaviours of the actors (Hill & Hupe, 2002). Commonly, these are economic, social and political factors (Van Meter & Van Horn, 1975; Sabatier & Mazmanian, 1980) such as resource availability, public support, political support (Sabatier & Mazmanian, 1980; Hood, 1976; Hogwood & Gunn, 1984), technological advancements and media attention (Sabatier & Mazmanian, 1980).

To summarise, the top-down approach to understanding policy implementation assumes a strong central government. It views the policy process as linear and

phased, in which policy implementers are separate from and subordinate to policy formulators. Therefore, its outcome-oriented and prescriptive policy advice is aimed at helping central government better to align formulated policy with actors and factors crucial to its implementation. Accordingly, it expects to address a more macro level implementation context of the wider economic, social and political environment.

However, the applicability of three key assumptions of this model have been challenged and criticised: that there is a clear distinction between policy formulation; that policy implementation is linear and rational; and that policy implementation concerns a central perspective emphasising control (Schofield, 2001).

Firstly, the top-down approach does not address politics at the stages of policy design and formulation, which can complicate and influence policy implementation in the long-term (Nakamura & Smallwood, 1980; Winter, 1986, 2006). Moreover, as summarised by Ryan (1995), “the policy design and implementation often occur simultaneously through common actors” (Anon, 1981; Linder & Peters, 1987; Hjern & Hull, 1982) through an iterative process informed by experience gained during implementation (Majone & Wildavsky, 1978).

Secondly, policy implementation is hardly a linear and rational process. Quoting the work of Berman (1978) and Baier et al. (1986), Schofield (2001) points out that the top-down model lacks “a great deal of macro and micro political reality”, including complexity of politics and behaviours, and ambiguity and contradiction in policy goals. An example given by Ryan (1995) is “implementation discretion” (Thompson, 1982; Burke, 1987; Marsh & Rhodes, 1992), where the implementation processes vary “according to programs, internal structures and external conditions”.

Thirdly, immediately following the example of “implementation discretion” is the concern that the top-down approach over-emphasises the importance of the central government and at the same time, neglects the influence of the actual policy implementers (Sabatier 1986:30). Arguing against this the centre-focused top-down approach, scholars interested in the opposing bottom-up approach contend that front-line workers at “the bottom” of the implementation system are in fact key decision makers in the implementation process (Winter, 2006). For example, Elmore’s work shows that actors who actually carry out activities for policy delivery can influence policy implementation significantly (1979: 614). Schofield (2001) notes that these

“street-level bureaucrats” Lipsky (1980) are the actual “interpreters of central policy” (Thompson, 1982).

b. Bottom-up approaches

Bottom-up approaches to understanding policy implementation turn the policy process upside-down by emphasising the influential role of the frontline implementers – the “street-level bureaucrats” (Lipsky, 1980) – in policy implementation (Winter, 2006). However, the emergence of the bottom-up approach is not a reaction of the top-down approach: the two existed in parallel from the beginning. Moving attention away from the central government, the bottom-up approach emphasises the person who is employed to do a job for the government, and caught up in policies representing the grand ideals of those that are much higher up. Inevitably it challenges the procedural view of policy formulation and implementation. The implementation process is no longer seen as a rational and designed exercise that emphasises control and seeks to delivery policy goals; rather, the nature of implementation concerns the way individual implementers tackle the immediate problems in their policy-related jobs. Due to limitations in resources and capacities, street-level bureaucrats unavoidably experience a gap between the demand of the official policy and the actual workload involved in implementation (Winter 2006: 153). Thus, they have to develop routine and stereotyped coping strategies so as to get through a typical day’s work, whilst managing pressures and expectations associated with the demands of the policy (Hill & Hupe 2002: 52). In this way, the activities of the street-level bureaucrats effectively “become” the public policies that they are responsible for implementing (Lipsky 1980: xii). Therefore, the actual outcomes of policy implementation may deviate from the original policy objectives and intended goals (Nakamura 1987: 150).

As with the top-down approach, theoretical frameworks have been developed around the key conceptual elements of the bottom-up approach. For instance, Elmore develops “backward mapping” (1979) as a strategy to map out factors and structures that are immediate to implementers at various levels that can only be “indirectly influenced by policymakers”. As opposed to “forward mapping”, which stresses the centralisation of control, backward mapping stresses the dispersal of control, and demonstrates that organisational structures, processes and environments revolving around the understanding, incentives and behaviours of street-level bureaucrats are integral to policy implementation in reality. The implications are twofold. On the one hand, it is necessary for policy objectives and designs to carefully consider the

behaviours and capabilities of the target implementers and the resources available to them in their organisational settings (Ryan, 1995). On the other hand, it is necessary to clarify that implementation research can address two closely related but fundamentally different research questions, namely “how to study implementation” and “how to control implementation” (Hill & Hupe 2002: 58). Bottom-up approaches are inclined to address the former question, while top-down approaches are inclined to address the latter.

Further, bottom-up literature has been developed to address the aforementioned analytical implications and methodological implications. Organisation-level analysis from Hjern and colleagues (Hjern & Porter, 1981; Hjern & Hull, 1982) aims to portray networks and relationships between organisational actors by first dissolving formal organisational structures and boundaries, and then reconstructing and mapping “the informal, empirical implementation structure around a given problem” (Winter 2006: 154). In their analysis, the methodological implications of bottom-up approaches, which highlight the importance of studying and understanding frontline implementers, are also reinforced (Hill & Hupe, 2002). By proposing snowballing of closely related actors as a method to inform the sampling and study of informal networks, bottom-up approaches are in effect advancing the use of inductive methods in the study of policy implementation (Schofield, 2001). The sampling procedures of this research, as described in Chapter 6 (Study Design and Methods), are inspired by this approach.

As a result, in contrast to the “analytical simplicity” that top-down approaches attempt to establish (Schofield, 2001), bottom-up approaches have greatly enriched the theoretical treatment of the implementation context by focusing on the context faced by multiple actors at “the bottom”. Bottom-up scholars argue that policy implementation and the problems therein occur through the interaction of between central policy and local institutional settings (Berman, 1978), and because of that theorisation of policy implementation cannot be free of either central or local contexts (Maynard-Moody, Musheno & Palumbo, 1990). Whilst they acknowledge the importance of the exogenous macro level implementation context including economic, social and political factors (Anon, 1981; Berman, 1978), the influence of these factors are far less dominant than micro level context pertinent to local organisations and individuals that deliver the policy. Whereas central policy actors can only indirectly influence the micro level context, local implementers’ adaptation to local context could decide whether a policy is to succeed or fail (Palumbo, Maynard-Moody & Wright, 1984). In effect,

bottom-up perspectives offer methods to capture factors pertinent to the micro level implementation context. For instance, backward-mapping provides a way to capture and describe “contextual factors which are located away from the centre” by moving towards multiple-actor analysis that does not assume that central policy is the only or major influence on the understanding, incentives and behaviours of frontline implementers (Elmore, 1978; Schofield, 2001).

To summarise, the bottom-up approach to understanding policy implementation sees local implementers to be critical to policy implementation, and assumes the influence of the local implementation context to be strong. Here, the policy process is a process of iterative adaptation initiated by local implementers. Therefore, it focuses more on the understanding, incentives and behaviours of local implementers and outputs resulting from these factors, as opposed to intended policy outcomes. Local policy implementation is then primarily situated in the micro level local implementation context, rather than the macro level context where policy formulation and implementation is initiated.

However, the disregard of “the Centre” in bottom-up approaches is also considered its weakness. Whilst the top-down perspective could be accused of under-estimation of the influence of the local implementers on the formal structures and processes, the bottom-up perspective could be – in exactly the same logic – accused of under-estimation of the influence of central actors and policies on local contexts (Schofield, 2001). Even decentralisation would have to occur “within a context of central control” (Matland, 1995). Also, the influence and discretion that can be exerted by local implementers can be overestimated (Ryan, 1995). In addition, a diversion from the Centre can represent a diversion from public interests and organisational authorities that are inherent to government policies (Hogwood & Gunn, 1984; Sabatier, 1986; Lester *et al.*, 1987). Therefore, despite the ability of bottom-up approaches to capture the importance of localness in policy implementation, scholars argue that from the perspective of theory development, attempting to generate overarching and generalizable theory based on descriptive phenomena at “the bottom” is to put the cart before the horse (Linder & Peters, 1987).

Because of the strong methodological implications of bottom-up approaches, their emphasis of “the bottom” also draws criticisms in terms of research methodology. Street-level bureaucrats and local implementers are unlikely to be representative of all policy actors concerned in policy implementation (Ryan, 1995). Their perception and

understanding of the policy of interest, albeit being highly relevant to their local implementation context, could be parochial and divorced from the wider economic, social and political context that top-down approaches address (Sabatier 1986: 35).

Moving on from the debate: synthesis and comparative approaches

The reconciliation of the two approaches results in a hybrid perspective that seeks to synthesise the two opposing approaches (Lester et al. 1987; Linder & Peters 1987b; Sabatier 1991; quoted in Schofield 2001). One of the key steps to synthesis is identifying and placing elements and variables that are responsible for the complexities that contribute to exacerbating the differences between the top-down and the bottom-up perspectives within one common framework. For example, Elmore (1985) suggests the use of both “forward-mapping” and “backward-mapping” to account for the considerations of central actors and implementers respectively. Majone and Wildavsky (1978) and Sabatier and Jenkins-Smith (1993) both highlight that policy formulation and implementation is a continuum subjected to constant changes and evolutions, and that the perspectives and involvement of various groups of actors are essential to policy change. Ripley and Franklin (1982) build on the work of Lowi (1972) to make a crucial case for distinguishing different policy types. Matland (1995) highlights the vital need to specify the context and perspectives under which variables identified in various theoretical models are important.

Despite attempts at synthesis, the differences between these two theoretical perspectives remain difficult to resolve, and efforts to reconcile the seemingly opposing theoretical arguments justly represented by either perspective are considered “protracted” and “not fruitful” (Saetren, 2005; Winter, 2006). In fact, some of the fundamental differences between the two perspectives represent those of “incommensurate paradigms” (Parsons 1995:487), so that each perspective “tended to ignore the portion of the implementation reality explained by the other” (Winter 2006:154). By seeking the common denominators, the synthesis approach also inevitably loses some of the analytical edges possessed by each of the opposing perspectives.

Therefore, it is important to recognise the relative merits of different conceptualisations of, and approaches to understanding policy implementation. Comparing different approaches as opposed to finding the “right” approaches can offer

valuable insights (Elmore, 1978), as approaches to study implementation depend on the specific circumstances and subjects of interest (Berman, 1980). Top-down approaches are best suited for more structured implementation that addresses specific problems, while bottom-up approaches are more problem-oriented than policy-focused, and suited to understanding the dynamics of local implementation contexts (Sabatier, 1986).

A theoretical framework for this research

Based on the previous discussion of top-down and bottom-up approaches, and how their different perspectives, strengths and weaknesses can be reconciled and suitably applied to explaining policy implementation at macro and micro levels, a theoretical framework for this research is proposed. This is described in Table 2-1, which illustrates the theoretical framework of this thesis. The macro level mainly concerns “the Centre”, and the examination of this level adopts the top-down perspective. In contrast, the micro level focus on the local settings, and the examination of this level adopts the bottom-up perspective. The influence of context on the implementation process at both levels is demonstrated by the line arrows: macro level contextual factors influence both levels of implementation process, whilst micro level contextual factors only influence local implementation process.

	Theoretical perspective	Factors pertinent to context	Implementation process to be examined
Macro level	Top-down: focus on “the Centre”	<ul style="list-style-type: none"> - National policy context: organisation of actors, political support and public perception - System level factors: financing, organisation, delivery and reforms 	<ul style="list-style-type: none"> - National implementation of policies formulated and dominated by central government
Micro level	Bottom-up: focus on the local settings	<ul style="list-style-type: none"> - Hospital level factors: financing, organisation and delivery at organisational level; - Individual level factors: understanding, incentives, behaviours of, and interactions and relationships amongst multiple actors 	<ul style="list-style-type: none"> - Local implementation and adaptation of national policies carried out by local hospitals

Table 2-1 Theoretical framework of the thesis

2.3 Conclusion

This chapter provided a narrative review of theoretical literature, summarising different perspectives of implementation research. The review of theoretical literature

identified theoretical approaches that could help provide frameworks for cogent analysis of policy implementation, and comprehensive conceptualisation of factors crucial to the implementation context. Both the top-down and the bottom-up perspectives of policy implementation were useful, but it was necessary that they were applied to the right implementation scenario. Whilst the top-down perspective could structure analysis of implementation of antibiotic stewardship policies at the government policy level, the bottom-up perspective offered ways to better understand implementation at the hospital level. The theoretical framework therefore provides a structure to construct research question, examine existing evidence, determine study design and analytical methods.

To identify gaps in knowledge and situate the research it is first necessary to examine existing empirical research related to the research topic of implementation of antibiotic stewardship policies in China.

Chapter 3 Literature Review

3.1 Introduction

Following the preceding analysis of the relevant theories, which explores approaches to understanding implementation process and different levels of implementation context, two structured literature reviews were conducted of the empirical studies relevant to the overall research topic: the first review examined the impact of *The Campaign*, and the second review examined implementation of antibiotic stewardship policies in various country contexts and of health policies in China.

The literature was identified through structured searches in academic databases based on key terms and tracking citations in relevant references. Structured searching was conducted in following databases:

- Embase
- Global Health
- HMIC Health Management Information Consortium
- Ovid MEDLINE(R)
- Econlit
- Social Policy and Practice

Additional searching was conducted on Google Scholar and the China-based China National Knowledge Infrastructure (CNKI). Furthermore, a recent government report on antibiotic use was obtained and included in the analysis. The search terms, inclusion and exclusion criteria and the results of the review are described below.

3.2 Review on the impact of *The Campaign*

To establish an overview of whether *The Campaign* impacted on antibiotic use in China, this literature review looked at both the studies that described overall trends in antibiotic use in China or parts of its regions before, during and after the periods of *The Campaign*, and those that explicitly evaluated the impact *The Campaign* as a whole. Search terms for both types of studies include core conceptual terms such as “China”, “antibiotics”, “prescribing” and “consumption”. For the studies of trends, relevant terms including “trends” and “patterns” were included. After initial pilot

searches, additional key terms that specified data sources, such as “sales”, “procurement”, “survey” or “surveillance” were also added. For the studies of impact, extra key terms related to evaluation such as “evaluate”, “impact” or “effect”, and concepts directly related to *The Campaign* such as “action plan”, “nationwide campaign” and “special campaign” were used. For CNKI, Chinese translations of these terms were used.

Initial inclusion criteria for the studies were kept broad. For trends in antibiotic use, studies based on data from public or commercial databases or surveillance networks at either national or regional levels were included as long as they covered multiple time-points over at least two years. For the evaluation of the impact of *The Campaign*, studies at national, regional and hospital levels from 2011 – the year *The Campaign* was implemented – were included, regardless of whether the subject of evaluation was claimed to be *The Campaign* as a whole or its constituting interventions. Exclusion criteria were formulated upon closer inspection of the studies. Studies that primarily focused on sales volume and revenue of antibiotics were excluded, as they were much less reflective on antibiotic consumption than standardised indicators that directly measured consumption, such as Defined Daily Dose (DDD) per 1000 inhabitants per day and DDD per 100 bed-days. Evaluative studies that did not provide important prescribing indicators such as prescribing rates and adjusted consumption measured in DDD per 100 bed-days (and to a lesser extent in this review, indicators pertinent to perioperative antibiotic use) were excluded, as these indicators were central to understanding antibiotic use and were assessed in *The Campaign*. Cross-sectional studies that only included one time-point were excluded, unless they were part of a bigger survey and could be joined up with related studies with multiple time-points. Finally, where clearly corresponding versions of Chinese and English articles were available, the version with the more detailed and clear described analysis – the English version most of the time – was included and the less informative version was excluded. These inclusion and exclusion criteria were applied in the screening process, and the outcomes of each stage of screening are summarised in Figure 3-1.

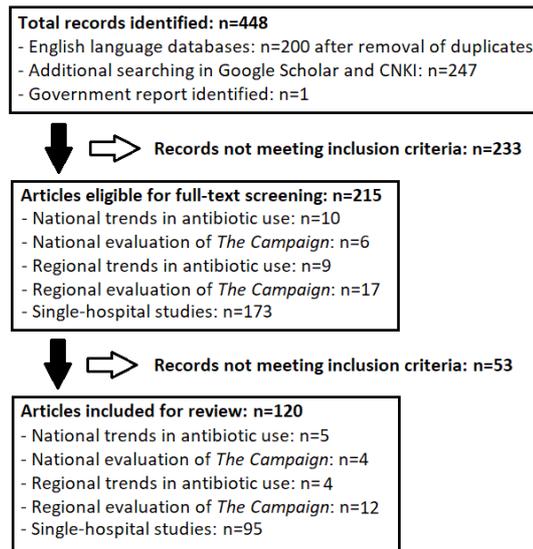


Figure 3-1. Selection process of articles for the review of the impact of *The Campaign*

One hundred and twenty studies were included in this review. All the studies were retrospective observational studies based on longitudinal datasets or surveys collected over specified periods of time. They could be categorised into four main groups based on their subject and regional focus:

- National trends in antibiotic use in China (5 studies)
- National evaluation of *The Campaign* (4 studies)
- Regional trends in antibiotic use in China (4 studies)
- Regional evaluation of *The Campaign* (12 studies)
- Single-hospital studies (95 studies)

These studies will be discussed in the following subsections. For consistency, the unit of DDD per 1000-patient-days will be converted to DDD per 100-patient-days by dividing a factor of 10 where applicable. As the purpose of the review is to examine antibiotic use in China in general, and use of specific classes of antibiotics are not discussed.

A brief description of the included studies for this part of the literature review is available in Appendix 1, where Table A1-1 listed national and regional level studies of trends in antibiotic and impact evaluation of *The Campaign*, and Table A1-2 listed single-hospital evaluations of *The Campaign*.

National trends in antibiotic use in China (5 studies)

Five studies (Van Boeckel *et al.*, 2014; Wushouer *et al.*, 2017a; National Health and Family Planning Commission, 2016; Li *et al.*, 2013; Ren *et al.*, 2015) drew on national-level databases to examine the trends in antibiotic use in China. These studies showed that despite an increase in the overall volume of antibiotic consumption over nearly two decades, consumption adjusted for patient volume and duration of treatment had been decreasing; as had prescribing rates in various clinical settings. On the whole, these studies provide recent evidence on national trends and a tangible starting point to understanding antibiotic use in China, but their descriptive analyses are insufficient to connect the broadly decreasing antibiotic use with *The Campaign* itself.

Van Boeckel *et al.* (2014) found that China as a whole was one the biggest consumers of antibiotics in the world between 2000 and 2010, but per capita consumption was quite low. The study analysed global sales data for both hospital and retail sectors obtained from the commercial database IMS Health MIDAS, and reported consumption using a “standard unit” as defined by the database (where one pill equals to one dose or one unit). It found that there had been a significant increase in total antibiotic consumption between 2000 and 2010 in China, and that China had become the second largest consumer of antibiotics in the world at 10^{10} units just before the commencement of *The Campaign*. But due to its large population, China’s per capita consumption at 7.5 units per person was considerably lower than most developing and developed countries, such as India (10.7 units per person) and the United States (22 units per person). The study did not provide a detailed analysis of China per se.

Wushouer *et al.* (2017a) covered the period right after Van Boeckel *et al.* (2014) left off, and described the rising trends in antibiotic consumption from 2011 to 2015. It extracted quarterly sales data from 468 out of 1000 city-level tertiary hospitals that voluntarily participated in China Medical Economic Information, a database of sales records run by the China Pharmacy Association. It reported consumption using defined daily dose per 1000 inhabitants per day or DID (where number of pills or drug units were divided by WHO’s recommended dosage and further divided by the total number of population of interest in a given year, before this result was multiplied by 1000 for standardisation). It found that the consumption of antibiotics in China had been rising throughout and after *The Campaign* between 2011 and 2015, from around 8 DID in 2011 to around 10 DID in 2015. But the study did not stop there: it offered a plausible explanation for this rising trend of consumption against *The Campaign*. Citing the

falling proportion of pharmaceutical expenditure on antibiotics (from 21% of total pharmaceutical expenditure in 2011 to 15% in 2015), rising total pharmaceutical expenditure (an average of 5.5% each year), and growing inpatient volume at tertiary hospitals across the country (almost doubled between 2011 and 2015), the study reasonably observed that the ever growing antibiotic consumption was not necessarily evidence against the effectiveness of *The Campaign*, but more of a result of ever rising healthcare demand and utilisation. However, as DID was calculated using the stable total population in China as the denominator rather than the rapidly increasing actual volume of patients served by the hospitals included in the analysis, consumption could skew unfavourably towards provinces with fewer patients. In partly addressing this problem, the study used inpatient volume as the denominator to explore regional differences and found that consumption in the affluent and resourceful eastern China – where population-adjusted consumption was highest – was much lower when consumption was adjusted for inpatient volume in comparison to western and central regions. From this, the study deduced that concentration of healthcare resources in the eastern regions attracted significant patient flows from the rest of the country, and it could be an indication of better antibiotic stewardship at tertiary hospitals in the more resourceful eastern China than the other parts. However, as better performing hospitals were more likely to join the network, the results from this study could be prone to positive selection bias.

Li et al. (2013) and Ren et al. (2015) offered some insight into prescribing practices instead of consumption of antibiotics in the years leading up to and during *The Campaign* by analysing changes in prescribing rates. Together, both of these studies surveyed members of the National Healthcare-Associated Infection Surveillance System, which included tertiary hospitals with established healthcare-associated infection practices in the country. The number of hospitals surveyed increased dramatically after *The Campaign* began, from around 200 in 2010 to over 1300 in 2012. Li et al. (2013) covered 5 data points at 2001, 2003, 2005, 2008 and 2010, and Ren et al. (2015) covered 1 data point at 2012. Together, these studies showed that overall prescribing rates in the hospitals studied had been decreasing before *The Campaign* began, from about 55% in 2001 to about 47% in 2010; this number fell further to just below 39% in 2012. The fact that these studies credited the decrease in prescribing rate to the effective implementation of antibiotic stewardship and surveillance that were in place even before *The Campaign*, but they were unlikely to represent the full picture, as hospitals included in these surveillance networks were

themselves highly aware of hospital-associated infections and antibiotic resistance, and already equipped with the resources to address the problems in antibiotic prescribing to start with. Importantly though, the two studies also provided breakdowns of antibiotic in different clinical departments, which demonstrated huge variances. Departments including respiratory medicine and paediatrics were amongst the heaviest users of antibiotics in the hospitals surveyed, and their antibiotic prescribing rates stayed above 70% between 2001 and 2012, and in some years, they were close to 80%. Surgical urology also had a high rate of antibiotic use between 60% and 70%. These rates were a stark contrast to those in departments such as obstetrics (below 50%), nephrology (below 30%) and cardiovascular medicine (about 20%). Antibiotic stewardship at department level is likely to be highly adapted and specific to their needs. Although these credible studies showed possible progress in antibiotic stewardship over a decade that overlapped with *The Campaign*, the fact these studies came from an early specialist network for the control of healthcare-associated infections implied that the positive progress could be the result of selection bias in member institutions, which were likely to be better-than-average performers in the control of antibiotic use.

The most authoritative data on antibiotic consumption and prescribing rates in China was provided by a recent report from the Chinese government, “The Administration on the Clinical Use of Antimicrobial Agents and the Status Quo of Antimicrobial Resistance in China” (National Health and Family Planning Commission, 2016). The report drew on the data collected annually by the national surveillance system, Center for Antibacterial Surveillance (CAS), which expanded from including only several hundred secondary and mainly tertiary hospitals in the early 2000s to around 2000 hospitals from 31 provinces by 2016. This first ever official report on antibiotic use and resistance shed light on various indicators on consumption and prescribing that were specified by *The Campaign*. Most prominently, it reported that antibiotic prescribing rates had significantly decreased in inpatient (from 67.3% in 2010 to 39.1% in 2015, including both surgical and non-surgical patients) and outpatient settings (from 17.2 % in 2011 to 11.2% in 2015). Inpatient consumption of antibiotics measured by defined daily dose per 100 patient-days, which accounted for both the volume of patients and the duration of their hospital stay, had also fallen (from 85 in 2005 to 50 DDD per 100-patient-days in 2015). It was worth noting that this adjusted consumption stayed above 78 DDDs per 100 patient-days until 2010, and did not start to fall until 2011, when *The Campaign* began. The report also described progress in antibiotic stewardship in surgeries, such as antibiotic use for various surgical incisions

and timing and duration of perioperative antibiotic use, where all results showed improvement from 2011 and 2012. Finally, similar to Wushouer et al. (2017a), the report described the downward trends in the proportion of revenue from antibiotic sales in total pharmaceutical revenue (from 19.7% in 2010 to 11.3% in 2015) and in per capita expenditure on antibiotics. The report largely reported positive improvements from the government's perspective and sought to attribute them to the implementation of *The Campaign*, but it did not have any analytical methods to support the claims.

National evaluation of *The Campaign* (4 studies)

Four studies (Zou et al., 2014; Zhou et al., 2016; Bao et al., 2015b; Sun et al., 2015a) attempted to examine trends in antibiotic use independently and investigate whether *The Campaign* was truly responsible for any substantial change. Although all these studies claimed to show significant reductions in antibiotic use since *The Campaign* began, none of these studies was equipped with a sufficiently robust design to attribute causality. Even so, two studies (Bao et al., 2015b; Sun et al., 2015a) employed rigorous analytical methods to provide compelling insight into changes in the trends in antibiotic prescribing before and after *The Campaign*. These evaluative studies confirmed the downward trends in antibiotic use observed by the non-evaluative studies and implied a possible role of *The Campaign* in generating the trends. However, the causal role of *The Campaign* in reducing antibiotic use could not be ascertained; also, questions about variation across regions, clinical settings and types of hospitals raised by some of the studies of trends as well as evaluative studies reviewed in this section need to be explored carefully.

Both Sun et al. (2015a) and Bao et al. (2015b) conducted time series analysis using the method of segmented regression and investigated changes in antibiotic use over several time periods defined by the authors, including one that overlapped with *The Campaign*. Both studies attempted to achieve representativeness at the national level, with respective shortcomings. Sun et al. (2015a) randomly sampled prescriptions and medical records from the 2000-strong national network, the Center for Antibacterial Surveillance, and surveyed 35 tertiary hospitals from its six constituent regions to achieve better representation, but it failed to acknowledge secondary hospitals. Bao et al. (2015b) had better representation of secondary hospitals, as they reached out to an informal hospital network based on common interest in research and eventually

extracted data from 65 public hospitals that responded (35 secondary and 30 tertiary hospitals). However, the peer nature of the network could have compromised the neutrality of the study as interested hospitals were likely to be more dedicated in antibiotic stewardship from the start. With Sun et al. (2015a) reporting 32 quarterly data points between 2005 to 2012 and Bao et al. (2015b) 48 monthly data points between 2010 and 2014, these studies jointly presented an account of contemporality between notable reduction in antibiotic use and commencement of *The Campaign*. Both studies reported a marked decrease in antibiotic use over their study periods, observing large reductions in outpatient (from about 15% to 10% in Sun et al.; from about 40% to 30% in Bao et al.) and inpatient antibiotic prescribing rates (from about 75% to 50% in Sun et al.; from about 60% to 35% in Bao et al.) and inpatient antibiotic consumption (from about 75 to 45 DDDs per 100 patient-days in Sun et al.; from about 80 to 30 DDDs per 100 patient days in Bao et al.). Further findings include reduction in medical expenditure and improvements in perioperative antibiotic use. Although the exact range of figures varies to some degree due to sampling differences, the trends in these indicators are largely in line with those observed in the national report (National Health and Family Planning Commission, 2016). Most crucially, these two studies used segmented regression to analyse and compare these trends in separate phases in relation to *The Campaign* and demonstrated an observable decrease in antibiotic use in the periods after the commencement of *The Campaign*. Sun et al. (2015a) separated their data into two phases: before (2005 – 2011) and after (2011 – 2012). Bao et al. (2015b) broke down their data into three phases: preparation (2010 – 2011), intervention (2011 – 2012) and assessment (2012 – 2014). With the intervention phase in both studies alluding to the possible effectiveness of *The Campaign* in driving down antibiotic use, Bao et al. (2015b) went further to illustrate that the effect had in fact significantly intensified across most of the indicators for antibiotic use when comparing the assessment phase to the intervention phase. Even though these two studies were unable to attribute direct causality between *The Campaign* and the observed reductions in antibiotic use due to the lack of a control group or counterfactual, they supplied convincing empirical evidence to further this theoretically plausible hypothesis by showing synchronicity between the timing of the two events. Together with the national trends depicted in the studies described earlier, these studies provided further evidence to support the hypothesis that the implementation of *The Campaign* may be related to the reduction in antibiotic use at a national level in large public hospitals, the target hospitals of the policies.

In comparison, two other national evaluations from Zou et al. (2014) and Zhou et al. (2016) were much weaker in terms of their analysis. Without using segmented regression, they were unable to measure changes in antibiotic use through phases of time in relation to *The Campaign*, even though their observations about decreasing antibiotic prescribing and patient-day-adjusted consumption were consistent the findings of the more rigorous evaluations above. As these studies had only two cross-sectional data points in 2011 and 2012, they were only able to show whether there were any significant differences in the observed indicators between the two years. As both studies focused on specialised hospitals only, they were highly unrepresentative of the broader healthcare context, where most hospitals were general hospitals. Their overall sampling frame was unclear, despite both having included over 200 hospitals from 30 provinces. To further undermine the validity of their analysis, Zou et al. (2014) sampled two different groups of hospitals at the two data points. Despite these limitations, these two studies performed subgroup analysis to provide some insight into variations across regions, types and sizes of hospitals. In particular, Zhou et al. (2016) performed a multivariate analysis to show that specialised hospitals in the central region were associated with better adherence to guidelines in antibiotic use for type I incisions. However, the confusing display of multiple data tables coupled with a lack of cogent descriptions of findings in reporting made drawing clear and useful lessons from these studies even more difficult.

Regional trends in antibiotic use in China (4 studies)

Four studies of the regional trends (Yin, Li & Sun, 2018; Wushouer *et al.*, 2017b; Lin *et al.*, 2016; Zhang *et al.*, 2017b) provided a limited but useful window to explore regional variations in antibiotic use, which were sometimes substantial. Time trends in antibiotic use were described in these studies, but not studied with statistical tools. Importantly, some of these studies provided a new angle of analysis by comparing antibiotic use at the primary care level with secondary and tertiary hospitals. In sum, the studies of regional trends in antibiotic use revealed heterogeneity and complexity in antibiotic use in different parts of China. The level of urbanisation could have huge bearing on the pattern of healthcare utilization and consequently antibiotic consumption. Therefore, even though there were indications that *The Campaign* could be associated with reducing antibiotic use, it was unlikely that all regions were equally affected by its implementation. The policy approach of *The Campaign* to focus on

secondary and tertiary hospitals could impact more significantly where they were responsible for most of the antibiotic consumption, such as Changsha and Shanghai.

Zhang et al. (2017b) described a falling inpatient prescribing rate across all three levels of hospitals between 2003 and 2014 in Changsha City, the capital of Hunan Province in southern China. It sourced annually reported inpatient prescribing data from the Urban Employees Basic Medical Insurance database, which covered nearly 60% of the population of Changsha. The study reported that the inpatient prescribing rate in hospitals steadily declined from close to 80% in 2003 to below 50% in 2014, a trend that was consistent with national studies. Notably, 2011—the year *The Campaign* commenced—marked the turning point for the increasing use of one single antibiotic and the beginning of a sharp decline in the use of multiple antibiotics for a given course of treatment, so that by 2014 the prescribing rate of single-antibiotic treatments far exceeded that of combination therapies by nearly 20%. The study provided a breakdown of prescribing rates by hospital level for only one data point at 2014, and it offered useful insight into the pattern of antibiotic use in hospitals across all levels of healthcare. For that year, 50 primary care hospitals, 26 secondary hospitals and 30 tertiary hospitals were included in the analysis. It showed that primary care hospitals had higher inpatient prescribing rate (53.5% at primary level versus 45.2% and 40.2% at secondary and tertiary hospitals respectively) and were seemingly more reliant on antibiotics for their revenue than higher-level hospitals (antibiotics accounted for 24.7% of the total health expenditure at primary level, versus 14.5% and 10.8% at secondary and tertiary hospitals respectively). Nevertheless, much lower per capita expenditure on antibiotics at primary level compared with higher-level hospitals (132.5 USD at primary level versus 160.6 USD and 314.8 USD at secondary and tertiary levels respectively) pointed to the fact that the more advanced (and consequently expensive) antibiotics were used mostly at tertiary hospitals. It is therefore necessary for further research to be undertaken to understand the appropriateness and the implications of the policy approach of *The Campaign* to prioritise tertiary hospitals and to a lesser extent, secondary hospitals in enforcing antibiotic stewardship.

Lin et al. (2016) and Yin et al. (2018) both reported antibiotic use – mainly in the form of population-adjusted consumption, DID – in all three levels of hospitals in two cities in eastern China, a region with high levels of antibiotic use identified in Wushouer et al. (2017a). Both studies analysed sales data from official procurement platforms for pharmaceuticals at the municipal or provincial level, which were used extensively by all

levels of public hospitals. Lin et al. (2016) measured 24 quarterly data points between 2009 and 2014, whilst Yin et al. (2018) measured 5 annual data points between 2012 and 2016. Despite the similarities, the regional settings of the two studies, and the subsequent pattern of antibiotic use across the three levels of healthcare were drastically different. Lin et al. (2016) investigated the highly urbanised and metropolitan Shanghai City, where healthcare was provided in about 180 hospitals (30 tertiary and 150 secondary hospitals) and close to 300 community healthcare centres at the primary level. Yin et al. (2018) studied one of the most agricultural regions in Shandong Province, where over 500 higher-level hospitals were significantly outnumbered by more than 2000 primary care providers in the urban (about 500) and rural areas (more than 1500). Over the studied period, Lin et al. (2016) saw a huge reduction in antibiotic use in Shanghai from over 20 to just below 16 DID, whilst Yin et al. (2018) observed a small increase from 13 to 14 DID.

These differing trends could be open to more detailed investigation and interpretation beyond these studies, because, as pointed out in the review by Wushouer et al. (2017a), the overall increase in the population-adjusted antibiotic consumption could well be a reflection of the rising demand for healthcare and increasing patient volumes. However, insightful interpretation could be made through comparing the contrasting study settings. Firstly, regional characteristics could give rise to very different patterns of antibiotic consumption across levels of healthcare: secondary and tertiary hospitals were responsible for most of the antibiotic consumption in mainly urban regions rather than regions with vast rural areas. For Shanghai, Lin et al. (2016) found that primary care accounted for 36% of antibiotic consumption, whereas hospitals accounted for 64%. For Shandong, Yin et al. (2018) found that primary care – the vast majority (nearly 90%) of which were rural primary care facilities – accounted for 80% of antibiotic consumption, and higher-level hospitals accounted for merely 20%. Secondly, given the first point, dramatic reduction in population-adjusted antibiotic consumption starting from 2011 in Shanghai, where higher-level hospitals consumed most antibiotics, was consistent with the designed impact of *The Campaign*. Antibiotic consumption in Shanghai had been on the rise until the first quarter of 2011, at which point it reached the highest recorded level of 29 DID. This level was even higher than those reported in Wushouer et al. (2017a), which did not have data from Shanghai but estimated that tertiary hospitals in the two bordering provinces of Shanghai in eastern China had the highest antibiotic consumption (>19 DID) across the country. Dramatically, consumption sharply reduced to around 17 DID

by the fourth quarter of 2011 and had since been fluctuating steadily around that level until the last period of the study in 2014. Considering that the DID estimates did not consider duration of treatment (DDD per 100 patient-days) and hence were not necessarily reflective of rational antibiotic use per se, and the fact that the study had not yet been adjusted for patient flows from other provinces, which would account for over 20% of the patients in hospitals in Shanghai, the drastic decrease in DID was a remarkable trend that could be indicative of the impact of *The Campaign*. Thirdly, the moderately upward fluctuations seen in population-adjusted antibiotic consumption during the years of *The Campaign* in Shandong, where primary care overwhelmingly dominated antibiotic consumption, could be better understood in the context of the study of Shanghai. Yin et al. (2018) estimated that population-adjusted antibiotic consumption in Shandong was around 14 DID between 2012 and 2016. This was higher than the estimate for Shandong at a range of 5 – 8 DID given in Wushouer et al. (2017a), which only estimated consumption in tertiary hospitals, and thus further showed that primary care was a key driver for antibiotic consumption in Shandong. Although it was fair for Yin et al. (2018) to note that *The Campaign* only addressed higher-level hospitals and further actions were needed to rationalise antibiotic prescribing at the primary care level for provinces like Shandong, the role of primary care in driving overall antibiotic consumption in China remained unclear. What was clear was that the more hospital-dominant Shanghai (16 DID) and the more primary-care-dominant Shandong (14 DID) were both reaching very similar levels of consumption after *The Campaign* started from 2012 onwards.

Wushouer et al. (2017b) outlined antibiotic consumption in the western Xinjiang Province between 2014 and 2016. It collected quarterly data on inpatient antibiotic use from 36 hospitals in the province, and showed that in this post-*Campaign* period, patient-day adjusted consumption of antibiotics remained relatively stable around 40 DDD per 100-patient-days. It was within the range of consumption reported in national-level studies and evaluations. As the purpose of the study was to articulate the relationship between consumption and resistance, it did not investigate in depth the trend in consumption per se.

Regional evaluation of The Campaign (12 studies)

Twelve studies (Tang *et al.*, 2018; Wang & Jin, 2013; Shi *et al.*, 2014; Zhang *et al.*, 2016; Qiu *et al.*, 2016; Liu *et al.*, 2014; Chen *et al.*, 2015; Zhang *et al.*, 2017a; Duanmu *et al.*, 2015; Ma, 2013; Shu *et al.*, 2015; Yang *et al.*, 2013a) evaluated impact

of *The Campaign* on antibiotic use in various cities and regions. However, only 1 study conducted rigorous analysis using segmented regression. Tertiary and secondary hospitals were the main interest, and in a few studies primary care was also studied. Most of these studies reported largely positive outcomes that need to be cautiously interpreted, but some of them conducted useful sub-group analyses and provided critical comments on deficiencies in the implementation of *The Campaign*. Even though the findings of the regional evaluations were consistent with national evaluations in saying that *The Campaign* had reduced antibiotic use, they did not sufficiently unravel and interpret variations of the impact in different regional and clinical settings.

Tang et al. (2018) employed segmented regression to examine the impact of *The Campaign* on antibiotic use at primary care level in Hubei Province in central China. They extracted monthly records for 31 months between 2011 and 2013 from the procurement database for urban and rural primary care centres in the province. Whilst the study observed some decrease in the total volume of unadjusted antibiotic consumption at primary care level, it did not find the decrease to be substantial. Therefore, *The Campaign's* impact on primary care remained inconclusive. As the study did not report population-adjusted consumption, its findings were difficult to compare with those from the studies of trends discussed above.

Eleven remaining regional evaluation studies were similar to the national evaluations from Zou et al. (2014) and Zhou et al. (2016) in the sense that their analytical strategies were too weak to support their purpose, and their presentation of findings was not effective at times. These studies did not adequately report their sampling frame and process and were likely to be subjected to selection bias of better-performing hospitals. The majority of the studies only conducted descriptive comparisons in antibiotic use and prescribing rates across different years and did not seem to have employed statistical methods in their analyses (Wang & Jin, 2013; Shi et al., 2014; Zhang et al., 2016; Duanmu et al., 2015; Ma, 2013; Shu et al., 2015; Yang et al., 2013a). The studies focused on urban settings in various parts of China, especially large cities exemplified by Beijing, Tianjin (both in northern China), Shanghai (eastern China), Guangzhou (southern China) and Chengdu (western China). Apart from a few studies that included a small number of primary care clinics, most studies focused on tertiary hospitals, and occasionally secondary hospitals and primary care clinics. Findings of the studies were generally positive about *The Campaign*, highlighting decreasing antibiotic use and prescribing rates even at primary care level. However,

there was insufficient interpretation of these positive findings and few studies critiqued *The Campaign* where findings were less optimal. A few studies did provide insightful analysis that echoed observations about variation in antibiotic use in different clinical and resource settings. For example, Yang et al. (2013a) noted antibiotic use in given clinical departments depended heavily on their patient mix (for instance, paediatrics and respiratory medicine sustained high levels of antibiotic use), so that uniform policies that were not adapted to clinical needs in those departments could hinder implementation. Shu et al. (2015) identified several problems in implementation associated with the suboptimal impact of *The Campaign* in some hospitals, including insufficient adherence to accountability and performance assessment mechanisms, lack of resources in some hospitals to devote to training clinical pharmacists and building adequate microbiology facilities, and slow introduction of information technology platforms in some hospitals to digitalise the prescribing system and its management.

Single-hospital studies (95 studies)

Ninety-five studies examined antibiotic use within single hospitals. More than three quarters of the 95 single-hospital studies were from tertiary hospitals (64 general, 6 specialist and 2 traditional Chinese medicine hospitals), and 21 out of the 23 remaining studies were from secondary hospitals (18 general and 3 specialist hospitals); only 2 studies were from primary hospitals. The majority of the single-hospital studies (67 studies) examined overall antibiotic prescribing in hospitals, whilst the rest (28 studies) focused on specific clinical departments or procedures, especially surgery (13 studies) and orthopaedics (5 studies). But the findings of these studies did not substantially add to those from the evaluative studies or studies of trends at regional and national levels.

Although these studies claimed to evaluate the impact of *The Campaign*, they provided nothing more than descriptions of cross-sectional trends for prescribing indicators from various timepoints before, during and after *The Campaign*. In doing so, they did not employ segmented regression to analyse the trends.

Furthermore, these methodological limitations in study design and analysis were further subjected to greater publication bias than studies at regional and national levels. These studies were overwhelmingly positive about and confirmed the impact of

The Campaign in their findings, consistently reporting reductions in prescribing rates and inpatient antibiotic consumption as well as improvements in perioperative prescribing practices without offering robust analysis of how *The Campaign* was related to improvement in antibiotic stewardship or critical insight into areas where implementation to *The Campaign* were less ideal. This potentially amplified publication bias was understandable: rather than being conducted by independent researchers, the lead authors of the studies were internal to the hospitals concerned, and they were unlikely to publicly critique their employers' performance in implementing *The Campaign* due to their professional interests.

3.3 Review of the implementation of antibiotic stewardship policies

To examine existing empirical studies pertinent to understanding the implementation of antibiotic stewardship policies in China, literature from two related subject areas was examined: implementation of antibiotic stewardship policies around the world (including China), and implementation of other health policies specifically in China. Therefore, two separate sets of search terms were used to reflect the two subject areas of interest. One set of terms were concepts related to “policy implementation” and “antibiotic stewardship”. The other set of terms were concepts related to “policy implementation”, “health” and “China”. To focus on implementation, both sets of terms actively excluded concepts related to “impact evaluation” by using the operator “NOT”. For CNKI, Chinese translations of the relevant terms were used.

There were three main inclusion criteria for the articles identified. Firstly, they had to be studies with clear study designs aimed at collecting primary data. Secondly, studies had to include explicit analysis of some aspects of policy implementation as part of their main aims and results. Thirdly, studies of antibiotic stewardship policies had to address hospital settings rather than other settings. Based on these criteria, titles and abstracts of the articles identified were screened, before the full-text articles were retrieved for further assessment for inclusion for the review. The outcomes of each stage of the selection process are described in Figure 3-2.

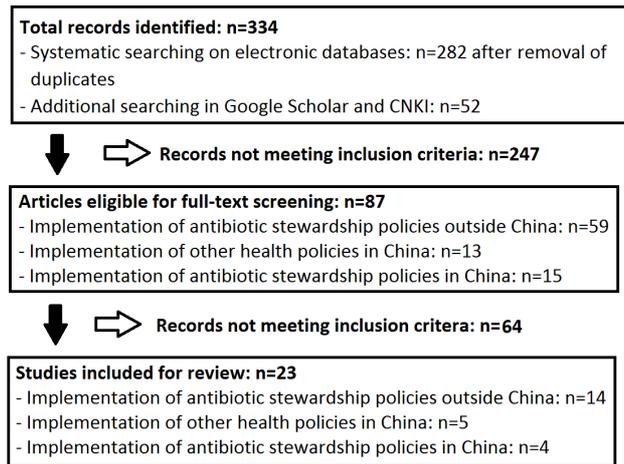


Figure 3-2 Selection process of articles for the review of empirical studies of policy implementation related to the research topic

In the end, 23 studies were included for review. As explained above, they were categorised into three main groups based on topic areas and methodologies:

- Implementation of antibiotic stewardship policies outside China (14 studies)
- Implementation of other health policies specifically in China (5 studies)
- Implementation of antibiotic stewardship policies in China (4 studies)

These studies are discussed in turn in the following subsections, which are followed by a summary of themes from the findings of all the studies.

Implementation of antibiotic stewardship policies outside China (14 studies)

Fourteen cross-sectional studies analysed the implementation of antibiotic stewardship policies in countries outside China. Although no explicit differentiations were made between the concepts of context and process, these studies commented on some aspects relevant to these concepts in reporting findings pertinent to policy implementation.

Nine cross-sectional studies (Hersh *et al.*, 2009; Pope *et al.*, 2009; Johannsson *et al.*, 2011; Doron *et al.*, 2013; James *et al.*, 2013; Howard *et al.*, 2015; Bryant, 2015; Enani, 2016; Wolf *et al.*, 2016) used internet-, email- or fax-based surveys as a data collection method to examine the characteristics of various antibiotic stewardship policies and their implementation across various hospital settings including acute care,

paediatrics, oncology, tertiary hospitals, and public and private hospitals. With sample sizes varying from just over 10 to over 500, these studies addressed several geographic regions around the world, particularly North America, Australia and the Arabian Gulf. In addressing implementation of antibiotic stewardship policies, these studies focused on identifying factors pertinent to policy implementation at the hospital level in the form of “barriers to implementation” perceived by various actors at the hospital level including prescribers, clinical pharmacists and directors sampled from professional or hospital networks from around the world. Prominent barriers to implementation identified included lack of funding, lack of the necessary personnel and capacity for antibiotic stewardship, lack of support from prescribing prescribers (especially senior prescribers), lack of support from the hospital administration and management team, lack of prioritisation compared with other programmes, lack of time, and lack of IT and data support.

However, these nine studies provided limited descriptive insights into some but not all aspects of implementation of antibiotic stewardship policies. Although the cross-sectional methodology enabled gross generalisation of hospital level contextual factors, the limitations of the survey method made it impossible for these studies to collect sufficient qualitative data to explore further how and why these contextual factors significantly hindered implementation. In addition, as the options in the survey instruments were predetermined based on expert opinions and literature reviews, they were too generalised to reflect the full range of opinions held by the respondents or the complexity of behaviours or interactions amongst various groups of medical professionals and specialists.

Five case studies (Charani *et al.*, 2013; James *et al.*, 2015; Jeffs *et al.*, 2015; Cotta *et al.*, 2015; Bailey, Tully & Cooke, 2015) adopted qualitative methods such as semi-structured interviews and focus groups to collect more in-depth information about implementation of antibiotic stewardship policies in various medical settings in Australia, the UK, and the United States. These studies encompassed the perspectives of a range of key actors of antibiotic stewardship at the hospital level including prescribers, infectious disease specialists, clinical pharmacists, microbiologists and hospital executives. Besides commenting on additional factors at the hospital level, these studies also addressed factors at the national and the individual levels. At the national level, the main barriers to implementation were lack of uniform international and regional guidelines, and the enabling factors were introduction of formal mandates.

At the hospital level, the barriers to implementation summarised previously were reaffirmed by these studies. Additionally, several enabling factors were identified, including reinforcement of other supportive policies; establishment of an effective administrative structure; establishment of an antibiotic stewardship committee; introduction of leadership by bringing senior and respected members into the committee; and creation of collaborative relationships across departments. At the individual level, barriers to implementation were exemplified by lack of knowledge and understanding of antibiotic use or policies; lack of consideration of patient behaviours and preferences; lack of considerations for prescriber-patient relationships; and interference with physician autonomy.

Two mixed-method case studies – Charani et al. (2013) and James et al. (2015) – combined quantitative and qualitative methods to understand implementation of antibiotic stewardship programmes, and their interviewees and focus group participants were representative of the actors involved in hospital level implementation, including medical professionals and administration personnel. The qualitative components of both studies essentially offered more detailed and grounded explanations for the “barriers” to implementation that they identified. These studies identified hospital-level factors that were broadly consistent with some of those which emerged from the cross-sectional studies described previously, but their thematic analysis was more detailed and grounded to the narrative within the data. In evaluating a smartphone application for the delivery of antibiotic stewardship policies, Charani et al. (2013) identified hospital level factors, such as support for timely updates of the programme, commitment of hospitals to different mobile platforms and their policies on use of mobile devices at work, were important to the implementation of the intervention. James et al. (2015) described specific issues in their many study sites, including variation of antibiotic stewardship practices, lack of arrangements to access relevant experts, difficulty in maintaining workforce capacity, and differing governance structures. Additionally, these studies also outlined how individual level factors such as perception and understanding of the policies of interest, social preferences of behaviours and prescriber-patient interactions could influence implementation.

However, these mixed-method case studies were only attempting to enrich quantitative findings using some qualitative data; neither of the studies above was fully devoted to providing in-depth analysis of implementation based on detailed description

of the actors' perceptions and behaviours. Neither study presented sufficiently detailed qualitative analysis.

Three case studies – Cotta et al. (2015), Bailey et al. (2015) and Jeffs et al. (2015) – relied solely on qualitative methods, and gave much more detail about the perceptions and reported behaviours of the actors involved in antibiotic stewardship. These case studies showed that by employing in-depth qualitative methods, more substantiated and systematic thematic analysis could be produced. Studying private hospitals, Cotta et al. (2015) interviewed comprehensive focus groups of actors including prescribers, specialists, microbiologists and executives to articulate how hospital level factors (such as enforcement, scope for introducing guidelines and resources) and individual level factors (such as knowledge of antibiotic use, and behaviours and interactions within and between different specialties) could contribute to “barriers” to implementation in the private hospital context. Jeffs et al. (2015) interviewed a small set of prescribers and pharmacists in academic hospitals and provided detailed analysis of how antibiotic stewardship policies were implemented at the hospital level under the themes of leadership, collaborative relationships and progress tracking. Furthermore, Bailey et al. (2015) highlighted factors crucial to policy implementation at the national level, including availability of uniform guidelines and introduction of formal mandates.

Despite providing more detailed qualitative data and analyses, these three qualitative case studies shared a common weakness: findings from these studies were often presented as descriptive themes, in which no clear conceptual distinctions were made concerning different levels of implementation, or factors pertinent to context and process respectively. Consequently, these studies were unable to take full advantage of the qualitative data they collected to provide cogent interpretations for the implementation of antibiotic stewardship policies.

Implementation of other health policies in China (5 studies)

Five qualitative case studies (Duckett, 2001; Tolhurst *et al.*, 2004; Schwartz & Evans, 2007; Dong, Christensen & Painter, 2014; Xiao *et al.*, 2013b) examined health policy areas other than antibiotic stewardship in China. Apart from Dong et al. (2014), who used secondary data only, all other studies employed qualitative methods, such as interviews and focus groups, to gather primary data. All five studies revealed factors

crucial to policy implementation specific to the Chinese context. At the national level, barriers to implementation were posed by lack of state capacity to enforce policy; lack of financial support at the central level; lack of coordinated reforms to address fundamental problems in the healthcare system; lack of alignment between the responsibilities of government ministries and their roles in policy implementation; lack of coordination across government ministries; lack of regulatory power of laws and regulations; and extensive decentralisation. Corresponding to some of these barriers were several enabling factors, such as strengthening of the capacity and effectiveness of administrative accountability and bureaucracy; provision of financial support; mobilisation of high level of political support and prioritisation; enactment of laws, policies and regulations; and mobilisation of support from non-state actors. At the local level, barriers to policy implementation comprised lack of financial support at the local level; lack of the necessary personnel and capacity; lack of alignment of interests of different actors; lack of local political prioritisation; lack of effective supervision and reporting, which could enable gaming behaviours; lack of realistic target management approach; lack of accountability at the local level; and lack of attention to service users' demands.

Three case studies (Duckett, 2001; Tolhurst *et al.*, 2004; Schwartz & Evans, 2007) described implementation of various health policies in China without using theory. All three studies were case studies of policy implementation at the local level in China with strong qualitative components: Duckett (2001) studied pilot reforms of social health insurance in several cities in China by drawing on interviews with both central and local officials; Tolhurst *et al.* (2004) investigated the implementation of Maternal and Infant Health Care Law in two poor counties in China at county, township and village levels using both quantitative and qualitative methods, which included key informant interviews with local officials, and in-depth interviews and focus group discussions with villagers; Schwartz and Evans (2007) analysed the implementation of public health responses of a township in Western China to the SARS epidemic based on mainly secondary accounts and few interviews. Situated in the background of local healthcare context, Duckett (2001) and Tolhurst *et al.* (2004) appropriately highlighted the complexity of local implementation due to the interaction between macro- and micro level factors. Although interpretation of the data was not aided by either top-down or bottom-up approaches to understanding policy implementation in both studies, these studies managed effectively to highlight the dynamics between the two approaches to understanding policy implementation in an implicit way. Duckett (2001) noted that

centrally formulated schemes encountered problems with implementation in local cities for several reasons. Firstly, micro level factors – the tensions and dynamics in the alignment of economic and political interests amongst local actors including government departments, enterprises, hospitals and medicine producers – were influential. Secondly, interaction between macro- and micro level factors further complicated local implementation in China’s political context. Thirdly, macro level factors such as weak state capacity, lack of necessary health reforms, misalignment between government ministries with their roles in policy implementation and extensive fiscal decentralisation coupled with micro level factors including lack of local government accountability, to strengthen the abilities and interests of local governments to resist reforms proposed by the central government. Tolhurst et al. (2004) identified several “barriers” to implementation at macro and micro levels, including the lack of local financial support from central government and decentralised local governments, personnel capacity, and alignment of political remits and interests of the various government departments involved. The discussions of these factors were situated in the background of local healthcare delivery and financing, including access, utilisation and demand for maternal and childcare services. There were also elements pertinent to implementation processes: the authors noted that there were reported gaming behaviours in the form of selective or false reporting when targets of the policy of interest were not met. Much of the analysis by Schwartz and Evans (2007) was based on secondary data rather than the highly limited primary qualitative data, and as a result, their empirical analysis of local implementation was not strongly supported. However, they shed useful light on a few macro level factors that could influence policy implementation at the national level, noting macro level factors such as capacity of the state, central budgetary support, political support, enactment of laws and regulations, local adaptation of the central policies, and the role of non-state actors such as civil associations and village committees.

Whilst the above studies managed to address elements pertinent to policy implementation at macro and micro levels in China, the absence of theoretical frameworks restricted the interpretation of their rich and interesting data. Although these studies showed that insightful qualitative case studies could be conducted without the use of theory, they also demonstrated the difficulty to clearly explain all the conceptual elements pertinent to different levels of policy implementation without implementation theory.

Two studies (Dong, Christensen & Painter, 2014; Xiao *et al.*, 2013b) made explicit use of theories in analysing policy implementation.

An analysis of policy documents and existing studies conducted by Dong *et al.* (2014) aimed to understand the lack of implementation in healthcare reform in China relying purely on secondary qualitative data sources such as policy documents and published studies. Despite all three approaches to understanding policy implementation – top-down, bottom-up and hybrid approaches – being described, application of these theories in analysis was absent. Even though policy implementation was not the main subject of the paper, it provided some useful analysis of the interactions and coordination amongst actors at the central level.

Xiao, Zhao, *et al.* (2013) presented a case study of the New Essential Medicines Policy at the local level. “Complex adaptive systems”, which “originated from running agent-based models on computers which attempted to model complex natural or artificial behaviours, or more recently complex social phenomena such as health interventions and reforms”, was used as the theoretical framework for the study to study the “non-linearity” of policy process generated by the dynamics of actor behaviours (Xiao *et al.*, 2013b). Based on the description provided by the authors, it was clear that this stream of theory was not entirely appropriate to understanding policy implementation. Firstly, despite the elements of complex adaptive systems perhaps sharing commonality with those pertinent to implementation theories, such as interactions amongst actors, adaptive behaviours and deviation from intended policy mechanisms and/or outputs, implementation theories would be much better placed to conceptualise and align these elements with the purpose of exploring and understanding policy implementation, which was what the authors explicitly tried to achieve. Secondly, heavily focused on actors and relationships but without incorporating elements that could allow for any conceptualisation of process or context at different levels, the theory of complex adaptive systems was likely to generate muddled interpretations that were indeed complex if not complicated, at best when it came to explaining policy implementation. Xiao, Zhao, *et al.* (2013) demonstrated these problems. Although their study highlighted the complexity of policy process introduced by local actors by drawing on qualitative data from local officials, prescribers and patients from three remote counties, the themes of the main findings, which concerned the unexpected outcomes, adaptive behaviours and non-linear implementation, merely presented rather than unpacked the complexity associated with policy implementation.

As a result of inappropriate use of theory, neither study above engendered insight into implementation of health policies in China compared with the three studies (Duckett, 2001; Tolhurst *et al.*, 2004; Schwartz & Evans, 2007) that were conducted without using theory.

Implementation of antibiotic stewardship policies in China (4 studies)

Four qualitative case studies (Liu *et al.*, 2011a; Li *et al.*, 2014b; Wang *et al.*, 2016; Jin *et al.*, 2011) specifically analysed Antibiotic stewardship policies in China. Apart from Wang *et al.* (2016), who used secondary data only, all other studies gathered primary data mainly through interviews. All the studies identified factors crucial to policy implementation at the national, hospital and individual levels. At the national level, barriers to implementation included lack of coordinated reforms to address fundamental problems in the healthcare system; lack of enforcement of existing laws and policies; and lack of coordination across government ministries. At the hospital level, barriers to implementation consisted of lack of necessary personnel and capacity for antibiotic stewardship; and lack of time. At the individual level, barriers to implementation were represented by lack of knowledge and understanding of antibiotic use or policies; and lack of trust in prescriber-patient relationships.

Two studies (Liu *et al.*, 2011a; Li *et al.*, 2014b) analysed some aspects relevant to the implementation of Antibiotic stewardship policies in China without applying implementation theory.

In their discussion about antibiotic stewardship in China, two case studies based on structured interviews, G. Liu *et al.* (2011) and M. Li *et al.* (2014), had some findings regarding the influence of macro level factors such as China's pharmaceutical distribution system, pharmaceutical regulatory system and health financing system on antibiotic prescribing and use, as well as micro level factors concerning prescribers' and patients' understanding and behaviours. In addition, they very briefly outlined hospital level factors that could influence implementation of guidelines, including deteriorating prescriber relationships, lack of laboratory resources and human resources.

However, the reporting in both studies was unsatisfactory. Both studies reported sample sizes in the range of several hundred people, which is highly unusual

for qualitative studies. It was unclear how these structured interviews were conducted, and at the same time the reporting of findings was insufficient. G. Liu et al. (2011) reported very limited empirical results, and in presenting their results they did not make clear which sections were authors' own prescriptive discussions and which sections came from data from interviews. M. Li et al. (2014) reported a series of descriptive statistics to summarise responses to their questions without presenting any themes. It was unclear if either study had the appropriate qualitative data to support more meaningful analysis.

Two other studies (Wang *et al.*, 2016; Jin *et al.*, 2011) explicitly applied theoretical approaches in their analysis of policy implementation.

In an ambitious study, Wang et al. (2016) attempted to apply the complex system theory first described in the discussion of Xiao, Zhao, et al. (2013) in an analysis of secondary data, with the aim of analysing how “adaptive activities and interactive relationships” amongst different parts and agents in the healthcare system “influence the implementation of policy interventions”. Their study sought to address issues related to both antibiotic stewardship and distribution of pharmaceuticals at all levels, including actors at the government policy level down to individual patients, from hospitals to the pharmaceutical distribution industry. There were two major problems with this study. Firstly, the study completely relied on secondary data sources of published studies and policy documents. The evidence base of the study was insufficient to support the ambitious scale of its investigation or its conclusions to start with. Secondly, as with Xiao, Zhao, et al. (2013), using complex system theory to explain policy implementation represented a case of misapplication of theory. The complex system theory was not suitable to understanding policy implementation. Similar to Xiao, Zhao, et al. (2013) the findings of Wang et al. (2016) rightly presented the complexity of policy implementation by highlighting the fact that there were many actors and complicated incentive mechanisms in a system where actors interact with antibiotic use at various levels. Again, however, the inappropriate use of theory greatly limited the extent to which the stated complexity could be unpacked and analysed.

In a qualitative case study, Jin et al. (2011) investigated perceptions and practices of antibiotic use amongst nearly 30 villagers from 4 villages in 2 provinces to understand “technology regulation”. Although this framing represented much broader policy issues, the scope of this paper was compatible with the concept of antibiotic stewardship, as the authors specifically referred to an antibiotic stewardship policy

when explaining their rationale. From the title, the authors make it very clear that it is their intention to apply the bottom-up perspective to understand individual level factors that could shape local implementation context of antibiotic stewardship policies, and explained the rationale by introducing the idea of “backward-mapping” (Elmore, 1979). Jin et al. (2011) study took on the bottom-up perspective in two significant ways. Firstly, the focus of the study eschewed “the Centre”, and instead emphasised the role of local actors pertinent to the policy issues. Secondly, instead of examining the intended outcomes of the policies of interest, this study explored the perspectives and behaviours local actors on the demand side: the villagers. Hence, this study revealed that local awareness and perception of antibiotics, patient preferences for pharmaceuticals, patterns of antibiotic use and perception of provider prescribing were varied amongst the villagers. Most of the villagers did not have a scientific understanding of antibiotics, and stronger preferences for antibiotics were associated with higher cost (which was seen to implied better quality) and intravenous administration (which was seen to imply greater effectiveness). It was not uncommon for patients to request specific antibiotics for both therapeutic and prophylactic purposes. Finally, the villagers voiced their views about the prescribing behaviours of village prescribers, and their mixed feelings about the prescriber-patient relationship, in which trust was eroded by the perceived financial incentives. Despite the lack of data from actors from the supply-side, this study effectively applied the bottom-up perspective to understanding policy implementation to inform its study design and data analysis, and provided insight into how individual level context could introduce complexities in the implementation of antibiotic stewardship policies.

These two studies showed that only the appropriate use of theoretical ideas on policy implementation could inform collection of the necessary data for a study on the implementation of antibiotic stewardship policies in China, and contribute to a more cogent and in-depth interpretation of the observed phenomena in respect of policy implementation.

The themes which emerged from the findings of all the studies discussed are summarised in Table 3-1. Despite differences in the subjects of interest, macro- and micro level factors that influenced policy implementation in different studies were similar. Although, in essence, barriers and enabling factors often overlapped, it is worth noting that most of the studies concentrated on barriers to implementation from

unsuccessful experience, rather than enabling factors for implementation from successful experience.

Chapter 3. Literature Review

	Implementation of antibiotic stewardship policies outside China	Implementation of other health policies specifically in China	Implementation of antibiotic stewardship policies in China
Macro level factors	<p>Barriers to policy implementation at the national level:</p> <ul style="list-style-type: none"> - Lack of uniform international guidelines; - Lack of uniform regional guidelines. <p>Enabling factors for policy implementation at the national level:</p> <ul style="list-style-type: none"> - Introduction of formal mandates. 	<p>Barriers to policy implementation at the national level:</p> <ul style="list-style-type: none"> - Lack of state capacity to enforce policy; - Lack of financial support at the central level; - Lack of coordinated reforms to address fundamental problems in the healthcare system; - Lack of alignment between the responsibilities of government ministries and their roles in policy implementation; - Lack of coordination across government ministries; - Lack of regulatory power of laws and regulations; - Extensive decentralisation. <p>Enabling factors for policy implementation at the national level:</p> <ul style="list-style-type: none"> - Strengthening of the capacity and effectiveness administrative accountability and bureaucracy; - Provision of financial support; - Mobilisation of high levels of political support and prioritisation; - Enactment of laws, policies and regulations; - Mobilisation of support from non-state actors. 	<p>Barriers to policy implementation at the national level:</p> <ul style="list-style-type: none"> - Lack of coordinated reforms to address fundamental problems in the healthcare system; - Lack of enforcement of existing laws and policies; - Lack of coordination across government ministries.
Micro level factors	<p>Barriers to policy implementation at the hospital level:</p> <ul style="list-style-type: none"> - Lack of funding; - Lack of the necessary personnel and capacity for antibiotic stewardship; - Lack of support from prescribing prescribers, especially senior prescribers; - Lack of support from the hospital administration and management team; - Lack of other aspects including: prioritisation compared with other programmes; time; IT and data support; and others. <p>Enabling factors for policy implementation at the hospital level:</p> <ul style="list-style-type: none"> - Reinforcement of other supportive policies for antibiotic stewardship; - Establishment of an effective administrative structure; 	<p>Barriers to policy implementation at the local level:</p> <ul style="list-style-type: none"> - Lack of financial support at local level; - Lack of the necessary personnel and capacity; - Lack of alignment of interests of different actors; - Lack of local political prioritisation; - Lack of effective supervision and reporting (which enables gaming behaviours); - Lack of realistic target management approach; - Lack of accountability at the local level; - Lack of attention to service users' demands. 	<p>Barriers to policy implementation at the hospital level:</p> <ul style="list-style-type: none"> - Lack of the necessary personnel and capacity for antibiotic stewardship; - Lack of time. <p>Barriers to policy implementation at the individual level:</p> <ul style="list-style-type: none"> - Lack of knowledge and understanding of antibiotic use or policies;

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	<ul style="list-style-type: none"> - Establishment of an antibiotic stewardship committee; - Introduction of leadership by bringing senior and respected members into the committee; - Creation of collaborative relationships across departments; - Conducting clinical audit programmes to rapidly demonstrate outcomes of policy implementation. <p>Barriers to policy implementation at the individual level:</p> <ul style="list-style-type: none"> - Lack of knowledge and understanding of antibiotic use or policies; - Lack of consideration of patient behaviours and preferences; - Lack of consideration of prescriber-patient relationships; - Interference with physician autonomy. 		<ul style="list-style-type: none"> - Lack of trust in prescriber-patient relationships.
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Table 3-1 Summary of themes emerged from the literature review

3.4 Conclusion

This chapter has reviewed both the theoretical literature and empirical studies that are relevant to the topic of this research.

The literature review highlighted several research gaps. Firstly, there was a lack of in-depth research on the implementation of antibiotic stewardship policies in China in general. Existing quantitative evidence could not conclusively attribute the observed decrease in the trends of antibiotic use in China – which varied widely across regional, healthcare and clinical setting – to the impact of *The Campaign*. Secondly, even if there were to be sufficiently strong quantitative evidence from the studies reviewed, none of them provided cogent explanation as to how *The Campaign* could produce the observed impact. Where existing studies attempted to analyse implementation of antibiotic stewardship overall, they tended to focus more on the context rather than the process of policy implementation. Particularly, none of the studies identified and reviewed provided information about the process of implementation of antibiotic stewardship policies in China. Thirdly, there was a lack of application of implementation theory in these studies. Despite several studies being well-conducted and well-reported qualitative case studies capable of generating detailed descriptive analysis, most of the studies reviewed did not take advantage of relevant theories of policy implementation to inform better study designs and inspire more cogent and in-depth interpretation of phenomena relevant to policy implementation.

Thus, the aim of this research is to bridge these research gaps by exploring and analysing the implementation of *The Nationwide Special Rectification Campaign on Antibiotic Use in Hospitals* (*The Campaign* for short) – a collection of antibiotic stewardship policies in China implemented between 2011 through 2013 – at both the macro (central) and micro (hospital) levels. To achieve this aim, specific research questions were framed under three research objectives that sought to identify and interpret factors pertinent to context and process of implementation at either level using appropriate theoretical approaches including the top-down and the bottom up approaches. The objectives and research questions were as follows:

Objective 1: to understand the national policy context of antibiotic stewardship policies in China

- a. What reasons led to actions on antibiotic use in hospitals?
- b. Who were the key actors at the central level?
- c. What were the antibiotic stewardship policies to date?
- d. How did *The Campaign* relate to these policies?

Objective 2: to understand the healthcare system context in which implementation of *The Campaign* took place

- a. What did the system level context comprise?
- b. What did the hospital level context comprise?
- c. What did the individual level context comprise?

Objective 3: to explore and analyse the implementation process of *The Campaign*

- a. How was The Campaign implemented at the central level?
- b. How was The Campaign implemented at the hospital level?

The considerations for the use of theory were also duly reflected by the study design of this research, which is introduced in Chapter 6 (Study Design and Methods). However, in order to understand policy implementation in China, it is crucial first to understand China's healthcare system background in Chapter 4, the next chapter.

Chapter 4. Healthcare System Background

4.1 Introduction

It follows from the discussion of theoretical ideas in the previous chapter that understanding the context of a given policy is pre-requisite to understanding its implementation. Therefore, this chapter introduces China's healthcare system, and comprises contextual factors that could influence policy processes and behaviours relevant to policy implementation.

By describing how China's healthcare system works, this chapter provides the necessary briefing on the healthcare system context in which policy implementation takes place. The description of China's healthcare system is focused on three aspects: governance and administration, organisation and delivery, and financing and provider incentives. It draws on a number of recent and comprehensive reviews, particularly one of the most prominent reviews to date (Meng *et al.*, 2015).

In the case of antibiotic stewardship policies, antibiotic prescribing is one of the most influential behavioural aspect for policy implementation, and therefore requires detailed discussion. Relating to the three aspects of China's healthcare system, this chapter also discusses how factors at the levels of healthcare system, hospital and individual could influence antibiotic prescribing by prescribers, and hence affect policy implementation.

4.2 Governance and administration

The main administrative bodies of health at the central level in China are the National Health and Family Planning Commission (NHFPC) – former the Ministry of Health (MoH) until 2013 – and its affiliated agency, the State Administration of Traditional Chinese Medicine (Meng *et al.* 2015:19). As a ministry of the State Council, or the Central Government, they enforce laws that are pertinent to health and healthcare, which are mainly formulated by the State Legislature in the form of the National People's Congress, or sometimes by the ministries.

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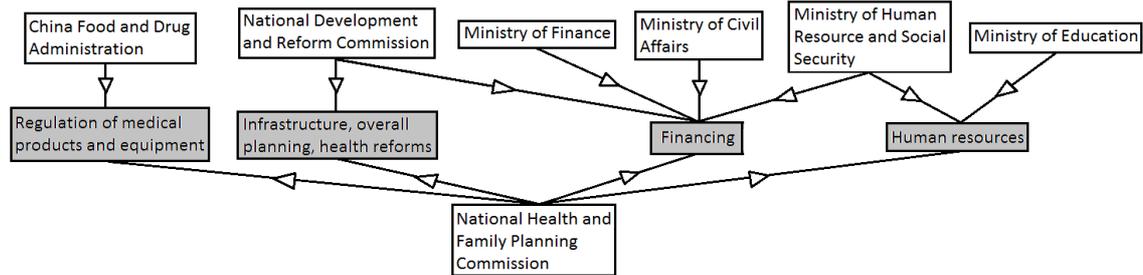


Figure 4-1 Collaboration of multiple ministries in health

Issues in healthcare often require multi-ministerial collaboration. Other ministries of, or closely related to, the State Council, for example the China Food and Drug Administration, Ministry of Finance and Ministry of Human Resources and Social Security, work closely with the NHFPC on different policy areas in healthcare. This is described in Figure 4-1.

The interplay between decentralisation and centralisation in the governance and administration of health in China has been a constant theme since the country underwent a market reform in the late 1970s (Wagstaff *et al.*, 2009). Both the governance and legal systems of China comprise a four-tier hierarchy of administrative or legislative bodies at the state level, provincial level, city level, and in the case of health administration, township level. The organizational structure of local health administrations is similar to that at the central level and their governing functions mirror those at the central level (Meng *et al.* 2015:20).

Provincial and city level governments have varying degrees of power and flexibility to formulate and implement variations of policies based on the guidelines and instructions provided by the Central Government due to extensive decentralisation, both in terms of function (Meng *et al.* 2015:34; Hipgrave *et al.* 2012), and in terms of geography (Ho, 2010). On the one hand, much of the administrative authority over the function of health is transferred to from the central government to the local governments (Ma, Lu, and Quan 2008; Meng *et al.* 2015:38), which is also a consequence of decentralisation of fiscal expenditure and revenue (Ramesh, Wu & He, 2014). On the other hand, local autonomy of different degrees also exists within geographically defined administrative subdivisions in China (Ho, 2010). Despite both forms of decentralisation, the Central Government “still plays a dominant role in both legislation and decision making”; in this sense, decentralisation allows all levels of local

governments “to develop their plans and policies in light of local realities” (Meng et al. 2015:35, 37) such as availability of local funding, so that all of them are effectively “both policy-makers and policy-implementers” (Meng et al. 2004:13).

Besides these state actors, non-state actors in the form of civil society organisations (CSOs) also play important roles in health administration in China. There are three forms of CSOs. “Civil organisations” are mass organisations and associations that are closely affiliated with government systems and have an established national network; “civil non-enterprise units” fill gaps in welfare functions by providing certain public and social services; “grass-roots CSOs” are community-based organisations that are involved with the disadvantaged populations that they work with (Li *et al.*, 2010; Schwartz & Evans, 2007). This thesis focuses on the first group of CSOs, which are legally recognised by the Chinese government and registered with the Ministry of Civil Affairs (Li *et al.*, 2010), and form a crucial part of the policy context of antibiotic stewardship. Some of the most notable and influential associations in this group are professional associations that represent interests of their respective professional groups, such as the Chinese Medical Association, the Chinese Pharmacists Association and the Chinese Preventative Medication Association, which frequently work alongside the government in public health issues by organising training and helping formulating professional guidelines (Ma, 2002).

4.3 Organisation and delivery

Government-owned public hospitals are the main providers of healthcare, as they account for 60% of all hospitals in China and make up almost 90% of the total number of existing ward beds (Meng et al. 2015:112). Due to their dominance in healthcare provision in China and relevance to the research topic of interest, this research focus on public hospitals. Unless otherwise stated, both “hospitals” and “healthcare providers” refer to public hospitals in this research.

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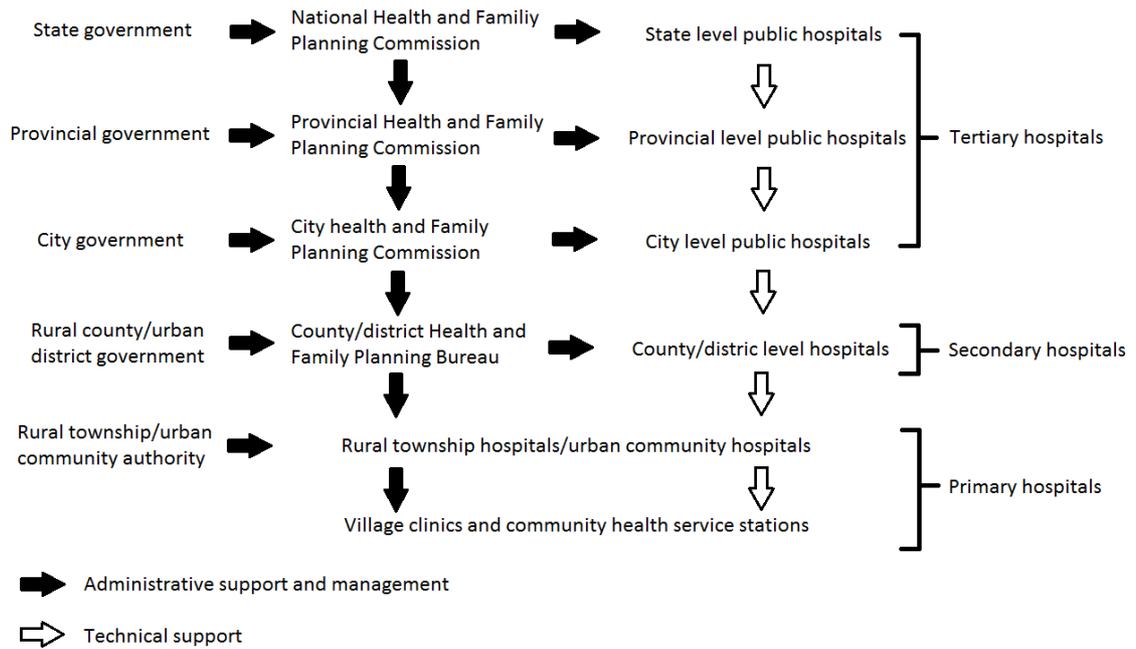


Figure 4-2 Organisation of healthcare providers in China (Xu et al. 2014, adapted)

From an administrative perspective, China's healthcare providers are organised into three tiers based on size of catchment area, represented in Figure 4-2. Primary care comprises clinics and health centres at the level of urban community or rural village and township. Secondary hospitals are designed to function at the level of district or county. Tertiary hospitals cover the level of city or above. In reality, the tiered system is also associated with the level of healthcare services a hospital provides. Primary care providers mostly provide limited healthcare services, whilst secondary and tertiary hospitals provide comprehensive services and conduct academic research. Within the three-tiered healthcare system, traditional Chinese Medicine (TCM) coexists with modern medicine (Hesketh & Zhu, 1997). TCM services are provided in the TCM departments of many hospitals at all three levels that mainly provide modern medical services. In addition, 12.5% of all hospitals are TCM hospitals that mainly provide TCM services. Increasingly, TCM hospitals also provide modern medical services (Shen *et al.*, 2011).

Healthcare resources are maldistributed across primary care and higher-level hospitals, and across urban and rural areas. Although the number of primary care providers is high in comparison with higher level hospitals, most of the healthcare resources (measured by, for example, possession of advanced technology and ward beds) are concentrated in the hospitals, especially those in urban areas (Meng *et al.*

2015:111-115; Hougaard, Østerdal, and Yu 2011). Advanced care in China's cities, especially metropolitan cities, is available at levels comparable with advanced economies (Bixi, Mu & Targa, 2013). Beijing, and Shanghai, for instance, report prevalence of advanced medical equipment that exceed levels common in European cities (Chen *et al.*, 2007), and they are two of the few cities that accommodate extremely large hospitals with 4000 beds or more (Barber *et al.*, 2014). Human resources are scarce and unevenly distributed in general (Yip *et al.*, 2012). Only about 6% of hospital personnel are prescribers with post-graduate degrees, while the vast majority act as prescribers but only bachelor-level education (Hougaard, Østerdal & Yu, 2011). Compared with rural areas, urban areas have more than twice the healthcare professionals per 1000 population, and more healthcare professionals with more advanced educational background (Meng *et al.* 2015:121-122; Hougaard, Østerdal, and Yu 2011). In rural areas, however, many prescribers are underqualified (Hougaard, Østerdal & Yu, 2011; Yip *et al.*, 2012). Most importantly, until recently, the development of workforces at the primary level in China's healthcare system has been a neglected area (Barber *et al.*, 2014; Yip *et al.*, 2010). Coupled with the lack of a gatekeeping system that allows patients to disregard the recommended ascending referral pathways within the system and self-refer to any level of hospital as they wish, the perceivable differences in resources and available services between primary care providers and higher level hospitals lead to a concentration of healthcare utilisation in higher level hospitals, and a general lack of confidence in primary care providers (Pan *et al.*, 2006; McCollum *et al.*, 2014). About 85% of all outpatient visits and inpatient admissions respectively take place in secondary and tertiary hospitals (Meng *et al.* 2015:139). In many instances, higher-level hospitals, rather than primary care providers, become the first contact point for patients (Wu *et al.*, 2017). To address overcrowding in higher level hospitals and increase the supply of services at primary level, ongoing pilot reforms are being implemented to strengthen the capacity of primary care providers and establish a functional gate keeping system and formal patient referral pathways (Wang *et al.*, 2015; Liu *et al.*, 2011b).

The performance and quality of services provided by all levels of hospitals – for example, rationality of prescribing, service provision and healthcare costs – are monitored and regulated by central and local governments, as well as non-state actors such as government-related research organisations and professional associations. On the government's side, the departments of NHFPC and its associated organisations, including the Centre of Inspection and Supervision and the National Clinical

Improvement System, are in charge of managing quality of healthcare at the country level by developing quality standards, implementing quality assurance policies, and monitoring and auditing quality of healthcare of all three levels of hospitals (Ma *et al.*, 2015). At the local level, these matters are administered by the arms of the NHFPC. Each tier of hospital contains another grading system based on provider performance and quality of healthcare (Hougaard, Østerdal & Yu, 2011). High-performing hospitals can be accredited to move up within the tiered system, or even be considered for an upgrade along the tiered system, whilst under-performing hospitals may be subjected to punitive measures. In addition, payers responsible for administering the social health insurance schemes also impose separate sets of regulatory controls on service provision and prescribing, primarily with the purpose of controlling healthcare costs. Hospitals failing to pass the standards would not receive payments through social health insurance, and in severe cases, could face de-listing by the social health insurance schemes. On non-state actors' side, professional associations contribute to promoting self-regulation amongst healthcare professionals by promoting ethical medical practices through enforcing internal disciplinary actions. The adequacy and the effectiveness of carrying out hospital accreditations and performance audits on the quality of healthcare and performance of hospitals is unclear, as the data and reports associated with these exercises remain internal to the government. However, it has been recognised that the grading system of healthcare significantly shapes the public's perception of quality of healthcare, drawing even greater demand for services at higher and better graded hospitals (Ma *et al.*, 2015).

4.4 Financing and provider incentives

Out-of-pocket payments, social health insurance schemes and subsidies from local (provincial and county) governments comprise the three main methods of healthcare financing in China. The three major social health insurance schemes in China, which covered more than 92% of China's total population (Yip *et al.*, 2012), are the New Cooperative Medical System (NCMS), the Urban Resident Basic Medical Insurance (URBMI) and the Urban Employee Basic Medical Insurance (UEBMI); which cover the rural population, urban unemployed population and urban employees respectively. In addition, the minority of civil servants, army personnel and other public sector workers are entitled to a special form of full-coverage insurance called

“Government Funded Healthcare” (Gongfei Yiliao), although it is now being gradually phased out and replaced by other social health insurance schemes.

Social health insurance is on course to replace out-of-pocket payments to become the largest contributor to healthcare financing in China. Since the first decade of the 21st century, the Chinese government has been dedicating efforts to reduce out-of-pocket payments by dramatically improving the coverage of social health insurance schemes and increasing government spending. In 2000, out-of-pocket payments, social health insurance schemes and government subsidies accounted for 59%, 26% and 15% of total health expenditure respectively; in 2012, they became a more balanced set of figures of 34%, 36% and 30% (Meng et al. 2015:76). This is despite the fact that the service packages of the social health insurance schemes for the more financially challenged populations – the NCMS and the URBMI – offer limited financial protection, so that their beneficiaries still have to bear over 50% of their medical expenditure (Yip *et al.*, 2012).

The current financing and pricing arrangements create dominant fee-for-service incentives for healthcare providers. As government subsidies are unable to cover all the costs, which include operational costs and capital investments in infrastructure and equipment, hospitals are required to generate revenue to cover the shortfall from fee-paying patients and payment from social health insurance based on a stringent fee schedule regulated by the government (Eggleston *et al.*, 2008). Although other provider payment mechanisms such as global budget and capitation exist, social health insurance payment is also predominantly fee-for-service (Meng et al. 2015:102). This incentive, coupled with the very low prices for medical services set by the official fee schedule in order to ensure affordability of healthcare, drives healthcare providers to provide profitable high-tech diagnostics and pharmaceuticals while stinting on unprofitable basic services (Eggleston *et al.*, 2008). The fee-for-service incentive at the level of hospital is then translated to the level of prescribers through their salary structure. As labour costs are mainly recovered from revenue generated by service delivery, prescribers' income and benefits are primarily determined by their ability to create revenue; workload is one of the major assessment criteria for assigning bonuses (Meng et al. 2015:103-104). Bonuses make up a substantial part of prescribers' pay. In big cities, bonuses are thought to have often equalled or exceeded basic salary (Munro, 2013).

One effect of this system is overprescribing, as pharmaceutical sales are in effect a major source of revenue for hospitals, especially secondary and tertiary hospitals. According to recent data, prescription pharmaceuticals take up nearly 50% of China's total healthcare expenditure, with the rest evenly split between inpatient and outpatient services (Daemmrlich & Mohanty, 2014). Higher level hospitals and primary care providers account for 60% and 18% of total pharmaceutical consumption in China in 2012 (Cheng & Wang, 2014). The mechanism that allows hospitals to profit from pharmaceutical sales is a government-sanctioned 15% mark-up over wholesale pharmaceutical prices (Herd, Hu & Koen, 2010). The actual mark-ups could be much higher ratios, because pharmaceutical distributors that act as agents between hospitals and manufacturers often introduce extra costs through their lobbying activities to gain market access for their products (Yu *et al.*, 2010). For example, pharmaceutical distributors could offer informal payments to prescribers to increase sales of their products (Munro, 2013). At the same time, the healthcare financing arrangements do little to stimulate healthcare providers to deliver immunizations and other public health services, or to engage in the broader determinants of health in the community (Eggleston *et al.*, 2008).

In order to realign mechanisms of healthcare financing with the aims of reducing overprescribing and encouraging provision of public health services, China introduced a series of interrelated health reform measures that revolved around the introduction of the New Essential Medicine System in 2009, including policies to strengthen the capacity of primary care providers and improve their provision of public health services. The primary purpose of these policies is to remove revenue associated with pharmaceutical sales and replace it with government subsidy and fees for providing services related to maintaining community health. As a starting point, the government stipulated that the vast majority of pharmaceuticals available at primary care providers must be limited to Essential Medicines, typically consisting of about 200 types of conventional pharmaceuticals and 100 types pharmaceuticals with Traditional Chinese Medicine formularies called "TCM patented pharmaceuticals". Most of the included pharmaceuticals are low-priced generics achieving the required Good Manufacturing Standards, and virtually all of them are eligible for reimbursement from all the social health insurance schemes (Yang *et al.*, 2013c). An integral policy element associated with the Essential Medicine Policy is the "zero-mark-up" policy, meaning that Essential Medicines must be sold to patients at procurement cost. To support this policy, the government created a regional procurement platform for collective

tendering, removing facility-level tendering that involves more steps and room for mark-ups related to pharmaceutical distribution (Barber *et al.*, 2013). In addition, to fill the deficit in revenue created by the zero-mark-up policy, the government increased financial subsidies available to primary care providers, which cover the basic salaries of all healthcare workers, including prescribers (Zhang, Wang & Zhang, 2014). Whilst the specific arrangements and percentages regarding the subsidy are likely to differ in different regions and districts, a general increase in government subsidy for primary care providers has been observed since the set of policies was first rolled out in 2009 (Cheng *et al.*, 2012). Several years into the implementation in 2013, public subsidies already accounted for 40% of primary care providers' revenue, significantly up from 14% in the early stages of implementation in 2011 (Meng *et al.* 2015:31, 82). To further encourage the provision and quality of public healthcare and basic healthcare services including setting up patient profiles for all the residents enrolled in the primary care provider to document their history, providing regular health check-ups and immunization services for the residents, and managing chronic diseases for the elderly patients, the governmental subsidies are delivered as a budget decided by capitation, and are tied to an annual performance assessment (Yip *et al.*, 2012). Under this system, basic salary funded by governmental subsidy, rather than performance-linked bonus based on service provision, constitutes the bulk of a prescriber's pay (Zhou, Li & Hesketh, 2014). The need for prescribers to fulfil requirements in provision of public health services has more to do with helping securing better governmental subsidies for their employers, the primary care providers. The sufficiency of government subsidy is therefore vital in maintaining the dissociation between service provision and revenue generation (Tang *et al.*, 2013). However, as of now, the full suite of policies comprising Essential Medicines Policy and the commensurate reforms in provider financing are only applicable to primary care providers (Guan *et al.*, 2011). Although essential medicines with zero mark-ups are also available in the more influential and sizeable secondary and tertiary hospitals, they are not restricted to using only essential medicines in the way that primary care providers are. In part, this is out of clinical considerations: the limited range of essential medicines is not sufficient to treat more complicated and severe diseases that higher level hospitals regularly deal with. Fundamentally, budgetary support from the government remain nominal for higher level hospitals – accounting for only around 8% of their total revenue (Meng *et al.* 2015:31) – so that they still primarily rely on the fee-for-service revenue generating model that emphasizes provision of high-margin services and pharmaceuticals. A negative effect

of the difference in availability of pharmaceuticals due to this policy arrangement is the increase in referrals from primary care providers to higher-level hospitals, as patients fail to obtain the appropriate treatments from the restricted range of pharmaceuticals available at the primary care level (Hu, 2013).

4.5 Factors influencing antibiotic use in hospitals

Most of the antibiotics in China reach patients through hospitals, particularly secondary and tertiary hospitals. As pointed out above, 60% of total pharmaceutical consumption in China takes place through higher level hospitals, compared with 18% through primary care providers and 19% through retail pharmacies in 2012 (Cheng & Wang, 2014). Consumption of antibiotics for systemic use (namely those that are applied to the whole human body as opposed to local areas) in secondary and tertiary hospitals made up over 20% of total pharmaceutical consumption between 2008 and 2011, the largest share of consumption amongst all types of pharmaceutical (Zhu and Cheng 2012:21). In comparison, antibiotics only account for less than 7% of all pharmaceutical sales in retail pharmacies (China Association of Pharmaceutical Commerce, 2015). Antibiotics are a particularly crucial class of pharmaceuticals for inpatient services, which take up 60% of total pharmaceutical consumption in China (Geng, 2014). Antibiotics for systemic use account for 20% of the total inpatient expenditure in public hospitals incurred through the social health insurance scheme UEBMI in 2013, and it is the largest share of all types of pharmaceuticals (China Association of Pharmaceutical Commerce, 2015).

As with other countries, antibiotic use in hospitals in China can be influenced by contextual factors pertinent to the healthcare system at system, hospital and individual levels (Teixeira Rodrigues *et al.*, 2013; Lopez-Vazquez, Vazquez-Lago & Figueiras, 2012; Hulscher, Grol & van der Meer, 2010); the nature of these factors is described in Table 4-1.

Level of determinants	Factors
System	Role and size of the pharmaceutical market; organisation, financing and other healthcare policies
Hospital	Hospital policies for healthcare delivery
Individual	Knowledge, attitude and behaviours of prescribers and patients; interactions between prescribers and patients

Table 4-1 Influencing factors of antibiotic use in hospitals

At the system and hospital levels, existing empirical research shows that factors pertinent to the organisation of hospitals, healthcare financing and provider incentives at these levels can influence antibiotic use in hospitals (Wang *et al.*, 2016).

As described previously, the current healthcare financing and pricing arrangements and provider payment mechanisms create strong fee-for-service incentives for healthcare providers to provide more services and prescribe more pharmaceuticals, including antibiotics. It has been observed that there was a tendency for prescribers to prescribe more expensive pharmaceuticals (Chen *et al.*, 2014). This fee-for-service incentive was transferred to prescribers through their fee-for-service salary system, which encouraged revenue generation (Liu & Mills, 2005).

With these arrangements in the system unchanged, health reform interventions aimed at making healthcare more affordable and accessible could lead to unintended and undesirable consequences. For example, pricing reforms that aimed to reduce prices for certain pharmaceuticals could lead to unintended effects such as increased utilisation of pharmaceuticals, especially expensive ones, and increased pharmaceutical expenditure (Meng *et al.*, 2005). Similar unintended effects in prescribing can be seen with insurance coverage, which lowers barriers to accessing healthcare for patients without necessarily changing the fee-for-service provider payment mechanism. On the one hand, insured patients, who had better ability to pay than the uninsured, were more likely to be prescribed more pharmaceuticals, antibiotics and injections than the uninsured (Sun *et al.*, 2009). On the other hand, although insured patients received more pharmaceuticals and more expensive pharmaceuticals, they may not be receiving better health treatment (Lu, 2014). Even though such prescribing patterns may be related to consideration of quality of pharmaceuticals – due to differences in production standards, cheaper pharmaceuticals in China can be associated with poorer quality and greater risk of adverse effects (Yao, Zhou & Wang, 2012) – there is still clear evidence that fee-for-service incentives are leading to overprovision of healthcare (Chen *et al.*, 2014).

Introduction of alternative provider payment mechanisms is one crucial step to removing fee-for-service incentives and reducing unnecessary prescribing. Even though fee-for-service remains largely the status quo, multiple pilots have been carried out to introduce other provider payment mechanisms through social health insurance. Recent studies on pilot reforms at primary care level (Yip *et al.*, 2014; Sun *et al.*, 2014, 2016) consistently showed that the use of capitation combined with pay-for-

performance can effectively reduce irrational prescribing. For secondary and tertiary hospitals, pilot reforms of case-based payments such as diagnostic-related groups were less well studied and required further research; existing results showed that these pilots could reduce pharmaceutical expenditure, but it was unclear whether or not quality of healthcare was affected (Yip *et al.*, 2010). In the meantime, moving the salary system of prescribers away from the reliance of fee-for-service bonus could also reduce overprovision of healthcare and overprescribing (Liu & Mills, 2005; Wang *et al.*, 2011).

However, there is a direct relationship between how providers are paid and how providers are financed: overprescribing is likely to persist if pharmaceutical sales and service provision are the main means of raising revenue for hospitals. Coupled with the financing reform, the Essential Medicines Policy reform, introduced along with the zero-mark-up policy, is a significant measure to correct the health financing drivers of overprescribing at the primary care level. The impact of this set of reforms has been widely assessed (Yang *et al.*, 2013c; Chen *et al.*, 2013; Tang *et al.*, 2013; Yin, Song & Bian, 2014; Song *et al.*, 2014b, 2014a; Yao *et al.*, 2015; Xiao *et al.*, 2016; Gong *et al.*, 2016). It has been found that by regulating the procurement and limiting the range of pharmaceuticals available for selection, removing the mark-up on price, and increasing government subsidy to replenish the gap in healthcare financing, the Essential Medicines Policy could effectively lower the average pharmaceutical expenditure per prescription. However, there is no clear evidence on whether the policy can effectively reduce antibiotic prescribing, or whether it can improve the medical rationality and quality of prescribing where reduction was observed. In addition, as described previously, these reforms are limited to primary care level only as of now, and the situations in secondary and tertiary hospitals largely remain unchanged. But existing evidence suggests that the Essential Medicine Policy per se does not lead to rational antibiotic prescribing. The direction of the impact of the policy on antibiotic use is heterogeneous among the existing studies. Even when reduction of antibiotic use is observed, the level of antibiotic use remains high and irrational or inappropriate use prevalent (Wei *et al.*, 2017; Xiao *et al.*, 2016; Gong *et al.*, 2016; Song *et al.*, 2014b; Yin, Song & Bian, 2014; Chen *et al.*, 2013; Yang *et al.*, 2013b). In explaining why this may be the case, the more recent studies explicitly point out that the essential medicines policy package is concerned with cost control rather than antibiotic stewardship, and effects associated with rational antibiotic use is better explained by the implementation

of the Essential Medicine Policy with antibiotic stewardship programmes (Wei *et al.*, 2017; Xiao *et al.*, 2016).

At the individual level, factors pertinent to the individuals involved antibiotic prescribing – prescribers and patients – can influence antibiotic prescribing (Mao *et al.*, 2015). Using common cold as a tracer condition, studies have shown that antibiotics, which are not needed for the common cold, are often prescribed for the common cold in China, particularly in rural areas (Reynolds & McKee, 2009; Sun *et al.*, 2015b; Zhao *et al.*, 2013a). Level of training and experience was influential in prescribers' prescribing practices, with better-trained prescribers working in higher-level hospitals more likely to have better understanding of rational antibiotic use (Bai *et al.*, 2016; Zhao *et al.*, 2013b). Another influential factor for antibiotic prescribing was patients' demand for antibiotics, including in the form of injections (Reynolds & McKee, 2009; Jin *et al.*, 2011). This was in part due to lack of medical understanding, especially amongst rural residents (Gu *et al.*, 2015). Patients' attitudes could also be informed by their belief in the efficacy of medicines, for example injections (Reynolds & McKee, 2011). Finally, growing medical disputes and deteriorating prescriber-patient relationships in China, which result from patients' negative perceptions of the misalignment between financial incentives and provision of healthcare, can lead to defensive prescribing behaviours in the form of over-prescribing, as patients' hostility towards prescribers becomes so significant that prescribers are afraid of the ramifications of not meeting patients' expectations or demands, which sometimes even escalate to physical violence (He, 2014; Hesketh, Wu & Mao, 2012).

4.6 Conclusion

The way that China's healthcare system is governed, organised and financed sets the scene for understanding the implementation of antibiotic stewardship policies in two ways. On the one hand, the structures of the healthcare system – the way that its resources are created, distributed and regulated – determine some of the vital parameters for the implementation process of health policies in China. On the other hand, healthcare system factors at the system, hospital and individual levels can influence prescribing behaviours and antibiotic use in hospitals, the prime target of antibiotic stewardship policies, in various ways. In light of these influential factors, the next chapter provides a summary of the antibiotic stewardship policies to date.

Chapter 5. National Policy Context

5.1 Introduction

The last chapter described China's healthcare system context and how it could influence antibiotic use and prescribing; this chapter outlines another crucial part of the context for policy implementation: the national policy background. By examining the policy context of antibiotic stewardship, actors in antibiotic stewardship and the purpose and content of *The Campaign*, this chapter seeks to address the first research objective proposed at the end of Chapter 3 (Literature Review), namely to understand the national policy context of antibiotic stewardship policies in China. In doing so, it lays the foundation for researching the characteristics of policy implementation and assessing the degree to which top-down and bottom-up approaches to understanding policy implementation described in Chapter 2 (Theoretical Background) are applicable to the implementation of *The Campaign*. This account in this chapter is based on existing official policy documents and academic literature.

5.2 Policy background of antibiotic stewardship

China has long recognised the importance of antibiotic stewardship in hospitals. Although defining antibiotic use and production as a multisectoral and multi-ministerial issue between the NHFPC, the China Food and Drug Administration (CFDA), the Ministry of Agriculture and the Ministry of Industry and Information Technology is a relatively recent development (Ministry of Health, 2010), policies relevant to rationalising antibiotic use in hospitals were conceived by the former Ministry of Health in the early 2000s (Sun & Hawkey, 2016; Cui *et al.*, 2017). These policy actions on antibiotic use in hospitals are motivated by domestic and international factors. Domestically, the government began to take notice of antibiotic stewardship for two reasons. On the one hand, the problems of rising antibiotic resistance and extensive irrational antibiotic use had reached a level critical enough to alarm the government to issue initial clinical guidelines and stewardship measures as a first step to rationalise prescribing (Ministry of Health, 2004) and establishing surveillance networks better to gauge the extent of the problems (Ministry of Health, 2005, 2006). On the other hand, antibiotic prescribing was quickly becoming a heated issue in public discourse. Increasing documentation of overprescribing of antibiotics associated with prescribers'

financial incentives (Li *et al.*, 2012) clearly highlighted some of the most fundamental problems with financing and delivery in China's healthcare system described in Chapter 4 (Healthcare System Background). On top of this, sensationalist reporting only served to fan the fame of patients' frustration with the system and misunderstanding of prescribers (Tucker *et al.*, 2015). Tackling antibiotic overprescribing, therefore, became an indispensable part of the health reforms to address those perceived healthcare system deficiencies (Yip *et al.*, 2010). International collaborations between the former MoH and the World Health Organization (WHO) also helped catalyse stronger policy actions on antibiotic use in hospitals. Through working with the WHO in the early 2000s, the former MoH became increasingly aware of the importance of rational antibiotic use and subsequently adapted measures proposed by the WHO to rationalise antibiotic use in hospitals, such as developing and monitoring indicators of antibiotic use and setting up expert committees on rational use of medicines (Chinese Center for Disease Control and Prevention, 2011; Hu, 2010).

Subsequently, a series of interconnected antibiotic stewardship policies were gradually introduced by the central NHFPC over a period close to 10 years, culminating in *The Campaign*. Prime examples of policy actions by the NHFPC to tackle overprescribing of antibiotics and improve antibiotic stewardship – summarised in Table 5-1 – can be divided into four strategic areas (NCCPAA Committee, 2015):

- Establishing and strengthening surveillance networks to quantify the levels of antibiotic use and resistance and inform policy making, monitoring and evaluation;
- Strengthening the technical capacity of medical professionals to improve the knowledge and capacity of prescribers, clinical pharmacists and microbiologists;
- Improving the rationality of antibiotic use in hospitals and the prescribing;
- Establishing laws on antibiotic stewardship to safeguard antibiotic stewardship activities in the long term.

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Strategic area		Year	Key documents	Summary of the policies
1. Establishing and strengthening surveillance networks (Ministry of Health 2005, 2006, 2009b, 2012d)		2005	Notice on Establishing Surveillance Networks for Antibiotic Use in Hospitals and Antibiotic Resistance	- Establishing surveillance networks for antibiotic use in hospitals (Centre for Antibacterial Surveillance, CAS) and antibiotic resistance (China Antimicrobial Resistance Surveillance System, CARSS) and expand their nationwide coverage
		2006	Notice of the General Office of the Ministry of Health on Further Enhancing the Surveillance of Antibiotic Use in Hospitals and Antibiotic Resistance	
		2009	Notice on Strengthening the Surveillance of Rational Use of Medicines	
		2012	Notice on Strengthening the Surveillance of Antibiotic Use in Hospitals and Antibiotic Resistance	
2. Strengthening the technical capacity of medical professionals (Ministry of Health & Committee of Experts on Rational Drug Use, 2012; Ministry of Health, 2008a, 2007, 2012c, 2012a)	Technical guidelines for antibiotic use	2012	National Guidelines for Antimicrobial Treatments	- Providing guidelines for treatments of infectious diseases, including in the case of paediatrics - Summarising the pharmacological properties of various anti-infectives
	Expert committee on rational use of medicine	2008	Notice of the General Office of the Ministry of Health on Establishing the Ministry of Health Committee of Experts on Rational Drug Use	- Establishing the CERDU to formulate and agenda on rational use of medicines, one of the six working groups being antibiotics
	Capacity building for medical professionals	2007	Notice of the Department of Medical Administration of the Ministry of Health on Conducting Pilot Programme of Clinical Pharmacist System	- Defining the role of clinical pharmacists and the departments of pharmaceutical affairs in advising and monitoring antibiotic use in hospitals
		2009	Large scale, nationwide training programmes exemplified by the Xinghuo Programme (2009-2011) and the Mengya Programme (2009-2012)	- Improving the capacity of medical professionals across all levels of healthcare in ensuring rational antibiotic use and conducting surveillance of antibiotic resistance
		2012	Notice of the General Office of the Ministry of Health on Organising Nationwide Training Programmes on the Stewardship of Antibiotic Use in Hospitals	
	Prescription reviews in hospitals	2010	Notice of the Ministry of Health on Issuing the Pilot Standards for the Review and Management of Prescriptions in Hospitals	- Specifying the standards and methods of reporting of prescription reviews in hospitals
3. Improving the rationality of antibiotic use and prescribing (Ministry of Health, 2004, 2010, 2011, 2012b; National Health and Family Planning Commission,	Early attempts to regulate prescribing	2004	Notice on Implementing the Guiding Principles for Antibiotic Use in Hospitals	- Outlining guidelines on antibiotic use and principles for treating different types of bacterial infections - Outlining early antibiotic stewardship strategies such as formulary restriction

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2013; Ministry of Health, 2008b, 2009a)		2008	Notice of the Ministry of Health on Further Improving the Stewardship of Antibiotic Use in Hospitals	<ul style="list-style-type: none"> - Improving rational antibiotic use in several key areas including perioperative antibiotic prophylaxis, prophylaxis treatment for Class I incision and the use of fluoroquinolones - Putting in place antibiotic stewardship policies including formulary restriction and a resistance alert system
		2009	Notice of the General Office of Ministry of Health on Issues Concerning the Stewardship of Antibiotic Use in Hospitals	
	Cross-ministry rectification campaign	2010	Notice on Issuing the Plan for the Nationwide Joint Special Rectification Campaign on Antibiotics	<ul style="list-style-type: none"> - Initiating a coordinated campaign across four government ministries (MoH, CFDA, MIIT and MoA) to improve manufacturing, supply and use of antibiotics in different sectors
	Nationwide campaign (<i>The Campaign</i>)	2011	Notice of the General Office of Ministry of Health on Effectively Conducting the Nationwide Special Rectification Campaign on Antibiotic Use in Hospitals	<ul style="list-style-type: none"> - Initiating a three-year nationwide campaign characterised by the requirement for hospitals to meet stringent numerical targets across several key indicators and to comply with other antibiotic stewardship policies
		2012	Notice of the General Office of Ministry of Health on Continuing to Further Carry Out the Nationwide Special Rectification Campaign on Antibiotic Use in Hospitals	
		2013	Notice on Further Conducting the Nationwide Special Rectification Campaign on Antibiotic Use in Hospitals	
	4. Establishing legal institutions for antibiotic stewardship (Ministry of Health, 2012a)	Enforcing laws on general medical and pharmaceutical affairs	Before 2012	Examples include: Pharmaceutical Administration Law of the People's Republic of China; Law on Practicing Prescribers of the People's Republic of China; The Administrative Regulations on Medical Institution; Measures for the Administration of Prescriptions; Measures for the Administration of the Control of Hospital-Acquired Infections; The Provisions on the Administration of Pharmaceuticals in Medical Institutions
Enforcing the law on antibiotic use		2012	Measures for the Stewardship of Antibiotic Use in Hospitals	<ul style="list-style-type: none"> - Enforcing antibiotic stewardship policies concerning all aspects of antibiotic use in hospitals, from the procurement process through to resistance monitoring; - Specifying accountabilities and responsibilities of the actors at government and hospital levels in antibiotic stewardship.

Table 5-1 Key antibiotic stewardship policies in China

Early efforts in respect of antibiotic stewardship were characterised by lack of implementation. Issued in 2004 as the first set of antibiotic stewardship policies, the “Guiding Principles for Antibiotic Use in Hospitals” were not backed by surveillance data or supporting policies to build the necessary human and administrative resources for policy implementation. Later policies – including the “Notice of the Ministry of Health on Further Improving the Stewardship of Antibiotic Use in Hospitals” in 2008 and the “Notice of the General Office of Ministry of Health on Issues Concerning the Stewardship of Antibiotic Use in Hospitals” in 2009 – were more likely to be better implemented as they were better supported by complementary policies. Since 2005, surveillance systems on antibiotic use and resistance have been established (“Notice on Establishing Surveillance Networks for Antibiotic Use in Hospitals and Antibiotic Resistance” in 2005, and “Notice of the General Office of the Ministry of Health on Further Enhancing the Surveillance of Antibiotic Use in Hospitals and Antibiotic Resistance” in 2006) and expanded (“Notice on Strengthening the Surveillance of Rational Use of Medicines” in 2009), which better enabled evidence-based policy making and progress monitoring. Other complementary policies also continued to build and strengthen human resources, such as the establishing of a new expert committee to administer rational use of medicines (“Notice of the General Office of the Ministry of Health on Establishing the Ministry of Health Committee of Experts on Rational Drug Use” in 2008), and initiating of training programmes to increase the professional capacities of prescribers, pharmacists and microbiologists (“Notice of the Department of Medical Administration of the Ministry of Health on Conducting Pilot Programme of Clinical Pharmacist System” in 2007; Xinghuo and Mengya Programmes in 2009).

5.3 Actors in antibiotic stewardship

As a distinct policy issue, antibiotic stewardship is related to existing policy areas in healthcare delivery with designated actors at central and hospital levels responsible for implementation. At the central level, actors are organised around two broader policy areas. The first area is “rational use of medicines”, a technical concept that concerns whether antibiotics should be applied given the medical indications, and how antibiotics should be applied, such as the choice of pharmaceuticals, route of administration, and dosing schedules (National Institute of Hospital Administration & China Hospital Association, 2011). The goal of this policy area is to achieve the best intended clinical outcomes with minimal toxicity and impact on resistance. The second

area is “healthcare quality and safety” (National Institute of Hospital Administration & China Hospital Association, 2011). In addition to ensuring quality and safety of prescribing, which overlaps with the “rational use of medicines” aspect, this policy area also examines the process of prescribing and the cost-effectiveness of treatment as part of the overall healthcare provision by the hospital as well as the measures to control healthcare-associated infection. Aligned with these two areas, policy actors at the central level – summarised in Table 5-2 below – include:

- Central and regional arms of the government, specifically those of the Bureau of Medical Administration (formerly the Department of Medical Administration) of the NHFPC;
- Government-affiliated research and expert groups including the National Institute of Hospital Administration (NIHA), and the Committee of Experts on Rational Drug Use (CERDU);
- Academic and professional associations including the Chinese Pharmacists Association (CPA), the Chinese Hospital Association (CHA), the Chinese Medical Association (CMA) and the Chinese Pharmaceutical Association (CPhA).

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Type of actors	Prominent example(s)	Summary of official roles and responsibilities	Alignment with policy areas
The government	Bureau of Medical Administration, NHFPC	<p>The Bureau is a Department-level organisation in the NHFPC, responsible for:</p> <ul style="list-style-type: none"> • Making and implementing policies for healthcare providers on administration, medical technology, quality, safety, service delivery and blood bank management; • Setting and implementing professional standards for healthcare professionals and healthcare service management, including pharmaceutical affairs, laboratory management and clinical trials; • Setting and implementing rules and criteria of audits of healthcare providers on administration and performance. 	“Healthcare quality and safety”
Government-affiliated research and expert groups	National Institute of Hospital Administration (NIHA)	<p>The NIHA is a research institute directly under the NHFPC, responsible for:</p> <ul style="list-style-type: none"> • Conducting audits and accreditations of hospitals; • Conducting research on the administration of hospital; • Training hospital directors and managers; • Collecting data pertaining to the administration of hospitals; • Providing scientific evidence for the making of policies, laws and standards. 	“Healthcare quality and safety”
	Committee of Experts on Rational Drug Use (CERDU)	<p>The CERDU is a committee set up by the NHFPC, responsible for:</p> <ul style="list-style-type: none"> • Organising expert meetings to discuss agendas and work plans on the management of rational use of medicines; • Advising on the implementation work plans; • Conducting research to inform the design of measures and standards for rational use of medicines; • Organising education and training activities to improve rational use of medicines. 	“Rational use of medicines”
Academic and professional associations	Academic and professional associations of pharmacists, prescribers, hospitals and so on	<p>Academic and professional associations are non-profit non-government organisations set up by health professionals that the associations represent, generally responsible for:</p> <ul style="list-style-type: none"> • Reinforcing professional standards; • Organising training and continuous education; • Setting up and participating in collaborations across public and private platforms; • Participating in making and implementing policies and laws pertaining to their respective professional areas. 	“Healthcare quality and safety” (e.g. CHA) and “Rational use of medicines” (e.g. CPA)

Table 5-2 Key actors in antibiotic stewardship at the national level

Their role in supporting the four strategic areas for antibiotic stewardship introduced earlier is illustrated in Table 5-3.

Strategic area in antibiotic stewardship	Alignment with the roles of the actors
1. Establishing and strengthening surveillance networks	<ul style="list-style-type: none"> - The surveillance networks for antibiotic use (CAS) and for resistance (CARSS) were managed by the NIHA and the CERDU respectively, collected and analysed data on use and resistance; - Officials and experts reviewed and formulated policies accordingly.
2. Strengthening the technical capacity of medical professionals	<ul style="list-style-type: none"> - Government-affiliated groups and academic and professional associations organised training programmes for medical professionals; - Prescribers, pharmacists and microbiologists were crucial to the inter-professional collaboration in antibiotic stewardship.
3. Improving implementation of the policies	<ul style="list-style-type: none"> - The government was the main enforcer of policies and laws.
4. Establishing laws on antibiotic stewardship	<ul style="list-style-type: none"> - Government-affiliated groups and academic and professional associations provide support in formulating, interpreting and promoting these measures and lawful requirements.

Table 5-3 Alignment between the strategic areas in antibiotic stewardship and the roles of the actors

At the hospital level, policy actors are also aligned with both policy areas that concern antibiotic use in hospitals. Managerial level actors are medical professionals who oversee a range of administrative activities and processes in the hospital in order to ensure safe and effective delivery of healthcare services. At this level, antibiotic stewardship involves the coordination of inter-professional collaborations of several types of expertise, most prominently infectious disease specialists, clinical pharmacists and microbiologists. Prescribing level actors are prescribers and patients, the dyad that comprises the smallest unit of antibiotic prescribing and use. Prescribers' responsibilities are to comply with antibiotic stewardship policies and improve their knowledge and understanding of rational use of antibiotics and other pharmaceuticals.

5.4 Purpose and content of *The Campaign*

The Campaign was widely seen as the most comprehensive policy intervention to improve antibiotic stewardship across China (Xiao *et al.*, 2013a; Xiao & Li, 2015). Whilst little is known about the impact or the state of implementation of the antibiotic stewardship policies prior to *The Campaign* – there are few descriptive accounts, let alone definitive evidence on the impact or implementation of the previous policies from official sources or academic research – there is no evidence to suggest that they were binding requirements for hospitals that could generate concerted implementation

(Zhang *et al.*, 2008b, 2008a). Given this context, *The Campaign*, which lasted for 3 years between 2011 and 2013, was set up by the NHFPC to introduce an intense phase of top-down policy implementation across the whole country (Sun *et al.*, 2015a; Bao *et al.*, 2015a; NCCPAA Committee, 2015). Contents of *The Campaign* are detailed by the following three policy documents:

- *The 2011 Plan for the Nationwide Special Rectification Campaign on Antibiotic Use in Hospitals* (released as part of the *Notice of the General Office of Ministry of Health on Effectively Conducting the Nationwide Special Rectification Campaign on Antibiotic Use in Hospitals*)
- *The 2012 Plan for the Nationwide Special Rectification Campaign on Antibiotic Use in Hospitals* (released as part of the *Notice of the General Office of Ministry of Health on Continuing to Further Carry out the Nationwide Special Rectification Campaign on Antibiotic Use in Hospitals*)
- *The 2013 Plan for the Nationwide Special Rectification Campaign on Antibiotic Use in Hospitals* (released as part of the *Notice on Further Conducting the Nationwide Special Rectification Campaign on Antibiotic Use in Hospitals*)

Collectively, these documents set out a range of key policies to be implemented in *The Campaign*, which are summarised in Table 5-4 below.

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Key Policy of <i>The Campaign</i>	Summary of the policy	Past policies referenced	Level of main actors concerned
Set up an accountability mechanism	Set up a clear chain of command of the key actors at the central level and the managerial actors at the hospital level; in particular, the chief director of a hospital is appointed as the First Responsible Person. Introduce indicators related to rational antibiotic use in the official performance audit of hospitals and managerial actors at the hospital level conducted by the government.	N/A	Central and hospital levels
Introduce stringent penalties for irrational antibiotic use in hospitals	In accordance with laws that govern the medical practice and the official performance audit of hospitals conducted by the government, the government introduces a stringent penalty system for irrational antibiotic use, which concerns the punishment of prescribers, managerial actors and FRPs according to the severity of irrational antibiotic use and the violation of relevant laws.	Pharmaceutical Administration Law of the People's Republic of China; Law on Practicing Prescribers of the People's Republic of China; The Administrative Regulations on Medical Institution; Measures for the Administration of Prescriptions; Measures for the Administration of the Control of Hospital-Acquired Infections; The Provisions on the Administration of Pharmaceuticals in Medical Institutions (before 2012)	
Maintain a formal report system between hospitals and the government	Hospitals provide regular annual and biannual reports on various aspects of antibiotic use to the government. On examination of the reports, central and provincial governments identify the problems and publicise the findings accordingly, and convene meetings with FRPs to issue cautions.	N/A	
Set up regional surveillance networks on antibiotic use and resistance	Set up subsidiary networks of the national surveillance networks on antibiotic use and resistance at provincial level, and connect them to the national networks.	Notice on Establishing Surveillance Networks for Antibiotic Use in Hospitals and Antibiotic Resistance (2005)	Central and hospital levels
Conduct internal surveillance of antibiotic resistance to inform antibiotic use	Improve the rate of microbiological culture-based diagnosis in inpatients in secondary and tertiary hospitals, and conduct internal surveillance of antibiotic resistance to inform antibiotic use in the hospital and set up resistance alerts. Submit relevant information in accordance with the requirements of the national surveillance mechanism.	Notice of the General Office of the Ministry of Health on Further Enhancing the Surveillance of Antibiotic Use in Hospitals and Antibiotic Resistance (2006)	
Conduct baseline survey of antibiotic use in hospitals	Gather baseline data for a range of indicators related to antibiotic use in hospitals that are directly related to the audit and other surveillance programmes.		Hospital level
Conduct internal surveillance and assessment of antibiotic use in hospitals	Conduct surveillance, with the help of information technology if possible, of antibiotic use in all departments of a hospital, and identify alarming trends in use, adverse reactions and potential breaches in sales by pharmaceutical companies. Analyse and assess the clinical rationality of antibiotic use in various departments.	Notice on Strengthening the Surveillance of Rational Use of Medicines (2009)	

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Strengthen the inter-professional support for antibiotic use in hospitals	Set up the required facilities and build technical support around the teams of infectious disease prescribers, clinical pharmacists and microbiologists.	Notice of the Department of Medical Administration of the Ministry of Health on Conducting Pilot Programme of Clinical Pharmacist System (2007)	Central and hospital levels
Introduce stringent checks for qualifications of relevant medical professional	Introduce training and examination on rational antibiotic use towards the attainment of relevant prescribing authorisations and qualifications for prescribers and clinical pharmacists respectively.	Xinghuo Programme (2009-2011) and the Mengya Programme (2009-2012)	
Strictly implement formulary restriction	Strictly define and implement the authorisation levels for prescribing non-restricted, restricted and reserved classes of antibiotics according to the professional grades of prescribers.	Notice on Implementing the Guiding Principles for Antibiotic Use in Hospitals (2004)	Hospital level
Strengthen the regulation of procurement and management of the antibiotic formulary	Refine, through the decision-making of the internal drug and therapeutic committee (DTC), the selection of the regular antibiotic formulary in a number of specific areas. In particular, tertiary hospitals are permitted to have no more than 50 types of antibiotics by active ingredient, and secondary hospitals no more than 35 types in the regular formulary; for each type of antibiotic of a particular route of administration, hospitals are permitted to select products from no more than 2 commercial brands.	Notice of the Ministry of Health on Further Improving the Stewardship of Antibiotic Use in Hospitals (2008)	
Control the frequency and strength of antibiotic use in hospitals	Control antibiotic use in outpatient, inpatient and surgery departments by meeting key targets for several indicators including outpatient and inpatient prescribing rates measured in percentages of total prescriptions, patient-day adjusted inpatient antibiotic consumption as measured by defined daily dose (DDD) per 100 bed-days, and rates of antibiotic use under specific pre-operative and post-operative circumstances, such as prophylactic antibiotic use for type I incisions.	Notice of the General Office of Ministry of Health on Issues Concerning the Stewardship of Antibiotic Use in Hospitals (2009)	
Conduct internal prescription review	Conduct, through the help of information technology, internal prescription review of a sample of prescriptions by authorised prescribers. Publish the outcome of the review, which is aligned with their performance appraisal, within the hospital. Impose punishments that restrict or remove certain levels of prescribing authorisation for prescribers who failed to comply to relevant prescribing regulations.	Notice of the Ministry of Health on Issuing the Standards for the Review and Management of Prescriptions in Hospitals (Pilot) (2010)	
Apply information technology in antibiotic stewardship in hospitals	Strengthen the capacity and increase the application of information technology in antibiotic stewardship policies, such as formulary restriction, surveillance of antibiotic use and resistance and prescription review.	N/A	
Improve health promotion for rational antibiotic use	Promote the activities of the hospital during <i>The Campaign</i> , educate patients about the importance of rational antibiotic use	N/A	

Table 5-4 Key Policies of *The Campaign*

The key policies outlined by *The Campaign* were clearly based on previous antibiotic stewardship policies and supporting policies: a lot of them inherited policy contents that had first appeared in previous policies, which were pertinent to three out of the four strategic areas for antibiotic stewardship described in Table 5-1 (establishing and strengthening surveillance, strengthening technical capacity of medical professionals, and improving rationality of antibiotic use and prescribing). For example, before appearing as one of the key policies of *The Campaign* in 2011, formulary restriction was first proposed in the 2004 “Guiding Principles for Antibiotic Use in Hospitals”, and it was reiterated in the 2008 “Notice of the Ministry of Health on Further Improving the Stewardship of Antibiotic Use in Hospitals”.

Five aspects mark the departure of the compulsory *Campaign* policies from previous non-binding policies. First, *Campaign* policies incorporated clearly stated targets into the policies. A target refers to a restrictive threshold denoting the highest numeric level at which the indicator of interest is permitted. Many of the targets concerned prescribing; these are summarised in Table 5-5 below. There were also prescribing indicators for antibiotic use in surgery, including timing and duration of prophylactic antibiotic use in surgeries, and rate of prophylactic antibiotic use in clean surgeries. In addition, there were indicators that measured stewardship activities other than prescribing, such as the percentage of prescriptions reviewed by pharmacists, and the rate of culture-based diagnosis in inpatients. Second, the *Campaign* policies explicitly addressed a defined range of actors at the hospital level, as the *Campaign* documents indicated that secondary and tertiary hospitals were the intended targets; however, this policy approach was not further explained in the documents. Third, the *Campaign* policies clearly delineated a chain of command in implementation that runs through the administrative system of the government, connecting central level actors with that of the hospital level actors. As described in Chapter 4 (Healthcare System Background), public hospitals were considered public organisations that were administered by branches of the Bureau of Medical Administration at corresponding levels of government. This chain of command was translated into a line of accountability in *The Campaign*, as the director of a public hospital was appointed as “First Responsible Person” for policy implementation, held accountable by government officials from the local branch of the Bureau of Medical Administration. At the same time, heads of clinical departments were held accountable by the director. All these actors were required to sign an assurance that they would implement the necessary activities. Fourth, the documents clearly stated that prescribing targets would be used

to evaluate the performance of a hospital and all the actors it encompassed, including its directors, managerial actors and prescribers, which could have implications for financial and administrative penalties, which were not described in detail in the documents. Fifth, *The Campaign* described specific monitoring and reporting mechanisms, which involved internal inspections at secondary and tertiary hospitals, external inspections by various levels of regional and national governments.

Indicator	Calculation	Target levels
Outpatient prescribing rate	(Encounters or cases with an antibiotic prescribed / total encounters over the same period e.g. a month) x 100%	20%
Inpatient prescribing rate		60%
A&E prescribing rate		40%
Inpatient antibiotic consumption	(Inpatient antibiotic consumption measured in DDDs/total number of inpatient patient-days over the same period e.g. a month) x 100	40DDD/100 patient-days

Table 5-5 Key prescribing targets of *The Campaign*

5.5 Conclusion

This chapter has explained the national policy background of *The Campaign* including the reasons for policy actions on antibiotic stewardship, its designated policy areas and actors, the role of *The Campaign* and its contents. In doing so, it has addressed the first research question

According to the theoretical framework of this study described in Chapter 2 (Theoretical Background), the national policy context discussed in this chapter is part of the macro level context that influenced policy implementation at both the central and the hospital levels. Under this framework, this chapter informed the study design in two crucial ways. First, more understanding of the policy approach of *The Campaign* to target only secondary and tertiary hospitals, and the implication of that for policy implementation in China's healthcare system was necessary better to inform the macro level context. Second, both the top-down and bottom-up perspectives of policy implementation are relevant depending on actors' perspectives, and a thorough understanding of *The Campaign* should encompass as many perspectives from "the top" and "the bottom" as possible. For the actors at the central level, the

implementation of *The Campaign* marked a very special top-down phase of policy implementation. Features of top-down implementation such as target management and accountability mechanisms suggested in the policies required close examination: were all those policies implemented as directed, and if so, how did they work in practice to enable top-down implementation? For the actors at the hospital level, *The Campaign* also represented another set of policies that affected their daily work. The fact that *The Campaign* was part of the continuum of antibiotic stewardship policies in China, and that it was preceded by numerous policies that had been implemented previously meant that all kinds front-line implementers – directors, manager-prescribers and prescribers – were likely to be acquainted with elements of *The Campaign* to various degrees. More fundamentally, some policies of *The Campaign* are directly addressing some of the drivers of antibiotic prescribing described in in Chapter 4 (Healthcare System Background). For example, at the organisational level, financial penalties associated with lack implementation could play an important part in shifting the ingrained financial incentives to prescribe within the healthcare system, especially given the context of health financing reforms that sought to dissociate revenue generation from sales of pharmaceuticals with profit margins; at the individual level, training of healthcare professionals could enhance their understanding of antibiotic use and improve prescribing behaviours.

Having established the theoretical framework (chapter 2), examined existing evidence, situated and formulated the research (chapter 3), and thoroughly reviewed the healthcare system (chapter 4) and national policy background pertinent to the implementation of *The Campaign* (chapter 5), the next chapter describes how the research itself was conducted by detailing its methodology.

Chapter 6. Study Design and Methods

6.1 Introduction

This chapter outlines the study design and the methods used to collect and analyse data. It also explains the alignment between the study design and the research questions, the potential limitations of the methodology, and the steps taken to mitigate these limitations.

As described in Chapter 1 (Introduction) and Chapter 3 (Literature Review), the aim of this research was to explore and analyse the implementation of *The Campaign* in China from 2011 and 2013 at the central and the hospital levels.

In accordance with the theories discussed, and theoretical framework established in Chapter 2 (Theoretical Background), specific research questions were framed under three research objectives as follows:

Objective 1: to understand the national policy context of antibiotic stewardship policies in China

- a. What factors led to actions on antibiotic use in hospitals?
- b. Who were the key actors at the central level?
- c. What are the antibiotic stewardship policies to date?
- d. How did *The Campaign* relate to these policies?

Objective 2: to understand the healthcare system context in which implementation of *The Campaign* took place

- a. What did the system-level context comprise?
- b. What did the hospital-level context comprise?
- c. What did the individual-level context comprise?

Objective 3: to explore and analyse the implementation process of *The Campaign*

- a. How was The Campaign implemented at the central level?
- b. How was The Campaign implemented at the hospital level?

Objective 1 has been addressed by the review of policy documents and literature reported in Chapter 5 (National Policy Context), which necessitated and

informed the empirical research for addressing objectives 2 and 3 described in this chapter.

6.2 Study approach and design

Overall, the research adopted a qualitative research approach. Due to the lack of information on antibiotic stewardship policies in China in general, this research focused on addressing exploratory “how” and “why” questions rather than explanatory questions. A qualitative approach is appropriate to address “fundamental and searching questions about the nature of social phenomena” (Pope & Mays, 2006). Whereas the aim of quantitative approach is to achieve statistical generalisation by making inferences about a population or universe on the basis of empirical data collected about a sample from that universe, the aim of qualitative approach is to achieve analytic generalisation by demonstrating the relevance of findings to a sequence of events described by existing theories, so that the refined and theoretically-informed description could be used to implicate other, similar situations where analogous events might also occur (Yin, 2009, 2010). Therefore, this research sought not to measure predetermined variables or test existing hypotheses based on *a priori* understanding of the phenomenon of interest, but to build that understanding from a fundamental level in reference to existing theoretical ideas on policy implementation and bridge knowledge gaps as identified and described in Chapter 2 (Theoretical Background).

To study the implementation process of *The Campaign*, this research first explored the perception and experience of policy implementation from the perspectives of actors, and then analysed in detail the interaction between context and implementation process at the hospital level using a case study. The overall study design is demonstrated in Figure 6-1 below. Phase 1 fieldwork, which took place between June and September 2015, sought to understand the perspectives on policy implementation by a variety of actors at macro and micro levels. Phase 2 fieldwork, which took place in October 2017, focused on analysing policy implementation in a hospital setting through conducting a case study.

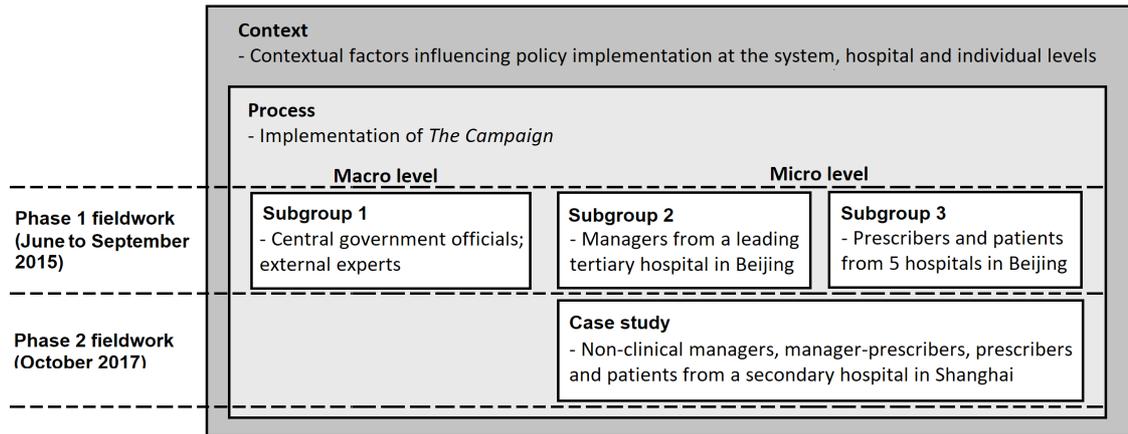


Figure 6-1 Overall study design

Phase 1 fieldwork explored and analysed the perspectives of policy actors at macro (crucial to central implementation) and micro levels (crucial to hospital implementation). Rather than analysing the implementation of specific activities of *The Campaign*, phase 1 fieldwork took a general approach to building initial understanding of both the context and process of policy implementation.

Three groups of actors were interviewed. Actors at the central level (subgroup 1) were those who had first-hand experience of the implementation process and the policy context of antibiotic stewardship policies in China. This group predominantly comprised actors that worked inside, or closely with, the central government. In addition, the composition of the group was supplemented by experts from academia and the pharmaceutical industry who had relevant insight and knowledge.

Actors at the hospital level consisted of two subgroups. Managerial actors (subgroup 2) were senior managers and administrators who, despite being leading medical professionals in their field, also dedicated much of their time to managing the day-to-day running of a hospital. They were the people who oversaw the implementation and delivery of antibiotic stewardship policies at the hospital level. Due to their managerial roles, they not only had first-hand experience of the implementation process of antibiotic stewardship policies in China at the hospital level, but also plentiful insight on system-level health policies and reforms initiated by “the Centre” that influenced various aspects of health service provision, such as financing and delivery.

The other subgroup of the hospital-level actors were the prescribing-level actors (subgroup 3), namely prescribing prescribers and their patients. From a bottom-up

perspective, they were considered part of the frontline implementers of antibiotic stewardship policies. Although it was difficult to know the extent to which these actors were aware of the actual antibiotic stewardship policies being implemented mainly by managerial actors at the hospital level or actors at the central level, they provided useful insight into the healthcare system context and what actually happened in terms of antibiotic use in hospitals.

Building on the understanding of actor perspectives from phase 1 fieldwork, a case study of policy implementation at the hospital level was conducted in phase 2 fieldwork so as to understand how “a planned change” such as policy implementation occurs “in a messy real world setting” (J & Keen, 2010), and to unravel granular details of a contemporary event exemplified by *The Campaign* (Yin, 2009). To achieve a detailed and in-depth analysis of policy implementation within one single hospital, the case study analysed implementation activities that were most pertinent to the hospital level. These included activities that embedded the top-down approach from the government (setting up an accountability mechanism, introducing stringent penalties for irrational antibiotic use in hospitals and maintaining a reporting line between hospitals and the government) and hospital-based antibiotic stewardship policies (including conducting internal surveillance of antibiotic resistance and use, strengthening inter-professional support, introducing stringent qualification requirements, implementing formulary restriction, regulating antibiotic formulary, controlling antibiotic use through targets, conducting internal prescription review, applying information technology platform and improving health promotion with patients).

The central conceptual element to the case study is the definition of “the case”, or the “unit of analysis” (Miles & Huberman, 1994). The case in phase 2 fieldwork of this research specifically refers to policy implementation at a secondary hospital in Shanghai. In one sense, the case does not have to be a tangible object: it can be an event, an entity, a decision, a programme, or even a conceptual idea such as the implementation process or organisational change (Yin, 2009). In this specific instance, the case is the hospital in which the implementation of *The Campaign* took place, which encompassed the actors, administrative arrangements and mechanisms that contributed to the implementation process representative of those in a typical urban healthcare setting in China. The case study research opted for a single case design. From a theoretical perspective (Yin, 2009), there are three reasons why a single case design is sufficient for this study. The single case here represented a “revelatory case”

in which a phenomenon of interest – the implementation of antibiotic stewardship policies in China – was very under-studied empirically. As illustrated by Chapter 3 (Literature Review), there are few empirical studies on this subject to date. This researcher was in a position to participate in a number of high-level meetings, and subsequently build a network of high-level informants who were at the heart of the implementation of antibiotic stewardship policies in China.

The case study is a flexible methodology that allows the researcher to explore in depth “a program, an event, an activity, a process, or one or more individuals” (Creswell, 2003). In a case study, a researcher can collect detailed information using a variety of methods (Stake, 1995). Despite that direct observation was not permitted by hospital collaborators when the fieldwork first took place in 2015 and then in late 2017, and that the possibility of quantitative analysis of antibiotic prescribing was precluded by the lack of access to data, major actors at various levels pertaining to *The Campaign* were all accessible for qualitative interviews, and their memory of the events during *The Campaign* was likely to remain sufficiently strong due to the high-profile nature of the policy. Therefore, qualitative data were collected from policy actors at the hospital level, including managerial (non-clinical managers) and prescribing-level actors (prescribers and patients). Additionally, a new group of actors—manager-prescribers—was identified. These actors were senior prescribers or heads of clinical departments who were responsible for policy and prescribing at the same time.

The two phases of fieldwork were designed in line with the theoretical framework set out in Table 2-1 in Chapter 2 (Theoretical Background). A conceptual map of the study linking the theoretical framework with the study design and the outputs of empirical analysis is illustrated below in Table 6-1. This conceptual map will be revisited later in this chapter, where an expanded version of this map will explain how the theoretical ideas pertinent to top-down and bottom-up implementation respectively reviewed in Chapter 2 will be used in data analysis, and how results will be presented in the result chapters.

	Theoretical perspective	Factors pertinent to context	Implementation process to be examined			Fieldwork phase	Policy actors concerned
			Level of implementation	Focus of analysis	Aspects of policy implementation with respect to the activities of <i>The Campaign</i> (introduced in chapter 5) to be examined		
Macro level	Top-down: focus on “the Centre”	<ul style="list-style-type: none"> - Policy factors - Health system factors 	<ul style="list-style-type: none"> - National implementation of The Campaign 	<ul style="list-style-type: none"> - Context and process of central implementation 	<ul style="list-style-type: none"> - The overall role and activities of the central government in top-down implementation 	- Phase 1	- Subgroup 1
Micro level	Bottom-up: focus on the local settings	<ul style="list-style-type: none"> - Hospital-level factors - Individual-level factors 	<ul style="list-style-type: none"> - Local implementation and adaptation of The Campaign carried out by local hospitals 	<ul style="list-style-type: none"> - Context and process of hospital implementation 	<ul style="list-style-type: none"> - The overall role and activities of the nationally leading hospital in implementing top-down policies at the hospital level 	- Phase 1	- Subgroup 2
				<ul style="list-style-type: none"> - Context of hospital implementation 	<ul style="list-style-type: none"> - Not applicable (contextual factors only) 		- Subgroup 3
						<ul style="list-style-type: none"> - Context and process of hospital implementation 	<ul style="list-style-type: none"> - A detailed analysis of the role of the secondary hospital in Shanghai in setting up an accountability mechanism, introducing stringent penalties for irrational antibiotic use in hospitals and maintaining a reporting line between hospitals and the government - A detailed analysis of the implementation of hospital-based policies including conducting internal surveillance of antibiotic resistance and use, strengthening inter-professional support, introducing stringent qualification requirements, implementing formulary restriction, regulating antibiotic formulary, controlling antibiotic use through targets, conducting internal prescription review, applying information technology platform and improving health promotion with patients

Table 6-1 Conceptual map of the study

6.3 Phase 1 fieldwork in Beijing: analysis of perspectives of policy actors at the central and hospital levels

Phase 1 fieldwork took place in Beijing between June and September 2015. During this phase of research, the researcher conducted research that would support the design and execution of the case study in phase 2 fieldwork.

Selection of phase 1 fieldwork sites

Based on the focus of the research on the urban Chinese setting and the researcher's existing contacts with gatekeepers and key informants, Beijing was selected to be the city where fieldwork would take place. Table 6-2 provides a summary of the fieldwork sites, including central government, a nationally leading hospital and 5 local hospitals in urban areas.

These study sites were chosen to capture a range of policy actors that reflected the composition of actor subgroups in the study design. However, constraints in research access led to several limitations that would influence the balance of the analysis. Firstly, access to the central government in subgroup 1 provided a crucial window to understand the perspectives of policy makers and implementers at the top of the chain of command, but the lack of access to regional government meant that the link between central and local implementation could not be examined. Secondly, access to managers at a nationally leading tertiary hospital in subgroup 2 offered an opportunity to tease out some of the interactions between context and process of policy implementation at the hospital level, but the hospital itself was far too advanced and atypical for the analysis to be generalised to other urban settings in China. Thirdly, the lack of access to prescribers and patients due to negotiation issues precluded the possibility of conducting a thorough case study at these hospitals. Fourthly, access to a limited number of prescribers and patients at five different hospitals in Beijing enabled a rich analysis of some of the crucial contextual factors influencing prescribing behaviours in the urban Chinese context, but restricted access to myriad policy actors across hospital departments and levels made in-depth analysis of policy implementation in each hospital impossible.

Level of policy implementation	Component of the study design	Focus of analysis	Corresponding study site(s)	Access	Strengths of study site(s)	Limitations of study site(s)
Central level	Subgroup 1, (central government officials and experts)	Context and process of central implementation	Mainly NHFPC and two key government-affiliated research and expert groups (Beijing)	The researcher had existing contacts who were gatekeepers to other study sites, and was acquainted with some of the key informants previously through participation of high-level meetings and previous collaborations	These highly central organisations were responsible for all the major policy processes, and they were the implementers of <i>The Campaign</i> .	<ul style="list-style-type: none"> • Access to regional-level government of Beijing could not be gained.
Hospital level	Subgroup 2, (hospital managers)	Context and process of hospital implementation	A nationally-leading hospital in China (Beijing)		The hospital worked very closely with the government and its related organisations, resulting in a strong link between the implementation process at the central level and the hospital level.	<ul style="list-style-type: none"> • Only the managerial actors at this hospital could be accessed for interviews; • A nationally-leading hospital was far too atypical a setting.
	Subgroup 3, (prescribers and patients)	Context of hospital implementation	Five local hospitals with various characteristics (Beijing)		Five local hospitals were selected to capture a range of different healthcare settings in urban Beijing, including: a small community health centre; a large community health centre; a tertiary hospital, and a TCM tertiary hospital.	<ul style="list-style-type: none"> • Access to hospital actors was restricted to few prescribers per hospital, severely limiting in-depth study of policy implementation.

Table 6-2 Rationale for the selection of study sites

The process of gaining access during this research was made more difficult by the fact that the research was not part of any formal collaborations; nor it was funded by any international research body or government. On one level, the researcher was not able to harness the machinery of these structures to enhance possibility of gaining access. On a more fundamental level, without any possible formal assistance that could take place at an organisational level, the researcher had to rely on building strong collaborative relationships with gatekeepers. To a large extent, the introduction by the gatekeepers helped the researcher to establish an initial relationship and trust with the interviewees and made phase 1 fieldwork possible, which would have been otherwise difficult for the researcher to achieve on his own in China's social context.

One key gatekeeper was Gatekeeper 1, who helped secure access to the sites for subgroup 1 and subgroup 2: the central NHFPC and two key government-affiliated research and expert groups (by late August, 2015) and the national tertiary hospital (by mid-August, 2015). Gatekeeper 1 was a high-level expert who worked very closely with both officials and medical experts. The researcher met this gatekeeper during official meetings and conferences in China in March 2015. After building a strong connection through working together on multiple projects, negotiations for access to the study site began in early July, 2015. Due to the position of this expert and his strong connections with both the study sites in Beijing, access to the study sites for subgroups 1 and 2, and some of the most senior personnel that the researcher had planned to interview – including high-level officials, senior officers, and departmental heads of the national tertiary hospital in Beijing – was successfully granted. However, as explained in Table 6-2, the researcher did not gain access to prescribers and patients at the national tertiary hospital. This was because gatekeeper 1 had other commitments and was not able to help negotiating that level of access.

Another key gatekeeper was Gatekeeper 2, who helped secured access to four of the five local hospitals in urban Beijing for subgroup 3 by late July to early August, 2015. Gatekeeper 2 was a high-level officer whose work involved working very closely with local hospitals in Beijing. The researcher met this gatekeeper through previous collaborations. This gatekeeper negotiated access to four hospitals on the researcher's behalf. Negotiations began in early July, 2015. Although the relationship between the researcher and the gatekeeper was strong and the gatekeeper was in a position of power, negotiations for access to the local hospitals proved more difficult than imagined. As the research was not part of a formal partnership, some hospitals did not

feel obliged to participate. Other hospitals felt uncomfortable with the idea of having a researcher talk to both members of their staff and patients in the hospital. Still others were sensitive about the relevance of the research topic to antibiotic use as a result of *The Campaign*, and refused to participate despite that steps taken to mitigate that sensitivity. These factors meant that the researcher could not afford the luxury to reject offers that were negotiated by the gatekeeper. The gatekeeper was very understanding of the dilemma, and managed to negotiate, to the best possible extent that met the researcher's criteria, initial access to four local hospitals (apart from the university hospital in the final five) and a point of contact in each of the hospitals. The researcher then negotiated further access to prescribers and patients in those hospitals with those contacts directly. The researcher did not have full control over the access to prescribers, and the point contacts at each hospital only agreed to give access to no more than 3 or 4 prescribers. However, the research did have full control over the access to patients in the waiting areas in the hospitals.

Before gaining access to those four hospitals, the researcher managed to gain access to a university hospital with the help of Gatekeeper 3 by mid-July. The access was limited to just one prescriber, and the one interview conducted there was regarded as the pilot interview for later ones conducted in those four hospitals.

The only occasions where no gatekeepers were needed in research access was when the researcher interviewed several respected academics and a former specialist at a pharmaceutical company. These people were accessed on a one-to-one basis at the initiative of the researcher, and no organisational access was required.

Data collection in phase 1 fieldwork

The methods of data collection employed in phase 1 fieldwork were as follows:

1. In-depth interviews with actors at the government and policy level (subgroup 1) including:
 - Academics and experts on antibiotic use and health policies in China;
 - Senior officers at the government-affiliated research organisations and expert groups;
 - High-level government officials;And with managerial actors at the hospital level (subgroup 2) including:

- Heads of microbiology, pharmaceutical affairs, infection control, outpatient affairs and medical affairs of the nationally leading hospital, and a senior emergency prescriber from the hospital;
2. Semi-structured interviews with prescribers and users at the hospital level (subgroup 3) including:
- Prescribers from the five selected hospitals;
 - Patients from the four selected hospitals.

Table 6-3 describes how the methods of data collection addresses the research objectives and questions through the nested subgroups of the case study. It also gives a summary of the sources of data for each method.

Subgroups concerned	Methods of data collection	Sources of data
Subgroup 1: the central level	In-depth interview	Key informants including: government officials, senior officers and experts at government-related organisations, academics, and other experts
Subgroup 2: the hospital level (i): the managerial level	In-depth interview	Key informants including: heads of various departments that managed antibiotic use in hospitals (for examples, medical affairs, outpatient affairs, and pharmaceutical affairs)
Subgroup 3: the hospital level (ii): the prescribing level	Semi-structured interview	Prescribers
		Patients visiting the hospitals

Table 6-3 Data sources to address the research questions

The interviews took place from June through September 2015 after access was secured in the relevant sites (as described in Section 4.3). Table 6-4 provides an overview of the timeframe of the research activities.

Time of year in 2015	List of informants interviewed (NOT arranged chronologically)	Case study component addressed
June to early July	Academics studying antibiotic use and health policies in China (n=4), former antibiotic specialist at a pharmaceutical company (n=1)	Subgroup 1: the central level
Mid-July to mid-August	Pilot: prescriber at a university hospital (n=1)	Subgroup 3: the hospital level (ii): the prescribing level
	Pilot: patients at a small community health centre (n=1) and a tertiary hospital (n=4)	
	Prescribers (n=3) and patients (n=7) at a small community health centre	
	Prescribers (n=3) and patients (n=4) at a large community health centre	
	Prescribers (n=3) and patients (n=9) at a tertiary hospital	
Mid-August to mid-September	Prescribers (n=3) and patients (n=8) at a TCM tertiary hospital	Subgroup 2: the hospital level (i): the managerial level
	Heads of microbiology, pharmaceutical affairs, infection control, outpatient affairs and medical affairs of the nationally leading hospital, and a senior emergency prescriber at the hospital (n=6)	
	Senior officers at government-affiliated research organisations (n=3) and expert groups (n=1)	Subgroup 1: the central level
High-level government officials (n=2)		

Table 6-4 Summary of fieldwork schedule

The details about the methods of data collection, including the review of key policy documents, are explained in turn.

In-depth interviews with key informants

The in-depth interview was an ideal method for the researcher to learn from knowledgeable individuals who possessed knowledge and/or personal experience of the subject of interest. They were, in this case, the high-level key informants at the central level, and the key managerial informants in the nationally leading hospital. The in-depth interview presents a less structured and highly flexible way to focus on exploring one or two issues that is tailored towards the interviewee's own expertise and interests (Green & Thorogood, 2009; Britten, 2006). Due to the less structured nature of the in-depth interview, the topic guides used in these interviews comprise some general questions and probes that were broadly aligned with the research questions and theoretical framework. In fact, most of the probes of the interview were largely based on the subjects decided by the interviewee and their responses. This iterative

probing process involves informed and rational improvisation (Legard, Keegan & Ward, 2003). After each interview, the researcher would reflect on the experience, and generate new items for inquiring and probing specific to the next informant. The information sheets, consent forms and topic guides for the key informants in phase 1 fieldwork are available in Appendices 2b, 2c and 2d respectively.

The types and numbers of key informants interviewed were listed chronologically in Tables 6-5a and 6-5b.

Dates	Informants interviewed	Purpose
25 th June to 15 th July	Academics studying antibiotic use and health policies in China (n=4), former antibiotic specialist from an international pharmaceutical company (n=1)	To reaffirm and reinforce existing knowledge, explore potential areas of inquiry to be used in later in-depth interviews, and gather data from the actors at the central level
13 th August	Senior officer at a government-affiliated research organisation (n=1)	To gather data from the actors at the central level
25 th August	Senior officers at government-affiliated research organisations (n=2) and expert groups (n=2)	To gather data from the actors at the central level
15 th September	High-level government officials (n=2)	To gather data from the actors at the central level
Total key actors at the central level (n=12)		
<ul style="list-style-type: none"> • Experts outside the government (n=5): academics D1, D2, D3, D4; former antibiotic specialist from a pharmaceutical company P; • Officials (n=2): government officials A1, A2; • Officers/experts working closely with the government (n=5): senior officers B1, B2, B3, C; medical expert M. 		

Table 6-5a In-depth interviews with key informants at the central level

Dates	Informants interviewed	Purpose
19 th – 23 rd August	Heads of microbiology, pharmaceutical affairs and infection control of the nationally leading hospital (n=3)	To gather data from the managerial actors at the hospital level
26 th August – 9 th September	Heads of outpatient affairs and medical affairs of the nationally leading hospital and a senior emergency prescriber at the hospital (n=3)	To gather data from the managerial actors at the hospital level
<u>Total managerial actors at the hospital level (n=6)</u>		
<ul style="list-style-type: none"> • Head of medical affairs MA; • Head of outpatient affairs OA; • Head of pharmaceutical affairs PA; • Head of infection control IC; • Head of clinical microbiology CM; • Senior emergency prescriber E. 		

Table 6-5b In-depth interview with key informants in the nationally leading hospital

Overall, 18 in-depth interviews were conducted. 17 interviews were conducted face-to-face in private locations of the interviewees' choices, so that they could talk in confidence in a comfortable environment. One interview was conducted over the telephone. As the researcher was introduced by a powerful gatekeeper with personal connections to the key informants, and that the researcher had already been acquainted with some of them through previous meetings, most of them gave consent for the recording of the interview. 16 interviews were recorded and transcribed verbatim in Chinese by the researcher. However, two interviews were not recorded because the interviewees were still uncomfortable with the idea of recording. Notes were taken by the researcher instead, and the interviews were written up within 24 hours. Each interview lasted between 30 minutes and 90 minutes. All the interviews – including the semi-structured interviews to be described later – were conducted in Chinese, the native language of the researcher and the interviewees. They were all included in the analysis.

The rationale for the sampling of key informants was based on the principle of purposive sampling. The aim of purposive sampling is to select “information rich cases, from which the researcher can learn a great deal about matters of central importance to the purpose of the research” (Patton 1990, in Emmel 2013). It was much more important to ensure that the key informants selected were “worthy of in-depth study, because they provided detailed insight” than to consider statistical representativeness, which is a different concern of probability sampling (Emmel, 2013). In addition, taking inspiration from the methodological implications of bottom-up approaches, the researcher also relied on the advice of gatekeepers to identify closely related actors and networks not obvious to outsiders (Schofield, 2001), as described in Chapter 2

(Theoretical Background). The researcher had identified a list of key informants before going into the field; during the fieldwork, the researcher constantly refined this list at the advice of Gatekeeper 1, who had a deep understanding of the machinery of the central level and the hospital level. Several managerial actors at the hospital level were added, as were a senior officer and a high-level official, and the researcher was then able to learn about how they worked together through the introduction of the gatekeeper. Even so, the final list of interviewees was broadly consistent with what the researcher had anticipated before the fieldwork.

The process of gaining access to these interviewees was generally successful. The researcher independently gained access to the academics and the pharmaceutical specialist without problems, and interviews with these actors took place very early on. Access to all the key informants at the central level and the hospital level was negotiated gradually and successfully through Gatekeeper 1, and interviews with these actors were conducted in the later stages of the fieldwork starting from mid-August.

To ensure that the researcher could gain knowledge from different perspectives and refine the interviewee agenda as the fieldwork progressed, the researcher planned and arranged the interviews strategically to allow for accumulation of information. As demonstrated in Tables 6-6a and 6-6b, the researcher first conducted interviews with the academics and the former pharmaceutical specialist early on during the fieldwork, which helped the researcher to reaffirm the findings and research gaps established from literature review, explore issues that were not covered by the literature, and gain more knowledge of China's health system and policies in general. Then, key informants at the central level and the managerial level of the hospital level were interviewed alternately to allow the researcher to contrast and process different sources of information and hone the focus of the next set of interviews.

Semi-structured interviews with prescribers and patients

Semi-structured interviewing was suited to examining prescriber's knowledge of antibiotic use and accounts of antibiotic prescribing at local hospitals in urban Beijing. The semi-structured interview is conducted "on the basis of a loose structure consisting of open-ended questions that define the area to be explored, at least initially, and from which the interviewer or interviewee may diverge to pursue an idea or response in more detail" (Britten, 2006). Whereas the agenda for the in-depth interviews used in

this research were much less pre-determined and had more room for informed and iterative improvisation in further probing, the semi-structured interviews used here contained more predetermined categories and probes, and the researcher kept a firmer hand on the wheel to make sure some of the key issues pertinent to the research questions were covered. The increase in the structure of the interview was justified by the fact that this part of empirical research, which essentially focused on the influence of health system on prescribing incentives and behaviours, was well researched and likely to contain more expected and confirmatory elements; this was supported by the findings of the overview of China's healthcare system in Chapter 4 (Healthcare System Background).

Semi-structured interviews were also conducted with patients to examine, from the other side of the prescriber-user dyad, their knowledge about antibiotic use and accounts of antibiotic prescribing at local hospitals in urban Beijing. Therefore, the predetermined categories and probes used here, as explained later in this section, matched with those used in the semi-structured interviews with prescribers. As patients showed little interest in being interviewed in the busy waiting areas of hospitals, the researcher modified the method of the interview and introduced a structured questionnaire to encourage patient participation. However, the purpose of, and the approach to the semi-structured interview remained the same. The questionnaire was used as an alternative form of interview guide for the patient to respond and the interviewer to probe. How the structured questionnaire was introduced as an adapted form of the interview guide for semi-structured interview with patients in this research will be explained later in this section.

The interviews with prescribers and patients were designed around a tracer condition being the common cold. Using a tracer condition as a proxy to study other conditions or phenomena in healthcare research was first introduced by Kessner et al. (1973). Using the common cold as a tracer for studying antibiotic prescribing has been established as a common method (Reynolds & McKee, 2009).

The common cold can be a good tracer for studying the influencing factors of antibiotic prescribing for several reasons. Firstly, it can help identifying unnecessary antibiotic prescribing. By medical definitions, the common cold is a viral infection that is self-limiting; the use of antibiotics cannot be justified in the early stages of the disease, when the lining of the epidermal cells of the respiratory tract is still relatively intact, and concomitant bacterial infections is yet to take place. Secondly, it can help clarifying the

rationale for, and the process of establishing a treatment decision. In reality, the line between the two phases of infections is blurred: a prescriber could prescribe treatments based on experience, or based on evidence. Here, several aspects could be examined: a prescriber's knowledge, the steps taken by the prescriber to diagnose the common cold, and a patient's understanding of the medical rationale and procedures involved. Thirdly, it can help understanding the preferences and incentives for certain treatments. As the common cold is very much self-limiting, technically nothing needs to be taken for treatment of the viral aetiology of the disease. Most of the common cold treatments available sought to relieve common cold symptoms. Therefore, there is great flexibility in the treatment selection. Besides medical rationale, other considerations are very likely to influence treatment selection; and these considerations may reveal the preferences and incentives of prescribers and patients.

The hospitals visited, and prescribers and patients interviewed, were listed chronologically in Table 6-6.

Dates	Informants interviewed	Source of informants	Purpose
17 th July	Prescriber at a university hospital (U) (n=1)	Internal medicine dept.	To pilot the semi-structured interview to be used with other prescribers
21 st – 22 nd July	Prescribers at a small community health centre (S) (n=3)	General practice dept.	To gather data from actors at the prescriber and user level
	Patient at a small community health centre (S) (n=1)	General practice dept.	To pilot the semi-structured interview to be used with other patients
29 th July	Prescribers at a large community health centre (L) (n=3)	General practice dept.	To gather data from actors at the prescriber and user level
30 th – 31 st July	Prescribers at a tertiary hospital (H) (n=3)	Respiratory medicine dept.	To pilot the semi-structured interview to be used with other patients
	Patients at a tertiary hospital (H) (n=4)	Respiratory medicine dept.	
	Patients at a tertiary hospital (H) (n=9)	Respiratory medicine dept.	
4 th August	Prescribers at a TCM tertiary hospital (T) (n=3)	Emergency medicine dept. (n=2), paediatric (n=1)	To gather data from actors at the prescriber and user level
	Patients at a TCM tertiary hospital (T) (n=8)	Respiratory medicine dept.	
5 th – 6 th August	Patients at a large community health centre (L) (n=7)	General practice	
	Patient at a small community health centre (S) (n=4)	General practice	
Total (n=46) Prescribers (n=13): <ul style="list-style-type: none"> • University hospital (U) (n=1) • Small community health centre (S) (n=3) • Large community health centre (L) (n=3) • Tertiary hospital (H) (n=3) • TCM tertiary hospital (T) (n=3) Patients (n=33): <ul style="list-style-type: none"> • Small community health centre (S) (n=4) • Large community health centre (L) (n=7) • Tertiary hospital (H) (n=9) • TCM tertiary hospital (T) (n=8) 			

Table 6-6 Semi-structured interviews with prescribers and structured interviews with patients

Overall, 13 interviews with prescribers and 33 interviews with patients were conducted in five sampled hospitals. Interviews with prescribers were conducted face-to-face in private locations of the interviewees' choice, so that they were comfortable with the environment, and could talk in confidence. Interviews with patients were conducted in the open waiting area. The wording of both interviews was designed to give an impression of neutrality to encourage both the prescribers and patients to respond to the more sensitive questions. In order to build trust and rapport and

encourage responses from the position of a stranger, the researcher actively stressed that the interviews were not recorded, and only notes were taken. The interviews were then written up within 24 hours. Each interview with a prescriber lasted between 30 minutes and 45 minutes. With patients, the length of each interview was significantly shorter, lasting between 15 minutes and 20 minutes. Not all interviews were included in the analysis: the pilot interviews with the patients did not produce enough information and were excluded. All other interviews, including the pilot interview with a prescriber at a university hospital, were all included in the analysis.

The sampling of hospitals was conducted with the purpose of capturing a range of characteristics reflective of healthcare settings that common cold patients visited in urban Beijing, even though the process was subjected to limitations due to pragmatic reasons, and it was achieved through the assistance of Gatekeeper 2. The background of the hospitals sampled is described in Table 6-7.

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	A small community health centre (S)	A large community health centre (L)	A university hospital (U)	A tertiary hospital (H)	A TCM tertiary hospital (T)
Tier of the hospital	Tier 1	Tier 1	Tier 1	Tier 3	Tier 3
Number of beds (approx.)	N/A	20	50	> 1,000	> 1,000
Number of prescribers (approx.)	20	Over 40	Over 40	Over 200	Over 200
Patient visits per day (approx.)	200	1,000	1,000	Over 5,000	Over 5,000
Main population served	Regular residents of the neighbourhood communities			Residents of neighbouring districts and sometimes provinces	Residents of Beijing and visitors from the northern part of the country
Provision of TCM services	Yes	Yes	Yes	Yes	Yes
Financing mechanism as described by interviewees	The district government allocates a performance-based global budget to cover all operational costs; the health centre hands over all the revenue to the district government.	The district government allocates a performance-based budget to cover a significant portion of the operational costs; the health centre is responsible for generating revenue to cover the rest.	The university allocates a global budget to cover all operational costs; the hospital manages the budget and keeps the surpluses.	The government allocates a small budget; the hospital is responsible for generating most of the budget required to cover all operational costs. The hospital keeps the surpluses.	
Composition of prescriber's remuneration as described by interviewees	Basic salary plus bonus based on the fulfilment of public health management in line with the performance indicators for the health centre	Basic salary plus bonus based on the fulfilment of public health management in line with the performance indicators for the health centre, and the volume of healthcare service provision	Basic salary plus a very small bonus based on capitation	Basic salary plus bonus based on a number of performance indicators based on capitation, volume and quality of service provision, in line with the performance indicators for the hospital	

Table 6-7 Overview of the hospitals sampled

This sample managed to capture two types of hospitals: community health centres, and tertiary hospitals. These hospitals differed in their catchment areas. Tertiary hospitals had a much wider catchment areas, sometimes reaching other provinces; in contrast, primary care providers mainly served residents in the neighbouring areas. These hospitals also differed in financing mechanisms. Tertiary hospitals were required to generate revenue to finance themselves whilst community

health centres largely operated on global budgets. These community health centres had varied degrees of incentives to provide services based on the size of the budgets: community health centre L had to generate revenues from service provision to supplement a comparatively partial budget to that of community health centre S. Due to the zero-mark-up policy for essential medicines, prescribing was precluded from revenue-generating services; instead, they provided healthcare services that were popular amongst the locals, such as TCM services. Provision of TCM services was prevalent amongst hospitals in China. All hospitals sampled either included TCM departments or specialist TCM prescribers to provide these services. These characteristics were in line with the descriptions in Chapter 4 (Healthcare System Background).

After access was secured at the local hospitals sampled, the researcher was able to negotiate directly with the contact person of each hospital to recruit prescribers. The researcher was also able to recruit patients of various characteristics in the public waiting area directly. As with the sampling of key informants, the principle of purposive sampling also applied here. The purpose is to capture, as many types as possible, prescribers and patients of various characteristics and backgrounds from which a diverse range of themes can be elicited, and a more enriched narrative could be constructed by building on the argumentative skeleton and sequence of events provided by the theory.

In recruiting prescribers, it was crucial to consider how to capture the possible range of prescribers in various departments that a common cold patient may see in urban Beijing. After consulting with Gatekeeper 2, the contact persons in each hospitals and spending time making observations and inquiring nurses inside the local hospitals, the researcher identified some of the departments that common cold patients were most likely to visit when they visit their hospitals, including general practice (for community health centres), internal medicine, respiratory medicine, emergency medicine and paediatrics (for other hospitals). All these departments above were outpatient departments. The characteristics of the prescribers sampled are summarised in Table 6-8.

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	Hospitals													
	S			L			U	H			T			
Prescriber	S1	S2	S3	L1	L2	L3	U1	H1	H2	H3	T1	T2	T3	
Gender	F	F	M	F	F	F	F	F	F	F	M	M	F	F
Age group	30 – 39	30 – 39	40 – 49	20 – 29	40 – 49	30 – 39	40-49	40 – 49	30 – 39	50 – 59	40 – 49	30 – 39	40 – 49	
Department	General practice	General practice	General practice	General practice	General practice	General practice	Internal medicine	Respiratory medicine	Respiratory medicine	Respiratory medicine	Emergency medicine	Emergency medicine	Paediatrics	
Professional grade	Attending physician	Attending physician	Chief physician	Attending physician	Associate chief physician	Attending physician	Associate chief physician	Associate chief physician	Attending physician	Chief physician	Attending physician	Attending physician	Associate chief physician	
Level of education	Undergrad	Undergrad	Undergrad	Masters	Undergrad	Masters	Undergrad	Undergrad	Undergrad	Undergrad	Undergrad	Undergrad	Undergrad	
Specialty at graduation	Clinical medicine	Clinical medicine	Clinical medicine: gastro-intestinal medicine	Combinatory medicine (TCM and western medicine)	General TCM	TCM: oncology	Clinical medicine	Clinical medicine: respiratory medicine	Clinical medicine: respiratory medicine	Clinical medicine: respiratory medicine	TCM: respiratory medicine	TCM: emergency medicine	TCM: internal medicine	

Table 6-8 Characteristics of the prescribers sampled

The researcher negotiated with the contact persons, who agreed to assist with the sampling of 13 prescribers with varied demographic background and professional experience from 5 hospitals. Three prescribers were selected in each hospital apart from the university hospital U, where only one prescriber was sampled for the pilot interview. The sample captured prescribers of three different professional grades, namely Attending Physician, Associate Chief Physician, and Chief Physician (in ascending order of rank). Professional grades were reflections of prescriber's clinical experience. Although these prescribers differ in levels of education and their initial specialties at graduation. Most importantly, all of them saw common cold patients daily.

Likewise, in recruiting patients, it was crucial to consider how to capture common cold patients of various characteristics visiting local hospitals in urban Beijing. The ideal scenario would have been to sample common cold patients who could be matched with the recruited prescribers, and the best way to achieve that would have been to recruit patients waiting outside the prescribers' consultation room in spaces assigned to specific departments. In reality, this was highly difficult to execute. Firstly, the prescribers usually invited the researcher for interviews during their off-hours, when no patients were visiting. That meant the researcher had to return to the hospitals on separate occasions for patient interviews. Secondly, patients very often sat where they liked, and patients with various conditions could be found in the waiting area originally assigned to one department. Sometimes these areas were simply unassigned. Thirdly, as many prescribers noted, summer was not a peak season for common cold patients compared with winter. Therefore, the most sensible thing to do was to try to recruit patients in areas assigned to the department to which the recruited prescribers belonged. An exception to this strategy was the TCM tertiary hospital, in which prescribers in both the paediatric department and the emergency medicine department were recruited. As the emotional tension was high in the paediatric department, and the conditions of patients in the emergency medicine department were too serious in general, it was decided that patients were to be sampled from the respiratory medicine department, in consistence with recruitment strategy in the tertiary hospital. In addition, due to lack of access, no patients were sampled from the university hospital. The characteristics of the patients recruited in each hospital were summarised in Table 6-9.

		Number of patients by hospitals				
		S	L	H	T	Total
Overall sample size		7	4	9	8	28
Source of sample		General practice		Respiratory medicine		
Gender	Female	4	3	4	4	15
	Male	3	1	5	4	13
Age group	20 – 29		1	2	2	5
	30 – 39		1	1	4	6
	40 – 49	2	1	3		6
	50 – 59	2		1	1	4
	60 – 69	2	1	2	1	6
	Over 70	1				1
Level of education	Primary education			1		1
	Secondary education	4	2	5	3	14
	Higher education	3	1	3	3	10
	Postgraduate education		1		2	3
Financing method	GFH (Government-Funded Healthcare)	1		2		3
	UEBMI (Urban Employee Basic Medical Insurance)	5	3	2	5	15
	URBMI (Urban Resident Basic Medical Insurance)	1			2	3
	NRCMS (New Rural Cooperative Medical Scheme)			2		2
	Self-funded		1	3	1	5

Table 6-9 Characteristics of the patients sampled

The researcher aimed to recruit at least twice the number of patients as prescribers, so that a range of characteristics and sufficient accounts could be included to compare and contrast with those of the prescribers. Overall, 28 patients were sampled from four hospitals, with 11 patients from two community health centres S and L, 9 patients from tertiary hospital H and 8 patients from TCM tertiary hospital T. With purposive sampling, the researcher was able to even out patients with various demographic characteristics including gender, age group and level of education across different healthcare settings. However, there was over-representation of patients with urban social health insurance for employed people (the UEBMI), and under-representation of patients with other financing methods including other social health insurance schemes and self-funding. Furthermore, only 5 patients out of the total of 28 were self-funded patients. Considering the study setting of urban Beijing, this sample could in a way reflect the pattern of insurance coverage of the urban residents, most of whom were employed. Finally, from Table 6-6, it could be seen that the number of patients sampled were decreasing over the course of the interviews. This was because the data collected by the researcher was gradually reaching saturation using the semi-structured interview. As explained earlier, the questionnaire was not employed as a structured and restricted instrument with limited capacity to capture qualitative data, which would be the case when it was used in a survey; rather, the questionnaire instrument was an alternative form of interview guide that enabled the researcher was

to probe effectively into patients' knowledge, perceptions and experience of common cold, antibiotic prescribing and health seeking in general. By the time 4 patients were interviewed in the large community health centre, the researcher decided that there was sufficiently similar information captured by previous interviews already, and did not carry on recruiting more patients.

In order to compare and contrast the accounts of the prescribers and patients, the interview guides for both the prescribers and the patients were designed to have the same pre-determined analytical categories. The interview guide designed before the fieldwork was piloted and worked well with a prescriber at a university hospital. Only minor changes were made in the final version, which was put to use with 3 prescribers at a small community health centre a few days later. However, the original format of the interview did not work well for the patients, yielding very limited responses after two pilot interviews. The patients were hesitant to engage, with some of them stating that they were unsure about where the questioning was heading despite the researcher's attempt to explain the purpose of the research and the themes that the interview would examine. In addition, as the interview took place in the waiting room, it was extremely difficult to get productive interviews, especially when the waiting times were sometimes unpredictably short. Eventually, as the researcher learned more about the local context from interviews with prescribers at three hospitals by 30st July, a pilot questionnaire instrument was developed for the purpose of improving patient engagement and response. The questionnaire was not left to the patients for them to complete on their own; instead, the researcher used questions from the questionnaire as a starting point of discussion and to conduct further probing where necessary in the same process as the semi-structured interview, so that patients could speak freely and provide more information in the process. Using the questionnaire as an instrument to initiate and aid the semi-structured interview markedly improve patients' willingness to speak and elaborate on their ideas in an open environment as patients had a much better idea about the interview itself upon reading detailed questions outlined on one page of paper: nearly 90% of the patients approached after the questionnaire instrument was introduced agreed to an interview, compared with less than 40% before the questionnaire was used. Furthermore, the questionnaire helped the researcher to control the duration of the interviews and improved completion rate of the interviews: apart from one interview which was incomplete as the patient left halfway, all other interviews were complete in the sense that responses were available for every question. After several trial interviews, the questions were adjusted and finalised on

31st July. The information sheets, consent forms and final topic guides for the prescribers and the patients are available in Appendices 2b, 2c and 2d respectively. towards the end of Appendix 2d is a table showing how analytical categories from prescriber and patient interviews were matched in data analysis.

The sequence of the interviews undertaken in various hospitals was largely determined by the process of negotiation of access, and by the way the interview techniques were developed. On reflection, conducting interviews with more prescribers before the patients was a sensible idea in any case, as they tended to produce much more in-depth information than the patients. The interviews with patients consequently served a better role in triangulating with the accounts of the prescribers, especially after the introduction of the questionnaire instrument that was developed based on the interviews with the prescribers.

Additionally, completing the interviews with prescribers and patients in Subgroup 3 (Table 6-6) before the bulk of the interviews with key informants in Subgroups 1 and 2 commenced (Table 6-5a and 6-5b) helped the research process. Effectively, interviews related to Subgroup 3 acted as a link between the early key informant interviews and the later key informant interviews. Later key informant interviews were able to benefit from operating on the information obtained from interviews with prescribers and patients.

6.4. Phase 2 fieldwork in Shanghai (hospital case study)

Phase 2 fieldwork took place in Shanghai in October 2017. Having gained understanding of the perspectives of policy actors on the context and process of the implementation of *The Campaign* at the central and hospital levels in phase 1 fieldwork, the primary purpose of phase 2 was to conduct a more detailed and comprehensive analysis of how top-down policies from the central government was implemented at a single hospital through a case study that examined the perspectives of all the policy actors involved, which was not the case for phase 1 fieldwork as interviews with managers from a nationally leading tertiary hospital (subgroup 2) and with prescribers and patients from 5 hospitals in Beijing (subgroup 3) were conducted separately, so that a single case study of policy implementation that drew on the perspectives of all the actors involved was not possible.

Selection of phase 2 fieldwork site

Phase 2 fieldwork continued to focus on the urban Chinese setting. However, contrary to the study of hospital implementation in Beijing that took place within a nationally leading hospital, the case study aimed to depict policy implementation in a more typical and less resource-rich urban healthcare scene in China instead, from which more generalised policy implications could be drawn. And for consideration of comparability to Beijing in terms of its metropolitan nature and predisposition for health reforms and policies, the site for phase 2 fieldwork would be ideally in a suburban district of a similarly metropolitan city with a sufficient level of activities in health reforms and policies.

Having explored options for the sites and possibilities of establishing functional collaborations vital for the research access and support for an in-depth case study, the metropolitan city of Shanghai was selected to be the city where phase 2 fieldwork would take place. Formal research collaboration was set up with Fudan University, who provided critical assistance in the selection of sites and negotiation of access. To reflect a more typical and representative urban Chinese setting with a track record in piloting healthcare reforms and policies, a suburban district in Shanghai was chosen by the researcher together with the local collaborators.

The researcher and his collaborators then successfully gained access to a small secondary hospital within the district. The 300-bed hospital was an intermediary between the smaller primary care clinics and the larger tertiary hospitals in the district, capable of providing a level of complex and specialised healthcare services, including CT scans and endoscopy that were not available at primary care clinics. However, it was not equipped to provide the same level of technologically advanced services offered by tertiary hospitals.

The choice of a secondary as opposed to a tertiary hospital for the case study also provided an extra element to investigate the extent of implementation of *The Campaign*. As described in Chapter 5 (National Policy Context), *The Campaign* mainly aimed at improving antibiotic stewardship at higher level hospitals, especially tertiary hospitals. Whilst implementation activities were expected to be pronounced at the previously studied nationally leading hospital in Beijing, the extent to which *The*

Campaign impacted on antibiotic prescribing in a typical secondary hospital remained to be seen.

Data collection in phase 2 fieldwork

The aim of the case study in phase 2 fieldwork was to achieve analytic generalisability to allow for in-depth understanding of a phenomenon in relation to interpretations by existing theory, rather than statistical generalisability to enable statistic inferences to be made (Yin, 2009, 2010). Due to lack of access to data on antibiotic use (which could have provided very useful background on changing prescribing patterns from before to after *The Campaign*), the case study in phase 2 fieldwork employed the semi-structured interview as the only data collection method.

The policy actors interview included:

- Non-clinical managers, who were part of the senior managerial team of the secondary hospital in Shanghai;
- Manager-prescribers, who were senior prescribers or heads of clinical departments who were responsible for both managerial duties and prescribing;
- Prescribers, who were supervised by manager-prescribers and did not have managerial roles;
- Patients in the area outside outpatient department.

The selection of the interviewees was informed both by previous research in phase 1 fieldwork and by constructive discussions with the senior managers of the hospital studied. Three of the actor groups above were derived from, and in line with those from subgroups 2 (managers) and 3 (prescribers and patients) in phase 1 fieldwork. After initial discussions with collaborators prior to the interviews, manager-prescribers were considered to be an additional group of actors that functioned differently to non-clinical managers; by having them as a separate group of actors in the case study, their dual role both as implementers and as prescribers could be better analysed. Further discussions with the collaborators then revolved around the types of clinical settings to be captured. Based on their feedback on my sampling strategy, which aimed to capture departments with frequent antibiotic use, the collaborators and I agreed that nephrology, respiratory medicine, orthopaedics, surgery, paediatrics, obstetrics and gynaecology, A&E and dentistry would be the key departments to

investigate for this case study. At least one manager-prescriber or prescriber was interviewed for each department; for larger departments with more antibiotic use, such as respiratory medicine, orthopaedics, surgery and paediatrics, at least one manager-prescriber and one prescriber were interviewed.

The interviews took place in October 2017. Over the course of 4 weeks, 17 hospital staff and 11 patients were interviewed. The information sheets, consent forms and final topic guides for all the actors at the secondary hospital studied in phase 2 fieldwork – managers, manager-prescribers, prescribers and patients – are available in Appendices 3b, 3c and 3d respectively. The details of the interviews are described in the next section.

Semi-structured interviews with non-clinical managers, manager-prescribers, prescribers and patients (more about sampling procedure)

Whereas the in-depth interview was used in phase 1 fieldwork to understand policy implementation at the central level and at the nationally leading tertiary hospital, the semi-structured interview was employed as the only method for data collection in phase 2 fieldwork, which was significantly informed by the findings of phase 1 fieldwork.

As opposed to general questions about policy implementation, the case study focused on the specific implementation activities at the hospital level as set out by *The Campaign* using a detailed instrument. The final version of the instrument, which is available in Appendix 3d, comprised 6 themes: overview of the hospital; background of the interviewee; perception of *The Campaign*; key actors for antibiotic stewardship; implementation process of *The Campaign* (which examined the policies of *The Campaign* that were relevant to the hospital level one by one); and the perceived influence of *The Campaign*.

Informed by the findings from phase 1 fieldwork in its design, the instrument was designed to gather detailed data from hospital staff, and it was fine-tuned and revised throughout the fieldwork process to reflect increasingly in-depth understanding of policy implementation at the hospital. The questions and probes for the non-clinical managers, manager-prescribers and prescribers were similar overall. During interviews with these actors, heavy focus was devoted to theme 5 – implementation process of *The Campaign* – which examined every antibiotic stewardship policy set out in the

Campaign documents. Questions and probes in this theme also incorporated top-down characteristics emerged from phase 1 fieldwork, especially line of command, target approach, punitive measures and redundancy. However, the instrument was not set up to be restrain the inquiry to merely the intended and seemingly linear implementation process specified by the contents of the official documents. In order to capture the nuances and complexities of hospital-level implementation from the bottom-up perspectives of frontline implementers, further probes and open questions to understand the roles of antibiotic prescribing in different clinical settings, and how actors reacted to those government policies and top-down measures and eventually translated them into implementation activities within their respective clinical contexts. For example, the question about the target approach (“Did the government or the hospital set any target for antibiotic prescription”) was followed by both the probes that examined the intended implementation activities (such as what the targets were, whether there would be punishment for not hitting targets) and the probes that explored how the policy implementation responded to contextual factors (such as how targets differed across clinical settings, and whether they were aligned with clinical needs). As all levels of contextual factors were explored, the researcher actively related the discussions to the clinical experience of manager-prescribers and prescribers throughout the interviews to understand how those factors effected on prescribing behaviours.

The focus of patient interviews was also on theme 5 (implementation process of *The Campaign*). Here, questions about policy implementation were indirect: to ensure patients could relate better with the interview subject, the questions were adapted around the common cold tracer and patients’ experience in getting antibiotic prescriptions rather than the actual policies themselves. Though not addressing contextual factors at higher levels, patient interviews provided a crucial angle to understand the influence of individual factors attributed to patients on antibiotic prescribing. Lessons learned from phase 1 fieldwork were reflected upon in the design of phase 2 patient interviews. Although the structure questionnaire introduced for patient interviews in phase 1 fieldwork did improve effectiveness of patient engagement, it was not an ideal instrument for use in semi-structured interviews; consequently, patient responses had the propensity to be framed around the very specific questions from the questionnaire. Therefore, a decision was made at the beginning of the study by the researcher to amend the tool and use a more conventional interview guide with more open questions and probes. With the feedback

from previous research, the predesigned instrument turned out to work well in the field and required minimal revisions during fieldwork when patients were willing to properly engage with the researcher. However, difficulties in the initial recruitment of and engagement with patients persisted; this issue will be discussed in detail in section 6.7 (Commentary on the methodology used).

The types and numbers of interviewees sampled are listed in Table 6-10.

Type of informant	Departments	Number of informants
Non-clinical managers	Medical affairs, pharmaceutical affairs, hospital infection control	n=3
Manager-prescribers	Nephrology, respiratory medicine, orthopaedics, surgery, paediatrics,	n=7
Prescribers	obstetrics and gynaecology, A&E, dentistry	n=7
Patients	Outpatient waiting area	n=11 (males: n=6, females: n=5; age 20-30: n=2, age 30-40: n=3, age 40-50: n=1; age 50-60: n=3, age 60-70: n=2; local residents: n=7, migrant workers: n=4)

Table 6-10 Interviews with hospital staff and patients at the secondary hospital in Shanghai

The 17 interviews with hospital staff were conducted in private rooms arranged by the hospital. Fourteen out of the 17 interviews were recorded and transcribed verbatim; notes were taken for the remaining 3 interviews. Each interview lasted between 40 and 90 minutes. The 11 interviews with patients were conducted in the waiting area of the outpatient department. The patient interviews were relatively short, each lasting not longer than 20 minutes. To encourage patient participation, none of the interviews were recorded, and notes were taken instead. All interviews were conducted in Chinese, written up within 24 hours, and eventually included in the final analysis.

As before, the interviewees for the case study were purposively sampled by the researcher. Key managerial staff were selected based on previous fieldwork in the nationally leading hospital in Beijing. Manager-prescribers and prescribers were sampled from a variety of clinical departments, which were likely to be dealing with very different patterns of antibiotic use and challenges in implementing *The Campaign*. The sampling of patients also aimed to capture patients with varied personal background. In

particular, a few migrant workers were sampled to reflect the demographic characteristic of the district.

As described earlier, the sampling process was a collaborative one between the researcher, academics from Fudan University and the senior management staff of the hospital. The sampling frame described above was put forward by the researcher, and it was large accepted by all collaborators; minor revisions were made as to the specific clinical departments from which manager-prescribers and prescribers were sampled based on the collaborators' description of the basic information of the hospital. Patients engagement was less of a concern that imagined as about 1 in 3 patients approached would be happy to be interviewed. However, the interviews did not come across any in-depth conversation that could last for more than 15-20 minutes, which was likely down to the constraints of the method of recruiting and interviewing patients waiting for treatments in the open space itself.

6.5 Analysis of empirical data

The thematic analysis of the transcripts and notes of the interviews, and field notes was conducted in a grounded approach, whereby themes and hypotheses were derived in an iterative cycle between inductive reasoning and deductive reasoning (Pope & Mays, 1995), and deviant cases were used to test the explanatory power of the themes and hypotheses (Silverman, 2006). This overall approach of analysis was applied to data generated from both phase 1 and phase 2 fieldwork. This process was repeated until all the data was accounted for, and the analytical categories, themes and hypotheses could explain all the data. As the sample size of each subgroup in phase 1 fieldwork and of the case study in phase 2 fieldwork was reasonably small, it was possible to examine all the data within each subgroup thoroughly to repeat the iterative analysis process whereby the inductive analytical categories, themes and hypotheses were constantly subjected to scrutiny and reorganisation to generate an overarching narrative that could account for the full set of data across the 2 phases of fieldwork.

Data analysis of phase 1 fieldwork

For the data from the in-depth interviews conducted in subgroups 1 (central actors) and 2 (managerial actors from a nationally leading hospital), initial themes and

analytical categories pertinent to both context and process of implementation were generated in a grounded and iterative approach. Where relevant, theoretical elements pertinent to policy implementation as described in Chapter 2 (Theoretical Background) were introduced to create theory-driven themes and analytical categories.

For the qualitative data from the semi-structured interviews and conducted with prescribers and patients in subgroups 3 (prescribers and patients from 5 hospitals in Beijing), the data analysis process was more structured than grounded. The qualitative data collected from prescribers using conventional semi-structured interviews were analysed in conjunction with those collected from patients using an atypical approach described earlier, which involved the use of a structured questionnaire as a tool to improve patient engagement and to probe. The approach was effective in collecting sufficient detailed responses from patients that constitute a limited body of qualitative data for this analysis. Some initial analytical categories about contextual factors influencing policy implementation had already emerged during the data collection process and were reflected in the instruments, as some of the findings from the semi-structured interviews with prescribers were fed the designing of the interviews with patients. Therefore, themes and hypotheses to be generated first from examining the data from the prescribers, and then tested by examining the qualitative data from patients.

Data analysis of phase 2 fieldwork

Data analysis for the case study was initially driven by existing themes that were derived from the findings of phase 1 fieldwork, including those about top-down implementation characteristics (subgroups 1 and 2), and those about contextual factors at system, organisation and individual levels (subgroups 1, 2 and 3). As explained in section 6.4 (phase 2 fieldwork in Shanghai), these themes had already explicitly fed into the design of the instrument and strongly informed the way that the data were collected, which gave the data from this phase of fieldwork much better structure comparing to those from phase 1 fieldwork. New themes under those bigger existing categories, which emerged through an exhaustive reading of the data in an iterative process that cycled between iterative and deductive reasoning, were then further developed as the analytical process zoomed in on crucial details of that data that revealed the relationships and interactions between context and process. These key

discoveries from the data were used as an analytical lens to apply to the interpretation of the whole dataset. This process was repeated until no further themes was identified.

Application of the theoretical framework for synthesis

In later stages of data analysis, all the themes and analytical categories emerged from all the subgroups were subjected to reorganisation and integration based on the theoretical framework set out in Chapter 2 (Theoretical Background). As explained in Table 6-11, the data analysis process was aligned with and guided by the theoretical framework, with the aim of creating a parsimonious narrative that explained the implementation of *The Campaign* in terms of both the context and the process.

Chapter 6. Study Design and Methods

	Theoretical perspective	Factors pertinent to context	Implementation process to be examined			Data analysis and results			
			Level of implementation	Focus of analysis	Aspects of policy implementation with respect to the activities of <i>The Campaign</i> to be examined	Fieldwork phase	Data source	Theoretical ideas pertinent to data analysis	Analysis of process and context in result chapters
Macro level	Top-down: focus on “the Centre”	<ul style="list-style-type: none"> - Policy factors - Health system factors 	- National implementation of The Campaign	- Context and process of central implementation	- The overall role and activities of the central government in top-down implementation	- Phase 1	- Subgroup 1	- Top-down implementation: preconditions for “perfect” implementation; managerial accountability; target approach	Chapter 7: <ul style="list-style-type: none"> - Top-down features of implementation - Implications of contextual factors for the policy approach - Influence of contextual factors on policy implementation
			<ul style="list-style-type: none"> - Hospital-level factors - Individual-level factors 	- Local implementation and adaptation of The Campaign carried out by local hospitals	- Context and process of hospital implementation		- The overall role and activities of the nationally leading hospital in implementing top-down policies at the hospital level	- Subgroup 2	
Micro level	Bottom-up: focus on the local settings	<ul style="list-style-type: none"> - Hospital-level factors - Individual-level factors 	- Context of hospital implementation	- Context of hospital implementation	- Not applicable	- Phase 2	- Subgroup 3	- Frontline implementers’ perception and experience of the implementation	Chapter 9: <ul style="list-style-type: none"> - Top-down features of implementation - Perception of top-down implementation - Interaction between contextual factors and policy implementation
			- Context and process of hospital implementation	- Context and process of hospital implementation	<ul style="list-style-type: none"> - A detailed analysis of the role of the secondary hospital in Shanghai in setting up an accountability mechanism, introducing stringent penalties for irrational antibiotic use in hospitals and maintaining a reporting line between hospitals and the government - A detailed analysis of the implementation of hospital-based policies including conducting internal surveillance of antibiotic resistance and use, strengthening inter-professional support, introducing stringent qualification requirements, implementing formulary restriction, regulating antibiotic formulary, controlling antibiotic use through targets, conducting internal prescription review, applying information technology platform and improving health promotion with patients 		- Hospital case study	<ul style="list-style-type: none"> - Top-down implementation: managerial accountability; target approach - Frontline implementers’ perception and experience of the implementation 	

Table 6-11 Extended conceptual map of the study illustrating data analysis and results

The theoretical framework, which incorporated theoretical ideas of both top-down and bottom-up implementation and conceptualised the relationship between context and process, were used in driving data analysis and deriving themes.

Top-down elements of implementation exemplified by managerial accountability and target approach were used to understand the process of policy implementation at the central (Chapter 7) and hospital levels (Chapter 9). Additionally, preconditions for “perfect” implementation were introduced in Chapter 7 to examine the role of the government in leading and shaping implementation at the central level for its suitability to understand the role of a strong government in an assumed linear implementation process.

The overarching influence of macro-level contextual factors on policy implementation at both central and hospital levels – which was conceptualised in the theoretical framework – was reflected in the way how system-level contextual factors shaped the policy approach of *The Campaign* into focusing on only secondary and tertiary hospitals. In analysing how the organisation, delivery and financing of China’s healthcare system and its relevant reforms influenced the policy approach, themes were drawn from data from multiple actors at both at both the central (Chapter 7) and the hospital levels (Chapter 8).

Finally, the bottom-up approach to understanding policy implementation was particularly vital in understanding implementation at the hospital level from the perspectives of local policy actors. As set out in the theoretical framework, frontline implementation was influenced by contextual factors at the system, hospital and individual levels; however, frontline implementers were likely to experience the results of the complex interactions between context and process merely as a need to change and adapt their routine clinical and administrative activities. Whilst phase 1 fieldwork focused on the managerial perspectives about how one of the best hospitals in China introduced measure to counteract contextual factors in policy implementation (Chapter 8), phase 2 fieldwork engaged all levels of actors at the hospital – most crucially prescribers and patients – to examined the dynamic interactions and mutual influences between top-down government interventions and frontline activities and prescribing behaviours at a typical secondary hospital (Chapter 9).

In order to aid the mechanics of the analysis process, NVIVO 10 was used to help the categorising and coding of the data. For Subgroup 3, which contained a

reasonable amount of structure, Excel was used to record the data from the structured interviews, and pivot tables were used to look for patterns in patients' responses and help testing and generating new hypotheses that could be tested in data from the prescribers.

The analysis of the data, which were in Chinese, was conducted first in Chinese. After the researcher became familiar with all the materials, the categories, themes and quotes were translated into English, and from that point on, English became the main language of analysis.

6.6 Ethical issues

In order to conduct fieldwork in Beijing and Shanghai, formal ethical approval was sought from ethics committees at LSHTM, Peking University and Fudan University. All approvals were gained before fieldwork started in July 2015 and October 2017. Consent of the organisations and hospitals in Beijing and Shanghai to participate in the research were sought individually, in line with the advice provided by Peking University and Fudan University respectively.

In conducting the research, the researcher was constantly heeding three crucial aspects of ethical issues – anonymity, confidentiality and informed consent – outlined by Goodwin (2006).

Firstly, anonymity was applied to all the organisations and individuals involved in the research. Necessary descriptions of the organisational contexts and the roles of the individuals were provided in order to allow readers to make sense of the analysis; however, the researcher ensured, to the best possible extent, that the level of detail provided were not sufficient for outsider readers to identify the organisations and individuals. In particular, the researcher opted to not to record the names of the patients in order to gain their trust and make them more comfortable in speaking in open space. However, as gatekeeper 1 worked very closely with a lot of the high-level informants (explained in Section 6.3), a few high-level informants from subgroups 1 and 2 in phase 1 fieldwork may be able to guess the identifies of some of the informants.

Secondly, concerning confidentiality, all the informants agreed that all the content discussed during the interview could be used as part of the study; none of the

data obtained during the interviews contained confidential information, and all the data were used in analysis.

Thirdly, informed consent was obtained before the start of every interview. The researcher used the information sheet for participants to explain the purpose of the research and the interview, and sought the signatures of the interviewees on the Informed Consent form, which included consent to participate and to allow quotes to be used in the thesis.

The ethical approvals from LSHTM and local collaborators for the 2 phases of fieldwork are available in Appendices 2a (phase 1) and 3a (phase 2) respectively. And, as previously described, the consent forms and information sheets used in the 2 phases of fieldwork are available in Appendices 2b and 2c (phase 1) and Appendices 3b and 3c (phase 2) respectively.

6.7 Commentary on the methodology used

Recognising that philosophical assumptions underpins all forms of research (Hammersley, 1992), it is necessary to explicitly identify and discuss the epistemological position – or the way of acquiring knowledge – taken by this research, and its implications for interpreting social data. This research takes the position of critical realism, which acknowledges the existence of independent, knowable phenomena (Silverman, 2006), but at the same time accepts that such phenomena cannot be accessed directly without mediation (Hammersley, 1992). In this research, this position is reflected by the fact that the knowledge of policy implementation had to be acquired through the researcher's interaction with interviewees who experienced policy implementation directly or indirectly in the social world. Such knowledge is therefore socially produced, contained within specific contextual accounts (Green & Thorogood, 2009) that reflects existing patterns and constraints in the social world (Hughes & Sharrock, 1997).

This epistemological stance has several implications for the methodology used in this research. Firstly, rather than scrutinise the truthfulness of the data, the aim of social research is to “discover the correct manner” to interpret the available data, taking into account the nature of the data source, and the social environment in which the data is obtained. In understanding the implementation process of antibiotic stewardship

policies in China through the lenses of the policy documents and the interviewees, the researcher's role was to maintain a panoptic balance of the different accounts and achieve a critical interpretation of the accounts within the research context.

Triangulation of data – the use of multiple methods or data sources in qualitative research (Patton, 1999) – may help this process. Yin (2009) argues that triangulation can increase the validity of a case study, in that hypotheses can be established and challenged from the perspectives of different actors, and the narratives generated from different methods. Although the concept of validity stems from positivist notion that accepts the existence of a “correct” version of truth (Silverman, 2006), triangulation of data in a qualitative study could help the researcher construct a more balanced and rounded version of the overall narrative that exists within the given dataset. In this sense, better “validity” can be achieved in a qualitative case study. In this study, the lack of publicly available quantitative data on antibiotic use and lack of access to the data at all the hospitals studied precluded the possibility of triangulation through the use of quantitative data collection methods; however, triangulation was instead achieved through counterbalancing the qualitative data from interviews with a critical literature review of quantitative studies on the impact of *The Campaign* in Chapter 3 (Literature Review) and a descriptive review of the national policy context based on literature and policy documents in Chapter 5 (National Policy Context).

Secondly, the social world has a “reflexive” nature; both the researcher and the interviewees in this research were part of the process of knowledge coproduction that took place in the form of conversation in very specific contexts (Giddens, 1993; Kvale & Brinkmann, 2009). Therefore, it was necessary for the researcher to be wary of the context and social situations in which these interviews took place in interpreting and understanding what the social data were really suggesting. It was equally important for the researcher – the “instrument” in social research (Patton 2002) – to be reflective of their own values and agenda. How a researcher viewed and studied policy implementation very much depends on “who we are, whom we want to influence and who is paying for our work” (Hill & Hupe 2002:83). These factors could implicitly shape a researcher's normative judgements, and inform their methodological choices (Ryan, 1995; Mays & Pope, 2008). Through critical reflection, these assumptions and their potential effects in shaping the research could be made explicit, and the bias introduced as a result of these assumptions could be mitigated (Mason, 2002).

An important factor to consider, therefore, was the social position of the researcher in different types of interviews that took place in different contexts. Most of the interviewees for subgroup 1 of phase 1 fieldwork (actors at the central level) were acquainted with the researcher before the fieldwork formally took place in high-level conferences or meetings. This meant that my identity, as viewed by these key informants, would be one of a credible young researcher. In particular, the introduction through gatekeeper 1 as described in Section 4.3 further enhanced the connections between the researcher and the government-related informants. These factors enhanced the rapport between the researcher and these informants. However, the accounts of the informants were inevitably influenced by their positions: academics may be influenced by some of their stronger views on the subject of interest; the former antibiotic specialist at a pharmaceutical company may be influenced by their experience and feelings with the former employer; and most prominently, the officials, senior officers and experts close to the government may be influenced by their political roles in the government to various levels. It is highly probable that officials and senior officers were inclined to provide rhetorical and official accounts on behalf of the government. It was part of their professional responsibility to ensure that the presentation of the government's public image in this research was in accordance with that in other academic outlets. In addition, as discreet and respectable civil servants, they were not necessarily at liberty to disclose all their personal opinions in their professional capacity.

Similarly, although the interviewees for subgroup 2 of phase 1 fieldwork (managerial actors at the hospital level) were meeting the researcher for the first time during the interview, the introduction through Gatekeeper 1 was instrumental in the researcher's mostly successful attempts to build trust and rapport with these informants as a trustworthy researcher. Still, out of their concerns as managerial actors for one of the best hospitals in China, some of the informants had initial doubts and reservations about the research, citing some of their concerns over the negative opinions about China's hospitals that they had read about in English-language journals. As the interviews took place in private settings, the researcher was able to allay these concerns by going into lengths explaining the purpose of this research, and the background of the researcher. By being honest and open, the researcher was able to encourage more productive engagements with these informants. However, similar to the situation described previously, it was very likely that the informants provided a lot of accounts on behalf of their hospital.

With the interviewees for subgroup 3 of phase 1 fieldwork (prescribers and patients), the situations were different, in that the researcher had to negotiate with new contacts in the local hospitals. Despite Gatekeeper 2 providing significant assistance in introducing the researcher, the researcher had to gain the trust of each and individual prescriber that was recruited. From the responses of the prescribers, it could be concluded that the researcher's attempts were largely successful, although some prescribers were less passionate in engaging in conversation in general due to their busy schedule, as they themselves explained. Recruitment of the patients was in fact more straight-forward. As previously explained, patients were hesitant to engage in the beginning due to the unsuitable format of semi-structured interview in an open setting. Seeing that the researcher was a university student trying to undertake serious work, prescribers and patients were generally supportive of the research. As the interview questions concerned personal incentives and reported behaviours, patients may be more likely to provide opinions that were closer-aligned with their actual experience or behaviours than prescribers, as prescribers may still feel obliged to provide responses that were in line with the public image of their hospitals.

For the case study in phase 2 fieldwork, interviews with all actors including non-clinical managers, manager-prescribers, prescribers and patients at the secondary hospital in Shanghai went smoothly largely due to the fact that formal collaboration between the researcher, Fudan University and the hospital had been in place before the fieldwork commenced. Engagement with the hospital staff were facilitated by the hospital, and engagement with patients was executed by the researcher alone at the hospital's approval. Similar to previous interviews, hospital staff were unlikely to be in a position freely to express their opinions due to their concerns about their employment at the hospital (especially when the researcher was introduced to them by the hospital), and patients were likely to have reservations about the interview process itself. But as the hospital staff were briefed fully about the research and the fact that it was part of a formal collaboration by both the hospital and Fudan University beforehand, they were very willing to engage with the research topic and spoke in-depth about some of the issues raised, often citing events, data and policies within the hospital that were confirmed by one another interviewees. Interactions with patients, on the other hand, proved more difficult. Although their recruitment in the waiting area of the outpatient department was expectedly easy and the patients generally accepted the researcher well upon learning the fact that the research was for a university thesis, few patients displayed real interest towards the interviews themselves. The semi-structured

interview process was unable to not last for more than 15 to 20 minutes. Some of the interviews raised concerns in respect of confirmation bias, as a couple of patients actively asked the interviewer whether or not they were “saying the right things”.

Another important factor to consider was the method through which the interviews were conducted. For all the interviews, questions were phrased neutrally in a non-judgemental manner. When asking sensitive questions (such as the financial incentives to prescribe), the principle of appreciative enquiry was applied, more positive rhetoric was used in questions concerning negative experiences (such as unsuccessful attempts of implementation), or socially undesirable behaviours (such as irrational antibiotic prescribing). No questions involved probing of personal details. Where appropriate, questions were asked in the third person to further distance the interviewee from the situation of interest, so that responses could be gathered for some of the less engaging questions. In addition, the researcher consciously tried to design the order of questions in a way that did not predispose the interviewees to a certain topic that was to be asked later. This was more difficult to execute in-depth interviews as the key informants were in charge of the flow; in the semi-structured interview, the topic guides were designed to achieve that purpose. For example, in the semi-structured interviews with patients, the question of whether antibiotics were necessary for the common cold was asked long after previous questions about the patients’ preferences for common cold medicines. Lastly, the researcher consciously sought to cross-examine information on a certain subject with different interviewees on the premise that it would not lead to the disclosure of the source of information or predispose the interviewee to responses from other interviewees.

Furthermore, the temporal arrangements of both phases of fieldwork meant that the research was likely to be subjected to potential recall bias. Phase 1 fieldwork took place in 2015 and phase 2 in 2017, which was 2 years and 4 years from the end *The Campaign* respectively. However, potential problems with recalling events during *The Campaign* was unlikely to be an issue of concern as interviewees recognised that the implementation of antibiotic stewardship policies was an ongoing effort. In particular, hospital staff from the nationally leading hospital in Beijing and the secondary hospital in Shanghai all felt that the policies and measures of *The Campaign* were lasting and becoming intensified.

Lastly, in order to ensure replicability of the case study (Yin, 2009), the research methodology and other related research activities were meticulously documented, as

evidenced by the descriptions made in this chapter. During the fieldwork, the researcher kept a research log that detailed the daily activities and meetings, and a notebook to record thoughts and field notes. The researcher also kept records of all the written materials over the course of the PhD. Particular to this project, the researcher created a list of Chinese to English translations of the important elements of vocabularies to ensure consistent translations.

6.8 Conclusion

Given the practical constraints, the qualitative case study design as detailed in this chapter presents an appropriate way of investigating the implementation of antibiotic stewardship policies in China whilst incorporating the crucial elements conceived of the theoretical framework: the study is organised into three nested subgroups representing three groups of actors at the macro (central) level and the micro (hospital) level. Considering the nature of social data, and the researcher's perceived roles in the different research settings, it is necessary that careful interpretation be made of the multi-faceted qualitative data collected through using different forms of interviews with different groups of actors and gathering key policy documents from the government. Overall, the study methodology achieves the balance between achieving what is practical possible and mitigating limitations and concerns. The following chapters will discuss the results of data analysis and how they relate to answering the research questions.

Chapter 7. Policy Implementation at the Central Level

7.1 Introduction

Drawing on the data from actor subgroup 1 in phase 1 fieldwork, this chapter applies the top-down perspective to analyse the implementation of *The Campaign* at the central level, including the relevant macro level (system level) factors pertinent to the healthcare system context that can influence policy implementation. The themes in relation to the implementation process are analysed in respect of the roles and activities of “the Centre”, namely the state and non-state actors at the central level, and the alignment between “the Centre” and local actors in policy implementation.

7.2 Top-down features of implementation at the central level

Having highlighted the external influence of system level contextual factors, it is now necessary to examine key elements that were intrinsic to the implementation process of *The Campaign* at the central level. Some of the elements identified through, and summarised in the literature review in Chapter 3 (Literature Review) resonated in the interviews with the key informants, including state capacity and mandate for policy implementation, support from non-state actors, administrative accountability, and extent of decentralisation. These elements will be discussed in light of the relevant theoretical ideas discussed in Chapter 2 (Theoretical Background), including the preconditions for “perfect implementation” (Hogwood & Gunn, 1984), the concept of accountability (particularly managerial accountability) (Mulgan, 2000; Bovens, 2007; Day & Klein, 1987), the target approach to monitor the delivery of policy (Hood, 2006, 2007; Bevan & Hood, 2004), and the “redundancy” of accountability mechanisms (Scott, 2000; Allen *et al.*, 2016).

Dominance of the state in policy implementation

As pointed out in Chapter 2 (Theoretical Background), a foremost premise of the top-down perspective of policy implementation is extensive control exerted by the central government (O’Toole, 1989; Ryan, 1995; Winter, 2006), which was required to represent, and have the mandate to protect public interest (Hogwood & Gunn, 1984). It

would therefore be necessary to examine the role of the state in *The Campaign* and the existing mandates for antibiotic stewardship in respect of the aforementioned concepts.

The dominant involvement of the central government in the implementation of *The Campaign* was explicitly recognised by all the central level key informants, without exception. In describing its compulsory, domineering characteristic of the implementation of *The Campaign*, the key informants had the tendency to attribute the perceived effectiveness of central-led, top-down administrative campaigns to China's autocratic political system in a positive way, despite that campaigns of such nature could take place in other political systems as well. This was clear from a series of responses from the key informants to the researcher's question, "*What was the greatest driving force behind the implementation of antibiotic stewardship policies during The Campaign*":

Senior officer (C): "*This is a Campaign implemented with 'Chinese Characteristic'. There's no better way to explain it. What we mean by that, is the extent and effectiveness of administrative intervention imposed by the central government of China.*"

Government official (A2): "*There's no fundamental difference between The Campaign and other social campaigns in China, except that this time the focus is on antibiotic stewardship.*"

Government official (A1): "*The effectiveness of policy implementation during the Campaign period has to do with the advantages of the political system of China compared with the Western democracies. Overall, China has a very centralised political system that can wield a huge amount of power in policy administration—much more than the Western countries. If the government is determined to push through an intervention through administrative brute force, it's definitely going to work over the short term. In other countries, the civil society has a much bigger role in driving changes. In China, the government is the most dominant agent for initiating policy change.*"

Given that the necessity for a top-down campaign – unsatisfactory progress of implementation of preceding antibiotic stewardship policies – was already established in Chapter 5 (National Policy Context), what was really being emphasized behind the official rhetoric was that the strong central government of China indeed provided extra

advantage to the implementation of top-down campaigns, in which a strong central government was exactly what was most required.

Using the example of expanding surveillance networks for antibiotic resistance and use – one of the Key Policies of *The Campaign* – the key informants described the marked improvement of policy implementation after the central government became on board:

Senior officer (C): *“Between 2005 and 2011, the surveillance network on antibiotic resistance, CARSS, only managed to cover about a hundred or so hospitals in China. During The Campaign in 2012, we decided to expand the network significantly. Our goal was to enrol many more hospitals and increase the representativeness of CARSS. By the end of 2013, we already covered more than 1,300 hospitals. Enrolment was mandatory: after the government decided which hospitals were to be enrolled based on scientific evidence, the enrolment process would go ahead with obtaining the hospital’s consent. Many hospitals only found out about their enrolment after they had been enrolled.”*

Senior officer (B3): *“Once The Campaign took off in 2011, the expansion of CAS, the surveillance network for antibiotic use, was even more rapid than that of CARSS. Within 3 years we were able to cover more than 2,000 secondary and tertiary hospitals in China. 80-90% of tertiary hospitals became enrolled in our network.”*

The dramatic improvement of policy implementation on such a scale was not only the result of the involvement of the central government in *The Campaign*; it was also engendered by the creation of new official mandate. Midway through the implementation period of *The Campaign* in 2012, the government enacted the *Measures for the Administration of Antibiotic Use in Hospitals* (*The Measures* for short), a Ministerial Decree that enshrined all the core antibiotic stewardship policies to date, including those of *The Campaign*. Rather than providing new means for specific legal rights for citizens, *The Measures* was used as a means to create and solidify the official mandate for antibiotic stewardship policies, and a “*statement of intent*” (interview with senior official B1) to mark the central government’s authority and resolution to implement antibiotic stewardship policies not only during *The Campaign*, but also beyond:

Government official (A2): *“The establishment of high-level legal institution for the stewardship of a particular type of pharmaceuticals set a precedent in China, making the enactment of The Measures a monumental event. With a law on antibiotic stewardship, strong actions against failure to implement the stated policies were now justified.”*

Government official (A1): *“The Campaign was short and intense, and it generated significant awareness of the importance of antibiotic stewardship in the short term. The establishment of The Measures heightened the importance even more, and it showed that antibiotic stewardship would be a priority in the long run.”*

With its strong presence and new mandate for policy actions, it could be concluded that the salient dominance of the central government of China in the implementation of *The Campaign* resonated significantly with the focus on “the Centre” in the top-down approach to understanding policy implementation, and the suitability of applying this approach to analyse this policy case became even more apparent when considering the top-down enforcement and mandatory nature of *The Campaign*.

Collaboration between the central state and non-state actors in policy implementation

Even in the case of a dominant central government, studies reviewed in Chapter 2 (Theoretical Background) revealed that proactive collaboration between central state and non-state actors was a key element to effective policy implementation at the central level. Literature on implementation theory also pointed out that policy implementation would involve multiple state and non-state actors (Buse, Mays & Walt, 2012). With appropriate coordination, their collaboration could lead to more effective implementation (O’Toole, 1986; Bowen, 1982). The roles of both groups of actors and the ways they worked together were therefore explored and examined in depth during the fieldwork.

As first introduced in Chapters 5 (National Policy Context) and 6 (Study Design and Methods), three groups of actors at the central level were explored in this research: the state actors were represented by the central government (specifically the

Bureau of Medical Affairs of the NHFPC) and the government-affiliated research organisations (such as the NIHA and the CERDU); the non-state actors were exemplified by the academic and professional associations including the CHA, the CPA, the CMA and the CPhA. An overview of the interdependent relationships between these three groups of actors are represented in Figure 7-1 below.

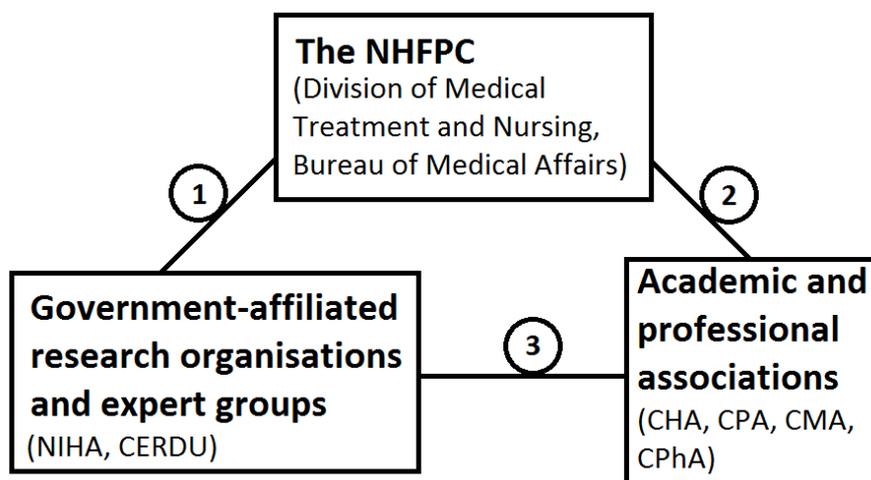


Figure 7-1 The relationships between the state and non-state actors at the central level (i)

The collaboration between the state and non-state actors at the central level in the implementation of *The Campaign* showed that complex yet orchestrated relationships could be crucial, if not indispensable, to delivering policy implementation. In the first relationship indicated in Figure 7-1, the government-affiliated research organisations and expert groups provided technical expertise in research and project support to the NHFPC. In the implementation of *The Campaign*, they were responsible for collecting hospital-level data on antibiotic use and resistance and reporting their findings to the government regularly. Surveillance of antibiotic use in hospitals was conducted by the Centre for Antibacterial Surveillance (CAS) managed by the NIHA; surveillance of antibiotic resistance was conducted by the China Antimicrobial Resistance Surveillance System (CARSS) managed by the CERDU.

In the second relationship indicated, the academic and professional associations worked actively with the NHFPC in developing and promoting best practices for key health policy areas, including antibiotic stewardship. As described in Chapter 4 (Healthcare System Background), their professional focus and self-regulating functions were beneficial to promoting antibiotic stewardship activities, and

their extensive networks were an especially valuable resource for the delivery of education and training activities.

In the third relationship indicated, the government-affiliated research organisations and expert groups and the academic and professional associations were essentially interconnected; in a way, they represented each other. It was not a coincidence that these groups had some overlapping roles in supporting the NHFPC. In fact, two of the most involved government-affiliated research organisations and expert groups – the NIHA and the CERDU – shared the same group of staff of two of the most involved academic and professional associations – the CHA and the CPA. Their relationships are represented in Figure 7-2 below.

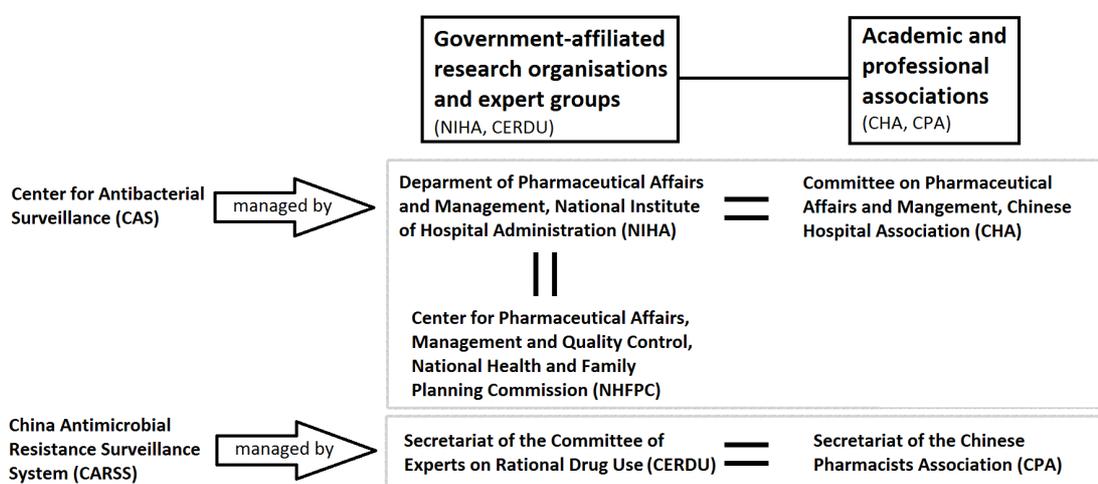


Figure 7-2 The relationships between the state and non-state actors at the central level (ii)

Figure 7-2 illustrates that the CAS was managed by a team based in the Department of Pharmaceutical Affairs and Management of the NIHA, and the CARSS by the Secretariat of the CERDU. This way, both networks were effectively controlled and managed by the NHFPC. These teams operated under different names according to the roles they played in different organisations: the team in the Department of Pharmaceutical Affairs and Management of the NIHA was the same one operating as the Committee on Pharmaceutical Affairs and Management in the CHA; similarly, the Secretariat of the CERDU was simultaneously acting as the Secretariat of the CPA.

These interdependencies and collaborations were crucial to the implementation of *The Campaign* in three ways. Firstly, these collaborations provided resourceful platforms for the central government to work with domestic experts. The key informants

mentioned plenty of examples: professional associations including the Chinese Hospital Association (CHA), the Chinese Medical Association (CMA) and the Chinese Pharmaceutical Association (CPhA) co-developed early antibiotic stewardship policies with the central government; the Committee of Experts on Rational Drug Use (CERDU), which brought together leading experts in China, reported directly to the central government on advancing policies that promoted rational use of antibiotics as well as other kinds of pharmaceuticals; the National Institute of Hospital Administration was a think tank for the central government that regularly advised on, and evaluated health policies that concerned healthcare providers.

Secondly, the non-state actors, especially academic and professional associations, created flexible platforms for the state actors to work with other stakeholders of antibiotic use, including the private industry and foreign governments. While the key informants agreed that official agreements in these collaborations were important, there were situations in which the lead time for the development of official responses was too long. In these cases, the central government could harness the established networks between professional associations with the relevant partners in pursuing official policy agenda in antibiotic stewardship:

Senior officer (C): “Our government has been working with foreign partners on antibiotic stewardship. Formal collaborations are the best options, but sometimes it takes time for these official channels to be established. The fact that academic associations are non-government organisations can be an advantage. They can organise unofficial seminars and visits in ways that are much more flexible, without all the administrative hurdles. And these exchanges can effectively pave way for official, government-level collaborations”.

Senior officer (B1): “It’s not uncommon for professional associations to work with the private pharmaceutical sector. Many pharmaceutical companies are willing to support work on antibiotic stewardship because it’s in their interest to ensure the sustainability of their products. However, any collaboration of this type must be transparent.”

Thirdly, the multiple roles held by the same teams of both the state and non-state actors provided a way for them to gather official and professional mandates necessary for implementing policies originated from the central government. This was especially important, because as described in Chapter 5 (National Policy Context), the

non-state actors were also directly responsible for implementing *The Campaign*. For example, both the CERDU and the NIHA benefited from having multiple organisational names and roles in the implementation of *The Campaign*:

Senior officer (C): *“The prescriber is the one who prescribes. But as it happened, the CPA was given the responsibility by the MoH to improve and promote rational use of medicines, including antibiotics. Although the MoH was hoping to enhance the status of clinical pharmacists through this move, it was still less than appropriate for the CPA to take on this task given the status quo. Therefore, the MoH established the CERDU, which shared the same Secretariat with the CPA, so that the CPA team can now legitimately carry out work to improve use of medicines by both prescribers and pharmacists”.*

Senior officer (B2): *“Collecting data on pharmaceutical use from hospitals at the national level involves working closely with the Department of Pharmaceutical Affairs of all the hospitals included in the CAS surveillance network managed by the NIHA. At the same time, this has been a responsibility of the Committee on Pharmaceutical Affairs of the China Hospital Association as well.”*

On a fundamental level, the central role and the dominance of the central government remained the most essential characteristic in all the foregoing forms of relationships and collaborations. Besides having *“absolute control over the databases”* of the surveillance networks managed by the non-state actors (interviews with Academic D1 and Senior officers B1, B2 and B3), the central government also closely monitored the activities of the non-state actors and took control in all forms of collaboration. In citing reasons for that, the key informants once again emphasised the characteristics associated with China’s political system:

Senior officer (B1): *“Domestic non-governmental organisations in China, especially professional associations that work with the private sector, may have incentive to pursue financial gains. Some academic and professional associations are excellent, but other less so. There are not sufficient mechanisms to regulate these organisations in China’s political system yet. Even if regulations are in place, it’s unlikely that China would commit to a small government. The central government always remains the most trustworthy and authoritative entity, and it has to take control.”*

Whilst the dominance of the state in policy implementation in China was repeatedly emphasized by the key informants and thus indubitably established within the context of this analysis, there were concerns with regards to the resources for policy administration at the central level. In face of the enormous workload due to high level of centralisation, the capacity of the central government became very stretched:

Senior officer (B1): *“Officials of the central government have to process a vast amount of information and work with many experts. For a huge country like China, we have only at most 500 officials working for the central NHFPC. In comparison, the Department of Health in the UK, a much smaller country, may enjoy more resources: the Care and Quality Commission alone had over 2,000 employees. Many policies in China would not have taken place without a lot of our officials voluntarily put in extra hours and sacrificing personal time.”*

Still, with much capacity of the central government dedicated to ensuring central control, it could be argued that the coordination amongst the state and non-state actors effectively enhanced the processes of implementation led by the central government, further extending its capacity for top-down implementation.

Clear line of accountability

A close relationship within the central actors alone was insufficient to ensure policy implementation; the next crucial conduit of implementation rested on the alignment between the central and the local actors. To understand how the central actors in authority “demand and obtain” a high level of compliance from the local actors (Hogwood & Gunn, 1984), the concept of “programme accountability” (Mulgan, 2000; Day & Klein, 1987) was introduced. This provides a lens to examine ways that the activities and priorities of the individuals delegated to deliver the desired outcomes of *The Campaign* were scrutinised and judged by those in higher authorities against their responsibilities in policy implementation.

Establishing accountability was a cornerstone for the implementation of *The Campaign*. As described in Chapter 5 (National Policy Context), programme accountability across all levels of actors introduced through a “chain of command” was enlisted as one of the Key Policies of *The Campaign*. “Pledges” for the implementation of *The Campaign* “as serious as military orders” were signed between adjacent levels

of actors in this reporting line that spanned across all the actors at every level, including: the central government; corresponding arms of the local governments; the chief director of each hospital; heads of departments within the hospitals; and individual prescribers (interview with senior officer C). In a move to translate central control to the activities at the hospital level, “*most of the responsibilities of ensuring implementation within this long reporting line rested with the chief directors of hospitals*”, who, in accordance with one of the Key Policies of *The Campaign*, were duly appointed the “First Responsible Persons” for antibiotic stewardship for their power over the activities within their hospitals (interview with government official A1).

Target approach

Programme accountability and further alignment between the activities of policy actors with predetermined policy goals could be introduced through the “target approach”, which involved setting measurable outcomes for various aspects of the policy of interest for the policy actors to achieve (Hood, 2006, 2007; Bevan & Hood, 2004). The three typical mechanisms of this approach were the target system, in which aspirational standards were expressed as numeric thresholds; the ranking system, in which comparable units were measured and compared against one another; and the intelligence system, in which background information and data that were not part of the previous systems were collected and analysed (Hood, 2007).

The heavy use of all three mechanisms of the target approach was a signature characteristic of *The Campaign*. At the heart was a target system of core numeric indicators of antibiotic stewardship activities at the hospitals level. As summarised in Chapter 5 (National Policy Context), these indicators included inpatient and outpatient antibiotic prescribing rates, antibiotic consumption, and rates of antibiotic use under specific pre-operative and post-operative circumstances. Achieving the defined target thresholds for these indicators – for example, antibiotics should be prescribed in less than 20% of all outpatient encounters and less than 60% of all inpatient encounters, and antibiotic consumption should be less than 40DDD/100 patient days – was set out as one of the Key Policies of *The Campaign*:

Senior officer (B2): “*The targets were there, and hospitals had to find their own ways to achieve them no matter what. The Key Policies in The Campaign were unlike technical guides, they didn’t tell prescribers what antibiotics to use and*

when; rather, they provided broad-brush directives on the general policies to implement if the ultimate targets were to be achieved.”

Complementary to the target system was a ranking system based on the foregoing numeric targets at both the central and the hospital levels. At the central level, after data on those targets collected by the surveillance systems was analysed by the government-affiliated research organisations at regular intervals, there would be both discreet feedback to the hospitals and some form of public reporting of the results:

Senior officers (B2): “Appropriate feedback was provided to all the hospitals. Without disclosing all the data – some of them were confidential, and the full dataset could be accessed only by the central government – they were given enough information to know how well or how badly they did, and how they compared to the best hospitals, so that they could improve on specific aspects.”

Senior officer (B1): “The results and findings were published in national conferences for hospital directors, so that they could their national standing in terms of not only antibiotic stewardship, but also standard of healthcare. That proved very helpful in motivating the directors to do better: if some hospitals could achieve the thresholds for the target indicators, other hospitals should be able to do the same.”

At the hospital level, similar processes took place based on the data collected by each individual hospital, and the ranking system concerns different departments within the hospital. From the perspective of the actors at the hospital level, however, the ranking system was a motivator for doing better as much as a deterrent for doing badly, as shown in the following quote:

Head of outpatient affairs of the national tertiary hospital (OA): “We rank the departments within our hospitals on the target indicators, and the health authority in Beijing ranks the hospitals, including us. Whoever exceeds the thresholds for the indicators will be seen by everybody else, and it won’t look good at all.”

Providing the fundamental data support for both the target and the ranking systems was the intelligence system, which comprised the surveillance networks for antibiotic use (CAS) and resistance (CARSS). As described in Chapter 5 (National Policy Context), the expansion of these surveillance systems was one of the priorities

in the Key Policies of *The Campaign*. The vital importance of data collection was recognised by the key informants, as was pointed out in the below quotes that measurement was the first step to understanding, and then improving antibiotic stewardship:

Senior officer (B2): *“Why do we need to control antibiotic use in hospitals? Why do we need to implement antibiotic stewardship policies? To what extent do we need to control antibiotic use in hospitals? Convincing answers to these questions need to be justified by data. Without data on antibiotic use and resistance, any policy would be purely guesswork.”*

Government official (A2): *“We’ve been developing the surveillance networks for antibiotic use and resistance for nearly 10 years now. They provide the absolutely crucial evidence base for policy making and the monitoring and evaluation of the policies.”*

Due to the importance of data, the actors at the central level went to great lengths to ensure the quality of data. The main measures of quality assurance including providing extensive training programs, and establishing a core set of data based on the more capable and resourceful hospitals, are illustrated in the following quotes:

Senior officer (C): *“The quality of data is of utmost importance. Since the establishment of CARSS, multiple training events on laboratory techniques and computerised data systems have been held at the provincial, regional and country levels. In the near future, a national centre also will be set up to monitor and help improve data quality for all the hospitals in the surveillance network.”*

Senior officer (C): *“The surveillance of resistance is conducted in both active and passive approaches. In the active approach, representative isolates of bacteria collected by the core member hospitals are gathered and analysed collectively by the central surveillance team. In the passive approach, the isolates were analysed locally within the member hospitals, before they upload the relevant data to the central database.”*

Senior officer (B3): *“Out of a total of over 2,000 hospitals, the 300 or so core member hospitals are considered influential and technologically advanced within their provinces. To ensure the quality of the analysis, data with quality concerns are sometimes analysed separately to account for their limitations.”*

What is more, with the surveillance systems becoming fully computerised, gaming on data reporting at the hospital level became difficult to conceal:

Head of outpatient affairs of the national tertiary hospital (OA): *“In theory, a prescriber could reduce the prescribing rate by writing antibiotic prescriptions as separate prescriptions from other medications, thereby increasing the total number of prescriptions and consequently, the rate of antibiotic prescriptions against total prescriptions. However, prescribers can no longer hide their prescribing patterns, because everything is on the electronic records. These records are passively uploaded and monitored by the health authorities, so are the suspicious prescribing patterns.”*

Punitive measures

The target approach in the implementation of *The Campaign* was also strongly associated with a punitive aspect in the event of failure to meet the targets (Bovens, 2007; Hood, 2006). To reinforce accountability, punishments in the form of deductions in performance-based bonus, or in serious cases, suspension of authorities and significant penalties in hospital accreditation could be incurred on all the relevant actors in the aforementioned chain of command, from *“the prescribers concerned to their line managers, their departments, or even the whole hospital”* (interview with senior officer C). Echoing Voltaire’s quote *“But in this country, it is sometimes good to kill an admiral to encourage others”* (1759), the key informants pointed out that the draconian punitive measures were meant to *“set negative examples to warn others”* by drawing blood, or in the local idiom, *“killing the chicken to warn the monkey”* (interview with senior officer C).

Coupled with the salient punitive aspects, the three systems that comprised the target approach effectively assisted policy implementation on two levels. On one level, the *“extremeness”* of the punitive measures and the stringent nature of the target system were vital to *“reshaping prescribers’ awareness of the importance of antibiotic stewardship at the hospital level”* (interview with senior officer C), so that *“even some of the more remote areas began to pay attention to antibiotic stewardship”* (interview with senior officer B3). On a more fundamental level, this approach successfully mobilised actions. As described in Chapter 5 (National Policy Context), *The Campaign* signified the central government’s intention to intensify implementation of antibiotic stewardship

policies, and the emphasis was on actions. In this context, the below quotes effectively demonstrated the central government's view of the target approach in advancing policy implementation:

Government official (A2): *“At the end of the day, the number is just a number. In principle, we are not pedantic about the numbers, and we know that some of our indicators are not perfect. But our view is that in China, it would be very difficult to operationalise any policies and get the wheels moving if you don't mention any numbers or targets.”*

Senior official (B1): *“Not all the people could fully understand the rationale for antibiotic stewardship; but The Campaign made clear there wasn't any other choice apart from implementing the policies and meeting the targets. They just had to do it.”*

Redundancy

Besides the target approach, a further way to strengthen accountability was having multiple, if not excessive or “redundant”, mechanisms of monitoring and regulations. Represented by the “belt and braces” approach, redundancy could provide fail-safe mechanisms by having two or more overlapping yet independent mechanisms that were capable of working on their own (Scott, 2000).

In the implementation of *The Campaign*, redundancy was manifested in two aspects. The first aspect concerned a two-way reporting mechanism described in the Enforcement sections of the *Campaign* documents. Whilst official inspections came from “*the top to the bottom*”, internal inspections at hospitals were reported from “*the bottom to the top*” (interview with senior officer C). The second aspect concerned the incorporation of target indicators for antibiotic stewardship into other regulatory mechanisms outside the inspection mechanisms associated with *The Campaign*. As introduced in Chapter 4 (Healthcare System Background), the performance and quality of services provided by hospitals in China were regulated both by government-associated organisations responsible for hospital administration, such as the NIHA, and by social insurance payers. As crucial aspects in the policy area of healthcare quality, criteria concerning antibiotic use in hospitals and the control of antibiotic resistance

were increasingly introduced into these regulatory mechanisms, as indicated by the following quotes:

Senior officer (B1): *“All of the target indicators and thresholds outlined by the Key Policies had become an important part of the hospital accreditation. Some of these indicators existed before The Campaign in the context of hospital accreditation, but it was because of The Campaign that they became some of the central indicators to which the hospitals pay due attention to.”*

Head of outpatient affairs of the national tertiary hospital (OA): *“In our internal prescription reviews we also have to comply with the regulations set by the social insurance payers. These regulations look at whether the types and dosages of medications used are appropriate to the clinical indications as defined by the rules of reimbursement. For example, omeprazole can only be reimbursed when used for treating stomach ulcers, but not other diseases including acid reflux. Another example, cephalosporin, can be reimbursed when used for treating mild upper-respiratory tract infections, but heavy dosage or the use of combinations of different antibiotics in this case will be judged as non-compliant and therefore can't be reimbursed.”*

Whilst these multiple independent regulatory requirements “*created extra workload*” to the actors at the hospital level (interview with academic D1), they were “*highly consistent*” with the target approach employed in *The Campaign* (government official A2). The combination of these approaches provided supporting arguments for the strong alignment between the central and the local actors in the implementation of *The Campaign*.

7.3 Implications of contextual factors for the policy approach

System level contextual factors posed “external constraints” (Hogwood & Gunn, 1984) to the range of policy implementation and the scope for policy action. *The Campaign* was tailored for secondary, and especially, tertiary hospitals. The levels of healthcare addressed by *The Campaign* were first discussed in Chapter 5 (National Policy Context), in which it was explained that *The Campaign* was intended to focus on secondary and tertiary hospitals as opposed to primary care providers. The rationale was that most of the antibiotics and healthcare services in China, as demonstrated in

Chapter 4 (Healthcare System Background), were provided by secondary and tertiary hospitals.

As illustrated in the theoretical framework of the study established in Table 2-1 of Chapter 2 (Theoretical Background), system level contextual factors pertinent to the fundamental aspects of China's healthcare system can affect policy implementation at the central level. As described in Chapter 4 (Healthcare System Background), these factors included the governance and administration of healthcare by multiple government ministries, the organisation, delivery and financing of healthcare, and the healthcare reforms that sought to address issues within the system. An important precondition for effective policy implementation was that these contextual factors, which were "external to the implementing agency", did not pose "crippling constraints" (Hogwood & Gunn, 1984). In this research, two important system level factors were identified by the key informants at the central level.

The first factor concerned the positive impact of existing healthcare reform measures on antibiotic use at different levels of healthcare. Whilst the key informants perceived that most of China's healthcare reform shared consistent policy goals with antibiotic stewardship in "*ensuring rational and cost-effective use of pharmaceuticals*" (interview with government official A2), the comprehensive policy package centred around Essential Medicines was designed specifically to tackle overprescribing by removing the link between pharmaceutical sales and healthcare financing. As described in Chapter 4 (Healthcare System Background), the implementation of the New Essential Medicines Policy in conjunction with concomitant healthcare financing reforms exemplified by the zero-mark-up policy and the introduction of global budget had made significant impact.

Even though the essential medicines policy package was not designed to directly impact on prescribing practices (empirical evidence reviewed in Chapter 4, Healthcare System Background, suggested that the policy package did not lead to improvement in the rationality of antibiotic prescribing), its chief functions as a restrictive policy on the availability of pharmaceuticals and as an instrument to facilitate reforms in healthcare financing provided an indirect boost for antibiotic stewardship at primary care level in two significant ways.

Firstly, these policies were perceived by the key informants to be effective at restricting the availability of advanced antibiotics at the primary care level, so that these

potent antibiotics were less likely to be used and the resistance against them was less easily developed. Aiming to include *“commonly available and affordable pharmaceuticals that are sufficient to meet the clinical problems encountered at the primary care level”* (interview with medical expert M), the Essential Medicines List only enlisted basic first-line and second-line antibiotics but not the more advanced third-line treatments and above, and considered these basic antibiotic range sufficient for the minor infections that primary care providers were likely to encounter and manage. Consistent with the description in Chapter 4 (Healthcare System Background), the New Essential Medicines Policy effectively became a gatekeeping policy for antibiotics accessed through healthcare providers, as the government stipulated that the vast majority of pharmaceuticals available at primary care providers must be limited to essential medicines; consequently, the more advanced antibiotics were now only accessible through secondary and tertiary hospitals. In this way, the scope of stewardship of advanced antibiotics could afford to become – and appropriately so – more focused on secondary and tertiary levels most of the antibiotic use in hospitals in China took place:

Senior officer (B2): *“Practically speaking the Essential Medicines List became a cap for antibiotics available at the primary care level. Not that the reforms themselves have helped primary care prescribers better prescribe antibiotics – to be honest irrational antibiotic use remains a big problem there – but now irrational use at primary level became much more limited because it concerned a smaller set of mostly basic antibiotics.”*

Senior officer (C): *“Secondary, and particularly tertiary hospitals, are more likely to receive and manage patients with more serious infections, which is one of the reasons why those hospitals require better, more advanced antibiotics to manage them.”*

Secondly, these policies were also considered to be effective in removing prescribers’ incentives to overprescribe antibiotics at the primary level. Consistent with the descriptions provided in Chapter 4 (Healthcare System Background), the key informants pointed out that the associated reform measures on healthcare financing at the primary care level, including the zero-mark-up policy on pharmaceutical sales and the introduction of global budget to cover operational and staffing cost, largely *“removed the means and incentives to generate revenue from prescribing”* (interview

with government official 1) where the set of reform policies were implemented by the beginning of the implementation of *The Campaign* in 2011.

However, at higher levels of healthcare providers, such impacts on antibiotic stewardship were absent. This was because the full Essential Medicines policy package was not implemented at secondary and tertiary hospitals. Firstly, as described in Chapter 4 (Healthcare System Background) and earlier in this section, higher-tiered hospitals were not restricted to using mainly the essential medicines in the way that primary care providers were. As China's healthcare system lacked meaningful gatekeeping at the primary care level, patients could circumvent the restricted range of antibiotics at the primary care level by self-referring to higher levels of hospitals, where advanced antibiotics became once again accessible. And secondly, unlike primary care providers, which were now funded mainly by global budgets, comprehensive healthcare financing reform to replace revenue generation through service provision did not take place at secondary and tertiary hospitals. Higher-tiered hospitals could apply the government-sanctioned mark-ups on the many pharmaceuticals outside the Essential Medicines range, and pharmaceutical sales remained *"a crucial source of revenue that could take up to 40-50% of the total revenue of secondary and tertiary hospitals"* (interview with senior officer B1). As already demonstrated in Chapter 4 (Healthcare System Background) the financing mechanism of public hospitals was unlikely to change when there were no viable alternative means of financing available:

Head of medical affairs of the national tertiary hospital (MA): *"In a pilot reform that took place in Beijing, five hospitals imposed zero-mark-up policy on all pharmaceuticals, including those outside the essential medicines range; at the same time, medical consultation fees were increased and paid for by the social health insurance schemes on behalf of the patients. However, this pilot reform stalled only after one year. Why? The revenues were not sufficient to fund the hospitals' activities in operation, construction of buildings and medical research. Revenue was the deal-breaker for such reforms."*

Head of outpatient affairs of the national tertiary hospital (OA): *"Any potential zero mark-up policy must ensure that hospitals can attain similar level of revenues in other areas, for example, medical consultation fees, nursing fees and other service fees. Medical consultation fees in China are ridiculously low. Some of our prescribers are amongst the best in the country, and their consultation fees are 5 Yuan per consultation (researcher's note: roughly*

equivalent to 50 pence), and not even all of that goes into his account. A prescriber's earning from the consultation fees of 20 patients would only be enough for a lunch box. The best quality of nursing in one of the best hospitals in the country costs 9 Yuan per day (researcher's note: roughly equivalent to 90 pence). These prices were fixed by the government in the early 1990s."

The second factor concerned the capacity for implementing antibiotic stewardship at different levels of healthcare in terms of resources available and policy administration. As described in Chapter 4 (Healthcare System Background), although the tiered system to organise hospitals was mainly based on the size of catchment area, in reality it was also associated with the level of healthcare services that a hospital could provide.

The gap in resources between primary care and the higher levels of healthcare was an evident theme. In general, secondary and tertiary hospitals were much more technically equipped for antibiotic stewardship than primary care providers. For example, the necessary microbiology tests to inform the use of advanced antibiotics, including the establishment drug sensitivity and resistance profiles, could only be performed in microbiology labs in higher-tiered hospitals, but not in primary care providers. Referring to some examples of stewardship policies, key informants perceived these differences to be sufficiently significant to affect policy implementation in different levels of healthcare providers. One important aspect of resources concerns technology:

Senior officer (C): *"Having a competent microbiology lab was the most basic criterion for enrolling in the surveillance network for antibiotic resistance. Tertiary hospitals were the first to be enrolled, followed by secondary hospitals with improved laboratories. Primary care providers don't have labs of sufficient standards."*

Senior officer (B3): *"Unlike secondary and tertiary hospitals, most of the primary care providers do not meet technical requirements for the surveillance of antibiotic use. Some of them didn't even keep a full record of patients' histories to start with."*

Another aspect of resources concerns human resources:

Government official (A1): *"There's a huge gap in the quality between*

prescribers working at secondary and tertiary hospitals and those working at primary care providers. The former are much better trained and more knowledgeable.”

Government official (A2): *“Many primary care providers simply don’t have the capacity to conduct stewardship activities. Some health centres at county level are operated by one single prescriber. This prescriber would be responsible for everything, from the provision of healthcare to administration affairs. It would be incredibly difficult to see how this prescriber could take up complex tasks related to antibiotic stewardship in this situation.”*

These significant differences between different levels of healthcare were reflected in the policy administration of healthcare providers, in which primary care was considered a separate policy area. Although the Bureau of Medical Affairs was responsible for the overall regulation of medical practices and standards, the Department of Primary Care was primarily responsible for health policies and reforms that specifically aimed at the primary care level. Consequently, *“the administration of health policies at the primary care level and at the higher levels of healthcare”* in the central government was *“notably different”*, as was the extent to which medical practices were regulated in different levels of healthcare (interview with senior officer B3). For example, regulatory policies and guidelines at the primary care level tended to be less detailed and less followed than those at higher levels of healthcare (Academic D2).

Therefore, at the primary care level, healthcare reform policies that limit availability of antibiotics and prescribing incentives could indirectly improve antibiotic stewardship, but the introduction of actual stewardship policies were likely to be hampered by the lack of resources and complicated by potentially disconnected policy administration. At the higher levels of healthcare, healthcare reform policies were much less effective at improving antibiotic stewardship, making the introduction of stewardship measures such as those delineated by *The Campaign* even more important; helpfully, hospitals at this level were equipped with the human and technological resources to implement stewardship policies. Therefore, by focusing on secondary and tertiary hospitals, the policy actors at the central level had chosen an appropriate area of policy intervention, and at the same time mitigated uncertainties and constraints posed by to the external circumstances (Hogwood & Gunn, 1984).

7.4 Influence of contextual factors on policy implementation

Ultimately, even with reinforced alignment between central and local actors, the influence of the central government in the implementation of *The Campaign* was bound to be more limited than what was assumed in the top-down approach to understanding policy implementation, which envisioned policy implementation to be a direct, rational and linear process (Schofield, 2001) that took place within a “completely unitary administrative system” (Hogwood & Gunn, 1984). On the contrary, as argued in Chapter 2 (Theoretical Background), the complex reality facing policy implementation could lead to heterogeneities in the implementation process, exemplified by “discretions in implementation” (Ryan, 1995).

Regional delegation, or even decentralisation in the implementation of *The Campaign* was inevitable. For example, without sub-national networks at regional and provincial levels, the administration of both the surveillance networks, which comprised thousands of hospitals across the country, would be “*practically impossible*” (interviews with Senior Officers B2, B3 and C). However, resources were unevenly distributed across different regions. Whilst hospitals in the more affluent areas could “*afford fully computerised systems and the most advanced models of laboratory equipment*”, some of the less advanced areas were “*still keeping hand-written records of all sorts of data*”; the more resourceful districts could conduct “*centralised prescription reviews*”, but the less resourceful districts lack the means to achieve that (interview with senior officer C). Consequently, local policy implementation had to consider resource availability along with other local sets of circumstances and constraints. Furthermore, as described in Chapter 4 (Healthcare System Background), extensive decentralisation – both in terms of fiscal capacity and administrative autonomy – meant that local governments were likely to have different policy priorities and approaches to implementation within a unified framework outlined by the central government. The inevitability of decentralisation was reflected in the below quotes:

Government official (A2): “*Central policies are very macroscopic, and there’s room for adjustment in local implementation. For instance, the central government is proposing that hospitals should strengthen their departments of infectious diseases within a proposed timeframe. However, if a hospital doesn’t even have any infectious disease specialists, then it would have to wait until*

they can recruit some. This is where the hospital can apply discretions in implementation.”

Senior officer (C): *“Within the policy framework set out by the central government, provincial governments make their adjustments and specific demands; then follow by city-level governments; then district-level governments; and then followed by individual hospitals. Although the targets remain the same, it’s very difficult to ensure the standardisation of the actual implementation process at different levels.”*

Therefore, the decentralised nature of China’s healthcare system raised a question for the long-term implementation of antibiotic stewardship policies beyond *The Campaign*. Even with dominant administrative interventions from the central government, decentralisation still strongly influenced the implementation process. Given that such high level of involvement of the central government was seen to be “unsustainable” post-*Campaign* (interviews with Government officials A1 and A2), the implementation of antibiotic stewardship policies in a decentralised system was much less likely to be dictated in a top-down manner, and much more likely to engender more variations and heterogeneity based on local context.

7.5 Conclusion

Based on empirical data, this chapter has described the implementation of *The Campaign* at the central level in respect of both context and process. It could be concluded that policy implementation at this level was relatively controlled.

Based on the system level context in terms of the impacts of existing healthcare reform policies and the capacity of different levels of hospitals, the central government of China – the most dominant actor in implementation – took steps to refine the scope of policy implementation to secondary and tertiary hospitals, so as to enhance the effectiveness of implementation.

With the central government exerting strong control, the implementation process could be appropriately analysed through the top-down approach to understanding policy implementation. The dominance of the central government was demonstrated by its role in enforcing mandatory policies, and was strengthened by new legal mandate for action during *The Campaign*. The central government also presided

over its collaborations with other state and non-state actors, and through these collaborations it broadened its reach in capacity, resources and networks. By introducing the target approach and a series of other independent regulatory mechanisms on antibiotic use, the central government reinforced the accountability of local actors through the administrative chain of command.

However, decentralisation in implementation could pose challenges to the extent of central control in local implementation, which was strongly influenced by the characteristics pertinent specifically to the local context and administration. To explore these factors, the next chapter examines the implementation of The Campaign at the hospital level.

Chapter 8. Policy Implementation at the Hospital Level, Part I: Analysis of the Perspectives of Multiple Actors from Hospitals in Beijing

8.1 Introduction

Chapter 7 (Policy Implementation at the Central Level) presented the first part of analysis of policy implementation in this research, and its conclusion drew on the importance of examining implementation at the hospital level in the context of China's decentralised healthcare system. Hence, as the second part of the analysis of policy implementation, this chapter analyses the implementation of *The Campaign* at the hospital level, including the relevant macro level (system level) and local level (hospital level and individual level) factors pertinent to the healthcare system context that can influence policy implementation, and the implementation process. The analysis of context is based on data from all three subgroups, including actors at the central level, managerial actors in the national tertiary hospital and prescribers and patients from other studied hospitals. The analysis of process is based on in-depth interviews with managerial actors in the national tertiary hospital from Subgroup 2 only.

Both the bottom-up and top-down approaches to understanding implementation are relevant in this analysis. On the one hand, actors at the hospital level – both the managerial and the prescribing levels – as a whole are as the frontline implementers of *The Campaign*, and their perception of policy implementation represents a bottom-up perspective. On the other hand, managerial actors at exert a high level of control within the hospital level, so that top-down characteristics of implementation are also present within this level.

In demonstrating the organisational structures, processes and environments revolving around the understanding, incentives and behaviours of policy implementers at the hospital level, the themes in relation to the implementation process are analysed in respect of some of the factors crucial to hospital level implementation identified through the literature review in Chapter 2 (Theoretical Background).

8.2 Implications of contextual factors for the policy approach

In section 7.3 of Chapter 7 (Policy Implementation at the Central Level), analysis of the data from central-level actors in subgroup 1 of phase 1 fieldwork showed that the policy approach of *The Campaign* to focus on implementation activities at higher-level hospitals was precipitated by 2 system level contextual factors, namely the effect of the New Essential Medicines Policy in constraining the availability of antibiotics at primary care level (which, in turn, concentrated the prescribing of the more advanced antibiotics to higher-level hospitals), and the disparity of resources between higher-level hospitals and primary care clinics (which constrained the ability of the primary care level to implement antibiotic stewardship). These themes have re-emerged from data from hospital-level actors in subgroups 2 and 3 of the phase 2 fieldwork, in which interviewees described in detail their perception of the crowdedness at higher-level hospitals especially tertiary hospitals and explained why that was the case.

Firstly, due to the implementation of the New Essential Medicines Policy, the availability of non-Essential Medicines at the primary care level became highly restricted, and at times they were not sufficient to meet the general needs of patients. Although limiting the range of antibiotics available at the primary care level was, as analysed in Chapter 7 (Policy Implementation at the Central Level), a positive enabler for antibiotic stewardship, limiting the range of other medicines could force patients to visit tertiary hospitals instead, where non-Essential Medicines were available:

Prescriber L2 from community health centre L: *“Now community health centres have to use Essential Medicines, but they often simply run out. The procurement system was not very responsive. The range of antibiotics included is sufficient for the problems at the community level, but the range of medicines in general is not. In my view, the Essential Medicines policy is restricting the ability of primary care providers to respond to patients’ need.”*

Prescriber H2 from tertiary hospital H: *“There’re not enough Essential Medicines for chronic diseases. Supposedly it’s more convenient for patients to manage their chronic diseases at community health centres, but too often they have to visit tertiary hospitals, where they can get what they need.”*

A patient complaining about availability of pharmaceuticals at the primary level: *“I don’t come here (community health centre S) very often. They don’t always*

have what I need for my condition. Sometimes I end up going to tertiary hospitals anyway.”

Secondly, the concentration of patients in higher-level hospitals was caused by the concentration of healthcare resources in the hospitals, which ultimately led to tertiary hospitals siphoning patients from lower levels of healthcare especially primary care level, leading to overcrowding.

Despite the government’s effort to improve the capacity of primary care providers, patients remained more attracted to tertiary hospitals, and found it “*difficult to trust community health centres*” (interview with prescriber H1 from tertiary hospital H) in face of the perceived disparity in resources and quality of services between primary care providers and tertiary hospitals. Fundamentally, patients’ trust was highly correlated with the availability of experts in a hospital. The lack of experts at primary level was perceived by all kinds of actors to be a crucial factor in patients’ preference for tertiary hospitals in general, where experts were based:

Head of medical affairs of the case study hospital (MA): *“Patients are after the best doctors. Before renovation our main building was old and cramped, but still more patients than we could manage came here. In contrast, many new community health centres have been rebuilt over the last few years and they have very decent facilities, but patients simply don’t want to go there.”*

Patients who felt prescribers at community health centres were less skilled than those at tertiary hospitals:

“Experts don’t come to community health centres. They’re always at tertiary hospitals.”

“Some people don’t trust the prescribers at community health centres. I wouldn’t go as far as that. I think they would do as well as those at tertiary hospitals in terms of dealing with general complains, say, common cold. However, specialists and consultants at tertiary hospitals are undoubtedly superior in their subject areas. Many of them are conduct academic research as well. This is not something prescribers at community health centres can do.”

The quality of facilities and equipment available at the primary care level was another main concern to the patients, as some of them experienced perceivable difference in the quality of healthcare offered by different levels of hospitals:

Patients who explicitly expressed concerns about the facilities in community health centres:

“Not every community health centre is equipped to do the blood tests. The community health centre near where I live is very poorly staffed, and they don’t have the right equipment to do the tests either. I’ve never had a blood test there, but it’s not because I don’t want to.”

“The labs of community health centres are second-rate at best, and very often their results are not recognised by secondary and tertiary hospitals. Perhaps basic tests like blood tests are ok; I wouldn’t count on community health centres for more advanced tests.”

“I don’t trust community health centres. Once I came to this community health centre to test the levels of a certain liver enzyme, and the result was astonishingly high – it indicated that I had a life-threatening condition. I had the same test at a tertiary hospital not long ago and that was several times lower! Deeply worried, I immediately went back to a tertiary hospital to do the test again, and luckily this reading was consistent with what I had last time. This goes to show the appalling standards of equipment at community health centres.”

Consequently, most of the caseload was heavily concentrated at tertiary hospitals. The average reported daily caseload for a prescriber working at tertiary level hospital was 80 patients, compared to 50 patients for a prescriber working at primary care level. The responses from patients also showed that despite certain advantages associated with visiting community health centres, they clearly had stronger affinity for tertiary hospitals than for community health centres. Community health centres offered convenience in terms of shorter waiting time. For example, for common cold, the typical waiting time for consultation at a community health centre reported by the patients was “5-15 minutes”, which was much shorter than the “more than 30 minutes” required at a tertiary hospital. According to some patients, they also offered “*slightly higher rate of reimbursement than tertiary hospitals*” (a patient at community health centre S), and the medicines they offer are “*generally quite cheap, unlike tertiary hospitals*” (a patient at community health centre L). Despite these advantages, patients were keen to explore options other than community health centres in the case of common cold. When having light symptoms, most of the patients interviewed would opt for self-

medication or rest, considerably more than those who would consider visiting a community health centre. When having heavy symptoms, most of the patients would consider visiting a tertiary hospital, significantly more than those who would consider visiting a community health centre. This health-seeking pattern was also noted by some of the prescribers:

Prescriber L1 from community health centre L: *“If their symptoms are worse than a cough and a sneeze, patients are likely to visit tertiary hospitals.”*

Prescriber T1 from TCM hospital T: *“The department of emergency medicines should deal with patients with severe and urgent infections. Still, it’s common for us to receive common cold patients. Some of them think they need to come here because of a fever, and about 20% to 30% of the patients don’t even have a fever.”*

Prescriber T3 from TCM hospital T: *“In theory, patients should first visit community health centres, and if necessary, be referred to tertiary hospitals. My department usually focus on complex respiratory problems, but with many patients sidestepping community health centres and coming here directly, we have to take up many very simple common cold cases.”*

8.3 Influence of contextual factors on policy implementation

Section 7.4 of Chapter 7 (Policy Implementation at the Central Level) also established that policy implementation in China was unlikely to be a uniform or linear process; regional decentralisation, a major characteristic of the Chinese political system, would likely engender adaptative approaches to policy implementation at the hospital level, which was strongly dependent on the local context. As established in Chapter 2 (Theoretical Background), the implementation context at the hospital level was a result of the interaction between central and local settings (Berman, 1978; Maynard-Moody, Musheno & Palumbo, 1990; Elmore, 1978). In this light, the theoretical framework of the study outlined in Chapters 2 proposed that the contextual factors that influenced policy implementation at the hospital level existed at system (financing, organisation and delivery of healthcare), hospital (specific organisational settings and characteristics of each hospital) and individual levels (prescribers’ and patients’ understanding, relationships and behaviours). Key informants and other

interviewees in this research identified several factors at each of these levels; they are discussed in turn in the sub-sections below.

System level contextual factor: increasing perceived demand for healthcare and pharmaceuticals

At the level of system, China's social health insurance schemes released high levels of perceived demand by patients for healthcare services and pharmaceuticals across all levels of hospitals. This posed significant challenges for maintaining the quality of healthcare service delivery and imposing restrictive measures on drugs in the implementation of *The Campaign*.

The very high level of demand facing healthcare service providers in China was in part encouraged by the successful expansion of social health insurance schemes in recent healthcare reforms. As described in Chapter 4 (Healthcare System Background), social health insurance was to become the dominant form of healthcare financing in China since the three schemes designed to provide universal health coverage for all Chinese citizens were introduced in the late 2000s. Its effect on stimulating healthcare supply – as described in Chapter 4, healthcare providers were incentivised to provide more care for insured than the uninsured – was matched by its effect on stimulating healthcare demand, which was achieved through the lowering of financial barriers to accessing healthcare services. Specifically, prescribers claimed that they were acutely aware of patients' ability to pay and only prescribe medications they were most likely to afford.

Patient demand for pharmaceuticals was stimulated by social health insurance commensurately. Due to the critical role of pharmaceutical sales in healthcare financing as discussed in Chapters 3 (Healthcare System Background) and 6 (Policy Implementation at the Central Level), prescribing was regarded to be "*integral to healthcare service provision in China*": not only was prescribing a main form of service "*integral*" to the healthcare financing, on an administrative level prescribing was also an activity "*integral*" to healthcare provision, in that clinical consultations and the acquisition of pharmaceuticals consequential to the consultations must take place within the same hospital, rather than separately in other hospitals or retail pharmacies (interview with Head of Pharmaceutical Affairs at the national tertiary hospital PA). This connection between prescribing and the provision of hospital-based healthcare

services was reflected in, if not reinforced by, the fact that social insurance schemes were more likely to offer reimbursements for pharmaceuticals prescribed at hospitals than those sold at retail pharmacies:

Prescriber H2 from tertiary hospital H: *“Hospital pharmacies are not connected with the outside network of retail pharmacies. Only hospital pharmacies can manage patients’ prescriptions consistently.”*

Prescriber L2 from community health centre L: *“When patients come to the hospital they want to get reimbursements for their prescriptions. Otherwise they can visit retail pharmacies: not all the retail pharmacies are points of reimbursement, and usually patients pay out-of-pocket there.”*

This view was confirmed by the patients themselves, as insured patients were much more likely to prefer obtaining pharmaceuticals from hospitals. Out of the 12 patients who prefer to obtain pharmaceuticals from hospitals as opposed to having no preference for either hospitals or retail pharmacies, all but one patient had social insurance, and a third of them explicitly cited the lack of insurance reimbursement as the main reason for their preference of hospitals.

As a result, patients were incentivised to take full advantage of the reimbursement system by obtaining reimbursable pharmaceuticals at hospitals, further creating hospital visits and increasing demand for hospital-based healthcare services:

Prescriber H1 from tertiary hospital H: *“The vast majority of patients now have health insurance. Some of them really know how to pick the best time to visit: they come in just before their insurance accounts are closed before the end of the financial year. This way they make sure they use up their annual reimbursements. We jokingly call these patients ‘the blitz squads for prescriptions’.”*

Prescriber S1 from community health centre S: *“Some of the common cold patients actually have cold-like symptoms. Others don’t have any symptoms: they just want to take advantage of their social insurance to obtain pharmaceuticals and stock them for later. It’s common practice.”*

Hospital level contextual factor: decentralised implementation

With decentralisation being a strong characteristic in policy implementation in China, policy implementation across all levels of hospitals was also dependent on the local circumstances. For instance, policy implementation was noted to be more stringent in Beijing than in other regions, where local health bureaus conducted annual inspections on rational use of medicines (interview with prescriber U1 from university hospital U). However, within Beijing, the requirements of different districts could be different. For example, although prescribers from all hospitals claimed that blood test results were pre-requisite to establishing whether or not antibiotics were needed for upper-respiratory tract infections, the actual rules in each hospital could be different:

Prescriber L3 from community health centre L: *“Every district has its own way of implementing antibiotic stewardship. Some stipulated that antibiotics can’t be prescribed without results of blood tests. We’re a bit more relaxed in this aspect. As we have to deal with a huge number of patients every day – more than most if not all the community health centre in this district – we’re forced to relax the rules a little bit.”*

Patients also reported mixed experience with antibiotic prescribing within Beijing. A good number of patients felt that it was not particularly difficult to get antibiotic prescriptions from prescribers, although it would depend on their rapport with specific prescribers. Although some patients perceived that there were clear restrictions on antibiotic prescribing, and prescribers were more reluctant to simply prescribe antibiotics without blood test results, most patients felt it was difficult to say whether prescribers were markedly less willing to prescribe antibiotics based on their experience. Therefore, in analysing the implementation of *The Campaign* at the hospital level, it would be very necessary to examine contextual factors that were specific to the hospital of interest.

Hospital level contextual factor: financing mechanisms of hospitals

Even though *The Campaign* accounted for variations due to specialty settings, other factors could still influence the implementation of *The Campaign* in different hospitals. As described in Chapter 4 (Healthcare System Background), the ways that hospitals were financed could determine the ways that prescribers were paid, and in turn influence their incentives to prescribe. In this research, the sampled hospitals in

urban Beijing employed different ways of financing, and they created incentives for prescribers to provide various services that did not necessarily involve prescribing, which were beneficial for the introduction of antibiotic stewardship policies.

Primary care centres were mainly supported by the government, and they were incentivised not to prescribe. The two community health centres, S and L, operated mainly on government budgets, with varied degrees of incentives to provide services based on the coverage of the budgets. Community health centre L had to generate revenues from service provision to supplement a comparatively partial budget to that of community health centre S. Consistent with the description in Chapter 4 (Healthcare System Background) and analysis in Chapter 7 (Policy Implementation at the Central Level), prescribing was precluded from revenue-generating services due to the implementation of zero-mark-up policy along with the New Essential Medicines Policy. To secure performance-based budgets vital to their operations from the district health bureaus, both community health centres were required to focus on providing public health services rather than healthcare services, such as “*providing immunization*”, “*building personal health profiles of neighbourhood residents*”, and “*managing patients with chronic diseases*” (interview with prescriber S1 from community health centre S). Salaries of the prescribers of the community health centres were also linked to these public health-focused activities. Whilst in the past salaries were linked to prescribing activities, they were now linked to the public health duties delegated to the prescribers by the hospitals (interview with prescriber L1 from community health centre L). The university hospital U, which was considered a tier 1 hospital, operated mainly on a global budget like the community health centres. However, the authority responsible for delivering the budget was the university rather than the district health bureau. As the university “*covered all the operational costs*” for the hospital, the hospital was required to “*maintain a healthy balance and surplus before the budget was renewed*”, and one of the key aspects of this was to “*limit the expenses on pharmaceuticals*”, which had to be sold at “*without mark-up*” (interview with prescriber U1 from university hospital U). Because of the capitation budget, the salary structure encouraged prescribers to serve more patients: a “*small bonus*” was added on top a regular salary, which was linked to “*the volume of patients served*” (interview with prescriber U1 from university hospital U).

By contrast, tertiary hospitals had to generate much of their own income, of which revenues from service provision were a vital source. Tertiary hospitals H and T

mainly relied on the revenue they generated through service provision. As a result, salaries of prescribers were in general linked to service provision as well. For example, in tertiary hospital H, part of the bonus was linked to the performance of the hospital overall, and part of it to the department to which a prescriber belonged (interview with prescriber H1 from tertiary hospital H). However, the performance indicators on which prescribers were assessed did not always promote prescribing. As discussed in Chapter 7 (Policy Implementation at the Central Level), these indicators at the same time reflected various regulations for healthcare cost and quality, such as the those by social insurance payers. In tertiary hospital H, the performance indicators concerned “*volume of patients*”, “*revenue generated through different means including medical services*”, “*prescribing and examinations*”, and “*adherence to prescribing indicators*”; some of these were positively correlated with bonus, others were negatively correlated with bonus – too much prescribing could incur a fine (interview with prescriber H1 from tertiary hospital H). However, even with regulations in place, prescribers’ incentives to prescribe could still be influenced by the pharmaceutical distribution industry outside hospitals’ management, as the industry “*took advantage of a grey area*” to offer a “*direct reward*” to prescribers who actively promoted the sales of certain products (interview with government official A1).

Hospital level contextual factor: variations across clinical settings

The specific characteristics of, and financing arrangements for, various hospital settings could both impact the scope for implementing antibiotic stewardship policies in healthcare providers, especially the larger and more differentiated higher-level hospitals.

The appropriateness of antibiotic stewardship policies in different clinical specialties could significantly affect their implementation. Due to different clinical needs, a one-size-fits-all solution was unlikely to be appropriate for all kinds of specialties. For example, it would be unrealistic and unreasonable to impose policies for outpatient settings to inpatient settings, because antibiotics were, as briefly described in Chapter 4 (Healthcare System Background), a particularly crucial class of pharmaceuticals for inpatient services, and the strength and frequency of antibiotic use in inpatient settings was bound to be higher for a start. Another notable example concerned emergency settings, in which the “*crucial need for timely and appropriate*

use of highly advanced antibiotics” could be in conflict with some of the stewardship policies that sought to restrict formula and authorities of prescribers (interview with senior emergency prescriber from the national tertiary hospital E). The differences in specialties was also manifested at the hospital level. Compared with comprehensive hospitals, which “*receive all types of patients*”, specialist hospitals such as children’s hospitals, psychiatric hospitals and oncology hospitals “*cater for very specific spectra of patients*”, and their respective specialties had “*significant implications on how and how much antibiotics are used*” (interview with medical expert M).

Some crucial policy adjustments were made to accommodate the needs in different clinical specialty settings at the level of policy design. In the 2011 version of the *Campaign* document, different target indicators and thresholds were set for inpatient and outpatient settings respectively. In the 2012 version of the document, new standards were specified for emergency settings and for different types of specialist hospitals, where target thresholds were appropriately revised. Furthermore, despite one of the Key Policies mandating hospitals strictly to restrict the number of types of antibiotics available in their antibiotic formulary (50 types of antibiotics for tertiary hospitals, and 35 types of antibiotics for secondary hospitals), hospitals were allowed to temporarily procure advanced antibiotics excluded from the selections in the existing inventories under verified emergency circumstances.

Individual level contextual factors

At the individual level, prescribers’ and patients’ understanding of antibiotics and attitudes towards antibiotic prescribing could strongly influence prescribing behaviours and the implementation of antibiotic stewardship policies across all levels of healthcare.

Prescribers’ understanding of rational antibiotic use was fundamental to the implementation of *The Campaign*. In this research, interviewed prescribers in urban Beijing showed competent levels of understanding of rational antibiotic use in the context of treating the common cold, despite uneven understanding of antibiotic stewardship. All the prescribers, regardless of training background (conventional medicine or TCM), were able to explain the common cold from a scientific perspective, pointing out that the common cold was an upper respiratory tract infection most commonly caused by viruses rather than bacteria, and stressed that it was generally a

self-healing condition. They also noted that due to the lack of cost-effective antivirals, symptomatic treatments were the most appropriate for the common cold. However, they also recognised that bacterial infections could present in the later stages of the common cold, and potential antibiotic use needed to be informed by indicative symptoms of bacterial infections such as the presence of pus in sputum, or elevated levels of white blood cells in blood test results. The prescribers were also prudent about the use of intravenous infusions. Noting its effect on health, all of them agreed that oral administration was the preferred option.

Prescriber S2 from Community health centre S: *“According to our supervisors we have to control the percentage of prescriptions containing antibiotics to below 15%. The district health bureau also monitors these figures.”*

Prescriber H2 from tertiary hospital H: *“We’ve been implementing antibiotic stewardship policies for about ten years now at this hospital, so prescribers are highly aware of rational antibiotic use. We have internal rankings for different departments based on indicators, and these are regularly published within the hospital.”*

However, not all the prescribers were as well-informed about the antibiotic stewardship policies in their respective hospitals. Whilst some prescribers had a good understanding of the policies in their hospitals, others were less well-informed:

Prescriber S3 from community health centre S: *“I know that some rules concerning antibiotic use are getting stricter. But I don’t know about the specific rules. I prescribe antibiotics prudently so I never got into trouble anyway.”*

Prescriber L2 from community health centre L: *“There’re some rules. The hospital doesn’t seem to be too strict about them.”*

Prescriber T3 from TCM hospital T: *“All of the prescribers in the hospital can check the statistics on antibiotic use, which are collected and monitored by the Department of Medical Affairs and the Drug and Therapeutic Committee. I’m not sure if there’s any punitive measures for those who fail to meet the standards.”*

As consumers of antibiotics, patients’ understanding of rational antibiotic use was equally crucial. In this research, their understanding was found to be less uniform

and more heterogeneous. In terms of understanding the common cold, the vast majority of patients identified with explanations based on meteorological aetiology, claiming that a combination of external factors, such as change of climate and temperature, and internal factors, such as weakened bodily strength and immunity, could cause the common cold. Some patients also identified elements of conventional medicine relating to infections, and these patients tended to be of higher educational status, having received at least college level education. Even though few patients explicitly pointed out antibiotics were inappropriate for viral infections, most of the patients showed caution and discretion to using antibiotics for the common cold, with none of them choosing “Yes” for the question “Is it necessary to take antibiotics for common cold”. Here, their rationale was mainly based on their perception of side effects and severity of symptoms. Patients who chose an outright “No” for this question noted antibiotics had strong side effects from their experience, and felt that there were other pharmaceuticals that were effective and with fewer side effects. Of the patients considered using antibiotics discretionally, about a half of them relied on their own judgement of the severity of disease based on heavy symptoms like fever or very sore throat, whilst the other half would consult prescribers’ advice. One of the potential reasons for the lack of use of scientific knowledge to inform patients’ antibiotic use was the lack of effective education: although many patients agreed that there was notably more promotion for rational antibiotic use in the past few years, few felt that the information helped them understand the science behind antibiotic use. Similarly, none of the patients considered intravenous infusion as the preferred route of administration for medicines. Many patients explicitly preferred oral administration, citing convenience, safety and side effects to the body as main criteria of consideration. Other patients would again seek prescribers’ advice.

The willingness of patients to follow prescribers’ advice, however, was a separate question that concerned the prescriber-patient relationship, a vital factor that could decisively shape prescribers’ and patients’ attitudes towards antibiotic prescribing. The contemporary context of prescriber-patient relationship in China was one of tension, which could at times escalate to violence. In recent years, there have been more and more incidents which involved patients “*causing physical harms to prescribers*” across the country, in which the patients felt justified to resort to violence for their “*demands were not met satisfactorily by prescribers*” (interview with head of medical affairs of the national tertiary hospital MA). Although all the prescribers agreed that, in general, most the patients they had seen were respectful, they also pointed out

that in their career, they had experienced a number of incidents in which patients strongly demanded antibiotics and were unwilling to back down; in these cases, the tense relationship could create very strong pressure for prescribers to prescribe:

Senior emergency prescriber from the national tertiary hospital (E): *“Prescribers in good hospitals are normally very good at sticking to the guidelines. But sometimes even they feel helpless and desperate in face of the pressure from the patients who demand antibiotics very strongly. The prescriber-patient relationship in society is already at a low, and it’s not uncommon for prescribers and patients to engage in heated disputes because of antibiotics. Sometimes certain patients would stop at nothing to get antibiotics, and we could do nothing but to prescribe in the end. It’s very, very difficult to handle sometimes.”*

Prescriber T3: *“Defensive medicine is very understandable; currently the tension between prescribers and patients can be unbearable.”*

In the setting of community health centre, some prescribers suggested that if good rapport could be established, patients could become more compliant:

Prescriber S1 from community health centre S: *“Many patients are our neighbours, we see them very often, and we have friendly chats. These patients are very willing to listen to us when we have differences. If they have reasonable demands, we’ll also try to work with them.”*

In the setting of tertiary hospitals, patients were more likely to be suffering from more severe conditions, and some prescribers found that to be a beneficial factor to increasing patients’ compliance:

Prescriber T1 from TCM hospital T: *“In the emergency department most of the cases are severe, and naturally prescribers take all of the decisions after consulting with patients. Very few patients make special demands here.”*

Prescriber T3 from TCM hospital T: *“By the time parents come to the specialist paediatrics they’ve probably tried many things out and are running out of options. They desperately want their kids to get better, and usually they’re very willing to listen to the prescribers.”*

Most of the patients interviewed identified themselves to be compliant in this

research, with most of them claiming that they were ready to follow prescribers' advice if they were told that their demands were not reasonable. Even so, some of them acknowledged that they had demanded and successfully obtained antibiotics from prescribers in their experience. Several patients explicitly expressed unwillingness to follow prescribers' advice if their demands were not met, especially so if the incidents took place in community health centres.

In the context of strained prescriber-patient relationship and strong demand for pharmaceuticals, the use of TCM became a helpful alternative to antibiotics especially in conditions that were not severe. As described in Chapter 4 (Healthcare System Background), provision of TCM services (excluding the prescribing of patent medicines of TCM formulas) was prevalent amongst hospitals in China. All hospitals sampled either included TCM departments or specialist TCM prescribers to provide these services. The main form of TCM prescribed by the prescribers and used by the patients was TCM patented medicines, which were pharmaceuticals made with TCM formulas.

TCM patented medicines were popular amongst prescribers of different training backgrounds, including those who were not trained in TCM. Many prescribers, regardless of their training background, reflected the view that TCM had less side effects than conventional medicines, and some even believed that they could complement the effects of conventional medicines when both pharmaceuticals were used together. This perception was more likely to be of a cultural nature rather than evidence-based scientific judgement, but it did influence prescribing practices, as almost all the prescribers reported experience of polypharmacy that involved using conventional medicines and TCM patented medicines at the same time.

Similarly, for the patients, TCM patented medicines were a very popular choice of pharmaceuticals, especially in the case of light cold symptoms. Almost all patients reported that they had been, or they were becoming frequent users of TCM patented medicines, with many patients believing that TCM had fewer side effects, compared to conventional medicines. Polypharmacy was frequent, as patients reasoned that TCM could help reducing the side-effects of the perceivably more efficacious conventional symptomatic treatments.

For these reasons, most of the prescribers agree that as access to antibiotics became increasingly regulated, TCM patented medicines could become more and more frequently used to satisfy demands from the patients, who welcomed their use.

8.4 Policy implementation at a national tertiary hospital

Having outlined the three levels of contextual factors that could influence policy implementation at the hospital level in the setting of urban Beijing, it is now necessary to examine key elements to the implementation process of *The Campaign* in the national tertiary hospital, which was first introduced in Chapter 6 (Study Design and Methods). This analysis uses elements from both the top-down and the bottom-up approaches to understanding policy implementation as described in Chapter 2 (Theoretical Background). Top-down elements as applied in Chapter 7 (Policy Implementation at the Central Level) such as accountability, target approach and coordination amongst different actors were present in the implementation process in the national tertiary hospital. At the same time, the bottom-up perspective was adopted through the identification representative frontline implementers from the national tertiary hospital and focusing on their conceptualisation of *The Campaign*, the internal organisational structures and the actions taken in respect of policy implementation within the national tertiary hospital (Elmore, 1979; Hjern & Hull, 1982; Hjern & Porter, 1981).

Whilst incorporating important aspects of hospital level implementation identified through the literature review in Chapter 3 (Literature Review) including prioritisation by the management, administrative resources, human resources and support from medical professionals, the analysis here also sheds light on the way the national tertiary hospital responds to the three levels of contextual factors during the implementation process, before finally reflecting on the role of policy implementation at the central level, which was analysed in Chapter 7 (Policy Implementation at the Central Level).

Perception of the impact of *The Campaign*

Even though the key informants from the national tertiary hospital repeatedly stressed that policy implementation took place well before *The Campaign*, they highlighted that the implementation of *The Campaign* on a macro level had far-reaching implications for policy implementation at the hospital level.

Firstly, *The Campaign* legitimised measures that would have been otherwise difficult to introduce. For example, formulary restriction was difficult to implement before *The Campaign* because it was “*against the interest of the pharmaceutical industry*”, which was concerned about its impact on market access; with the central government stipulating formulary restriction, hospitals were “*emboldened*” to become more discerning about product quality, so that in effect new market forces were created to “*put products that were of lower standards out of the market*” (interview with head of pharmaceutical affairs PA). It was important, too, that “*all the hospitals had to implement antibiotic stewardship policies*” such as this: “*when everyone had to do it, everyone felt equal*” (interview with head of medical affairs MA).

Secondly, *The Campaign* helped formalise existing stewardship policies in the national tertiary hospital. Whereas most of the policies were “*advisory*” and their implementation relied on “*knowledge and self-discipline of medical professional*” in the past, after *The Campaign* these policies became “*formalised and institutionalised*” (interview with head of pharmaceutical affairs PA), which led to much more effective implementation:

Head of medical affairs (MA): “*The Campaign was a useful exercise in a sense that it helped us formalise and standardise the specific practices. For example, we trained and introduced clinical pharmacists to advise and monitor antibiotic use before The Campaign; after the Campaign, we were able to further develop their job specifications, detailing the specific departments and prescribers that each pharmacist worked with. As we’ve had a lot of progress with antibiotic use, our focus is now on the rational use of other pharmaceuticals in general with a similar approach.*”

Thirdly, *The Campaign* was aligned with China’s on-going effort towards healthcare reform, which introduced and normalised new understanding and practices that were crucial to rational antibiotic use and beyond:

Head of infection control (IC): “*The Campaign could be considered as a political movement. In the even grander scheme, it also had to do with the political concept of ‘Creating the New Norm’, which is the flagship project of the current government promoting ethical practices and eradicating corruptions in the Chinese society.*”

The top-down nature of the implementation of *The Campaign* was also reflected in the implementation in the national tertiary hospital to an extent. The target approach stipulated by the central government to strengthen programme accountability was indeed reinforced in the national tertiary hospital:

Senior emergency prescriber (E): *“There’s a host of target indicators related to antibiotic stewardship that would be public published within Beijing’s hospital system at the end of the year. These are also publicly reported within the hospital across the various departments and within each department. Along our reporting lines, prescribers report to their supervisors, and the supervisors report to departmental directors. If we’re told that we’ve used excessive antibiotics, we’d try to reduce it. There had never been any administrative interventions as formal as this, but as prescribers we can see the benefit for controlling antibiotic resistance is huge.”*

Even so, it was not seen by the key informants as the main approach to implementation. Key indicators of antibiotic use and resistance had been monitored since 2009, which was before the Campaign started, to inform strategies to contain hospital-acquired infections in the national tertiary hospital. As a result, key informants pointed out that they were well aware of the fact that the targets represented means rather than ends, and ultimately the focus was the implementation of policies that were designed to improve rational antibiotic use in hospitals:

Head of medical affairs (MA): *“We didn’t direct our energy solely to paying attention to achieving those indicators when The Campaign started. We knew we had to reduce the overall antibiotic prescribing rate from 78% to 40%, but looking at the numbers alone would not give anyone any clue as to how this could be achieved. Our strategy was to focus on things we could do to improve rational antibiotic use instead.”*

In order to implement the policies effectively, the national tertiary hospital took measures to address contextual factors at system, hospital and individual levels as described in the earlier sections.

Interaction between contextual factors and policy implementation

Even with *The Campaign*, managerial actors at the national tertiary hospital actively employed strategies to counteract the influence of contextual factors in the implementation of *The Campaign*, which came at system, hospital and individual levels.

Addressing system level factors

As a leading tertiary hospital in Beijing and in China, the national tertiary hospital processed a very high volume of patients, averaging more than 10,000 patient visits per day. Volume of services at such stupendous scale mounted an enormous challenge to implementing antibiotic stewardship policies. For example, in an ideal situation, the hospital should “*review all the prescriptions prior to handing them to patients*”, but this was made impossible by the huge number of patient visits (interview with head of pharmaceutical affairs PA). In response, the national tertiary hospital introduced measures to limit the supply of healthcare services, and in effect refer patients in a reverse direction to lower tiers of hospitals, so that the number of patient visits could be reduced.

One of the key measures was the cancellation of intravenous infusion services in the outpatient department, which targeted patients who sought infusions for minor conditions:

Head of infection control (IC): “*If patients want to come here simply for getting intravenous infusions, they can do that no more. They would have to go back to their community health centres.*”

Head of medical affairs (MA): “*We may not be able to prevent patients from coming to our hospital for minor complaints, but at least we’re reducing the services that we provide, services that we consider to be redundant at tertiary levels of healthcare. Tertiary hospitals should be dedicated to serving patients with complicated conditions, not minor complaints. As China’s gatekeeping system is still in its early stages, we have to come up with other approaches to achieve similar effects of encouraging patients to visit community health centres for minor healthcare services.*”

Another measure was to introduce other services such as prescription consultations to divert patients from prescribers, and thus relieving some of prescribers' workload:

Head of outpatient affairs (OA): *"With our prescription consultations, patients who simply wanted to learn more about how they should manage their conditions using existing prescriptions, or the potential side effects and interactions of their prescriptions can directly consult clinical pharmacists in an open area next to the pharmacy inside the hospital. This service also aims to improve rational use of medicines in general, including antibiotics."*

Aligning hospital level factors

In line with the approach of *The Campaign* discussed earlier, the national tertiary hospital took further steps to adapt the Key Policies for different specialty settings. For emergency medicine, in particular, relaxation was introduced in the policy of formulary restriction, which stipulated that the authorisation levels for prescribing non-restricted, restricted and reserved classes of antibiotics be assigned to the prescribers according to their professional grades: a junior prescriber, for instance, would not be authorised to prescribe the most advance antibiotic treatments. Although this policy could limit access and ensure prescribing decisions were made by appropriately qualified prescribers, it could also prevent patients from timely access of antibiotics in absence of the authorised prescribers. In emergency situations, the implications of this policy could be very negative. Therefore, alternative measures to resolve the potential problems surrounding access in emergency situations were introduced, which involved temporary authorisations and retrospective review of actions:

Senior emergency prescriber (E): *"In emergency medicine, when no other prescribers with higher levels of authorisation are present within 24 hours, a prescriber may override their authorisation and prescribe advance antibiotics in the best interest of the patient. The patient is seen, and the prescriptions are reviewed within 24 hours by prescribers of higher professional grades. This measure can help us ensure rational antibiotic use and work towards the prescribing targets without jeopardising patient's safety."*

As discussed previously, accounting for specialty settings was not sufficient to ensure effective policy implementation at the hospital level, as the ways that hospitals were financed could influence prescribing incentives and behaviours strongly. In this respect, the national tertiary hospital possessed certain enabling characteristics that could enhance implementation of *The Campaign*.

The national tertiary hospital was very capable of generating revenue from activities outside prescribing, as it was a highly resourceful and technologically advanced tertiary hospital that could attract patients from all over the country. Being less reliant on pharmaceutical sales, the national tertiary hospital could find greater room for manoeuvre in the regulation of prescribing, and prescribers were less incentivised to prescribe as a result:

Head of infection control (IC): *“In this hospital, there has been an increase in revenue that is not related to prescribing. Mostly its down to the significant increase in the number of patients that we serve, and consequentially, the amount of services that we provide. For us, the year-on-year percentage of increase in patient visits could reach 20%.”*

Head of outpatient affairs (OA): *“Our revenue generation never relies on pharmaceutical sales, which only takes up about 15% of our total revenue; its a very low figure. Prescribers’ bonuses have nothing to do with prescribing either. Here the pursuit of revenue generation is linked to the pursuit of technological advancement, such as cutting-edge devices for radiotherapy. Prescribers’ pay is linked to performance, which is represented by the provision of advanced medical services.”*

Also, as one of the leading hospitals in China, the national tertiary hospital prided on its ethos, which was underlined by a heightened sense of professional ethics. As an internationally renowned hospital, the national tertiary hospital also frequently faced close scrutiny by government authorities. This helped to create an environment relatively immune from prescribing activities associated with outside financial rewards:

Head of medical affairs (MA): *“We uphold very high standards of professional ethics. Financial probity is at the heart of this hospital’s value. We have zero tolerance for any under-the-table dealings between prescribers and other interests.”*

Head of pharmaceutical affairs (PA): *“Having achieved excellent results in our work, we had the honour to be appointed by the government to receive high-level foreign delegations to share our experience. Our prescribers always need to give their very best.”*

Given the background and characteristics of the national tertiary hospital, several factors crucial to policy implementation at the hospital level were identified, which were highly consistent with the factors summarised in Chapter 2 (Theoretical Background). Firstly, underlying the initiation of these activities – some of which were not necessarily well-received by prescribers at the beginning – was an effective administrative structure of the management, which is represented in Figure 8-1, and their responsibilities are described in Table 8-1. In this structure, the Department of Medical Affairs were given a stronger mandate than other departments, as the Head of the Department was jointly appointed as Assistant Director of the Hospital.

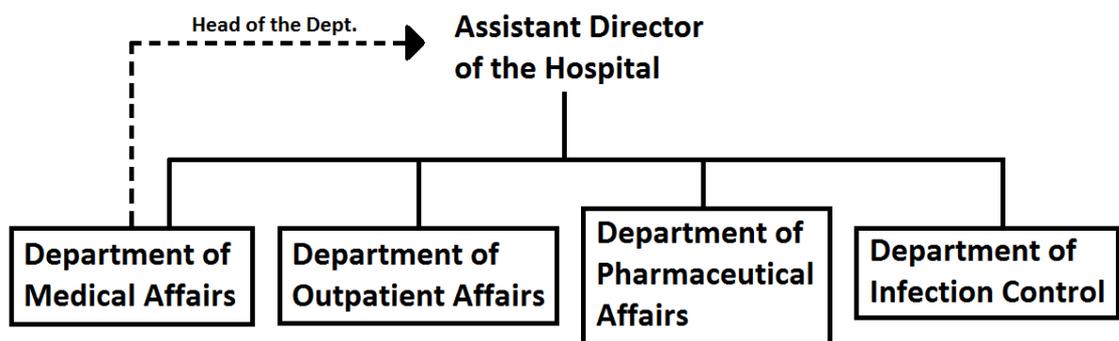


Figure 8-1 The structure of the management of the national tertiary hospital

Administrative department	Summary of roles and functions and remits
Department of Medical Affairs	Supervision of all activities pertaining to the delivery of healthcare services across all departments of the hospital, with a focus on the inpatient departments
Department of Outpatient Affairs	Supervision of activities pertaining to the delivery of healthcare services in the outpatient departments
Department of Pharmaceutical Affairs	Supervision of activities pertaining to the procurement, supply and prescription and application of pharmaceutical products for use in medical treatments and clinical trials for research
Department of Infection Control	Supervision of activities pertaining to the surveillance, prevention and control of nosocomial infectious diseases in the hospital, especially in the inpatient departments

Table 8-1 Summary of the roles and functions of the managerial departments in the national tertiary hospital

Secondly, this structure ensured that the Department of Medical Affairs could take on “*a leading role*” in prioritising antibiotic stewardship policies, and rolling out its implementation (interview with head of medical affairs MA). This was especially crucial, as the key informants identified “*early prioritisation of antibiotic stewardship*” by the management of the hospital to be the prime factor for effective implementation, which took place even “*before The Campaign came into existence*” (interview with head of infection control IC). Perceived as a continuum in the way described in Chapter 5 (National Policy Context), antibiotic stewardship policies had been framed as a vital aspect of “*healthcare quality and safety*” by the key informants at the hospital (interview with head of medical affairs MA). This policy framing was also consistent with that by central level actors, also described in Chapter 5:

Head of medical affairs (MA): “*Rational antibiotic use is an issue of healthcare quality and safety. At the beginning, alarms were raised by the potential risks and detrimental consequences of hospital-acquired infections, especially those that could take place in surgical wounds. Inpatient departments, especially the intensive care units, are likely hotbeds for hospital-acquired infections by highly resistant bacteria. That’s because most of the antibiotic use takes place in inpatient departments as opposed to outpatient departments.*”

Head of infection control (IC): “*Controlling hospital-acquired infection is a task that is stipulated by the health authorities. In our profession, it’s considered to be the litmus test for quality of healthcare.*”

Thirdly, this administrative structure also ensured effective coordination across departments of different disciplines and functions within the national tertiary hospital. As described in Chapter 5 (National Policy Context), antibiotic stewardship required interdisciplinary collaboration amongst clinical pharmacists, prescribers and microbiologists. Clinical microbiologists “*provide the necessary molecular evidence for prescribers*”; prescribers “*make the diagnoses and prescribe antibiotics*”; and “*clinical pharmacists review the prescriptions, provide further advise for difficult cases*” (interview with head of clinical microbiology CM). Such interdisciplinary collaboration at the departmental level to ensure rational antibiotic use was underlined by the set-up of the Drug and Therapeutic Committee (the DTC), an expert committee that functioned in parallel with the administrative departments reporting to the medical director of the example hospital. Similar to the Committee of Experts on Rational Drug Use at the government policy level as described in Chapter 5 (National Policy Context), the DTC comprised working groups of different specialties with experts appointed from various departments of the hospital including expert consultants, clinical pharmacists, clinical microbiologists, specialist nurses, epidemiologists and IT specialists, and it was responsible for monitoring and reviewing prescriptions both prospectively and retrospectively. As discussed in Chapter 7 (Policy Implementation at the Central Level), the coordination of multiple prescribing indicators as dictated by different policies could be challenging; in the example hospital, these indicators were collectively managed and monitored by the DTC:

Head of outpatient affairs (OA): “*The DTC monitors and reviews our prescriptions based on a number of criteria. To start, there’re indicators on rational antibiotic use in line with antibiotic stewardship policies. Then there are similar indicators with hospital accreditation. Last but not least, social health insurance schemes also stipulated some indicators in order to control medical expenditures. These indicators overlap quite a lot. To make sure that we can achieve all these indicators, the DTC has created an overall indicator framework that accommodates all of them, and use it to guide our internal prescription reviews.*”

In line with its responsibilities in pharmaceutical affairs, the Department of Pharmaceutical Affairs played a pivotal role in coordinating the DTC and organising monthly meetings on the state of pharmaceutical use in the example hospital, of which antibiotic use was a main working group. At the same time, other departments actively

work with the DTC to address aspects of antibiotic stewardship within their respective remits based on the DTC's findings and feedback:

Head of clinical microbiology (CM): *“As part of the DTC we work closely with other Heads of Departments. Besides the Department of Pharmaceutical Affairs, the Department of Infection Control also chairs a session on the state of hospital infections in the monthly meetings.”*

Head of outpatient affairs (OA): *“The DTC produce reports on antibiotic use for both the government and the hospital itself. They provide feedback for administrative departments as well as individual medical departments on the patterns of antibiotic use and potential issues of concerns. They also compare the results across different departments and publish them publicly in the hospital. Administrative departments such as Medical Affairs and Outpatient Affairs engage with medical departments based on the results, so that the problems and the relevant personnel can be addressed in a timely fashion, and appropriate cautionary measures are issued duly.”*

Fourthly, in order to strengthen the capacity of clinical pharmacists, who were vital to the technical and administrative functions of implementing antibiotic stewardship policies but were generally under-developed across China, the managerial actors of the national tertiary hospital devoted much support to the training of clinical pharmacists before the implementation of *The Campaign* started:

Head of medical affairs (MA): *“Our hospital was one of the first in China to have a team of clinical pharmacists. When they were first introduced in the early 2000s, they felt too underqualified to speak in front of prescribers because of lack of clinical experience. Therefore, very early on they were asked to participate in mandatory clinical work and work alongside prescribers in their diagnosis. With time, their clinical experience became much more enriched.”*

A crucial step in this process was to develop support from prescribers, who were *“at first unwilling to listen to the clinical pharmacists”* as they feared that *“their clinical independence would become compromised”* (interview with head of medical affairs MA). In order to create trust, the managerial actors first introduced clinical pharmacists in cases that prescribers found difficult to handle, to create opportunities for the two groups of professional to develop appreciation of each other and ways to collaborate:

Head of medical affairs (MA): *“For example, surgeons realised that with the help of clinical pharmacists, they could focus precious energy on conducting surgeries, rather than all aspects of the follow-up treatments and infection prevention. Also, prescribers realised that clinical pharmacists possessed expertise that they lack when working on rare and complicated cases of infection.”*

Managing individual level factors

In the national tertiary hospitals, the key informants identified that a gap in knowledge was responsible for the overuse of prophylactic antibiotics after surgeries. Many prescribers applied antibiotics prophylactically to clean and uninfected Type I surgical wounds, when in fact antibiotic use could increase the potential of infection by increasing the selective pressure for resistant bacteria. In order to improve prescribers’ understanding of rational antibiotic use, behavioural interventions and interdisciplinary trainings were introduced in the national tertiary hospital:

Head of medical affairs (MA): *“To improve their understanding, clinical pharmacists gave prescribers regular briefing on best practices, and demonstrated the positive impact of lessening antibiotic use using the data on prescribing and antibiotic resistance. Also, we introduced an annual “Hand Hygiene Week” several years ago, and showed that good hand-washing practices could effectively reduce hospital infections, further reducing incentives to prescribe antibiotics prophylactically. Once prescribers saw the evidence, they became convinced.”*

The key informants also identified that the strained prescriber-patient relationship remained a key driver of irrational antibiotic use, and prescribers became accustomed to practicing defensive medicines in order to *“mitigate patients’ dissatisfaction and blaming”* (interview with head of pharmaceutical affairs PA). Although as described in Chapter 5 (National Policy Context) improving health promotion and patients’ understanding of rational antibiotic use was part of the Key Policies of *The Campaign*, this element did not appear to be a focus area in the national tertiary hospital. Instead, the national tertiary hospital relied on other solutions to counter the effect of patient expectations. An effective intervention was the introduction of information technology in managing prescriptions:

Senior emergency prescriber (E): *“Formulary restriction has been built into our new IT system. If a prescriber of lower professional grade isn’t authorised to prescribe certain antibiotics, their computer system would prevent them from prescribing should they attempt to do so. Persisting patients would be able to see a notification on the prescriber’s computer about the rules of formulary restrictions. This way prescribers have a better way to explain to patients why they can’t simply prescribe what they want and satisfy their demands.”*

Head of pharmaceutical affairs (PA): *“Now that patients can see what happens with formulary restrictions on prescribers’ screens, they’re less likely to read the situation with misunderstanding or feel that they’ve been unfairly treated. If one patient gets it but another doesn’t from the same prescriber, patients are bound to find this ‘unfair’.”*

8.6 Conclusion

Based on the perspectives of the frontline implementers, this chapter has described the implementation of *The Campaign* at the hospital level, especially in the national tertiary hospital. Despite the complex set of challenges to implementation posed by multiple levels of contextual factors existing in China’s healthcare system, implementation at the central level, which was described in Chapter 7 (Policy Implementation at the Central Level), created significant impetus and an enabling environment for the national tertiary hospital set out measures to counteract some of these challenges.

In addition, the national tertiary hospitals set out measures that addressed elements that were crucial on an operational level in the implementation process. The strong leadership of the managerial actors in policy implementation showed that top-down implementation also took place at the hospital level. The managerial actors, especially the Department of Medical Affairs and the Drug and Therapeutics Committee, benefited from an enabling organisation structure that helped them prioritise and coordinate the necessary activities across multiple clinical disciplines in order to implement antibiotic stewardship policies effectively.

Implementation at this level differed with that at the central level in a distinct way. Bottom-up perspectives based on the key informants’ perception demonstrated

that for the frontline implementers, policy implementation existed as a continuum over a number of years, with the necessary activities spanning the period before the implementation of *The Campaign*, much in the same way as described in Chapter 5 (National Policy Context). Consequently, at the hospital level, the processual view of policy implementation became much less distinct, as past policy implementation was seen as integral to, and inseparable from the events that took place during the implementation of *The Campaign*.

However, hospital-level research in phase 1 did not sufficiently examine how *The Campaign* created the necessitating changes in prescribing incentives and behaviours that were crucial to policy implementation. On one hand, top-down processes at the hospital level were not explored in detail. On the other hand, where policy process was examined in some detail at the national tertiary hospital in Beijing, there was an absence of bottom-up perception and understanding of policy implementation, as it revolved around managers rather than prescribers and patients. Furthermore, the interactions between implementation process and contextual factors in shaping prescribing behaviour were not explicitly examined. Lastly, policy implementation at the tertiary hospital in Beijing was unlikely to be the same as in a more typical urban hospital setting in China. As a result, phase 2 fieldwork – a case study at a typical secondary hospital in Shanghai that involved all levels of hospital-level actors – was set up in response to these issues. The case study is described in the next chapter.

Chapter 9. Policy Implementation at the Hospital Level, Part II: A Case Study of a Secondary Hospital in Shanghai

9.1 Introduction

Chapter 8 (Policy Implementation at the Hospital Level, Part I) delineated a range of contextual factors that could influence implementation of antibiotic stewardship policies at the hospital level and presented a partial case study of hospital level policy implementation that was based on the views of managerial actors at the hospital level. The partial case studied revealed that policy implementation at the tertiary hospital studied had top-down characteristics consistent with policies set out by the government, but at the same time these characteristics were tempered by the need to address contextual factors that made introducing behaviour change in prescribing more difficult. In order to gain a more comprehensive picture of implementation within a hospital, a further case study was conducted to capture the views of the prescribers as well as that of the managers within a single hospital. The purpose of the case study was to elucidate how the hospital responded to top-down demands from the government and the dynamic influence of contextual factors, and more importantly whether and how this process generated the behavioural changes in prescribing necessary for policy implementation.

The analysis of policy implementation draws on the data from all four types of actors included in the case study, namely non-clinical managers, manager-prescribers (the unspecified term “managers” is used in this chapter to refer to both types to managers collectively), prescribers and patients (to a lesser extent, as discussed in Chapter 6, Study Design and Methods). As implementation of *The Campaign* ended in 2013 – four years prior to data collection in 2017 – interviewees were asked to recall policy implementation as a past event. Throughout the interviews, the researcher asked interviewees to clarify the timeframe of events that they were describing, and explicitly contrast their experience prior to and after implementation of *The Campaign* where possible. To situate the case study, the background of the hospital will be briefly described, including its location, mechanisms of financing and patient mix. This will be followed by a description of its administrative structures and the policy actors for

antibiotic stewardship at the hospital and their respective roles. Whilst recurring top-down features of implementation – policy approaches that aligned with the government’s description and intention – will be briefly highlighted, the bottom-up approach to understanding implementation through the eyes of “street-level bureaucrats” will be the emphasis, in which policy actors’ interpretation of the policies and their behavioural change during policy implementation were examined. The concern here is less about the existence of top-down features per se, but more about understanding how different actors perceived and enacted these features in their respective roles and unravelling how the subsequent interplay between top-down features, bottom-up perspectives and existing contextual factors resulted in behaviour change in prescribing during policy implementation.

9.2 Background of the hospital

The hospital studied was a small secondary hospital with about 300 beds, capable of providing a level of complex and specialised healthcare services, including CT scans and endoscopy. It was located in a suburban district in Shanghai that was known for its track record in piloting healthcare reforms. The hospital was directly accountable to the local district government. Although data on antibiotic prescribing at the hospital was not made available for this study due to lack of agreement from the collaborators, Chapter 3 (Literature review) demonstrated that antibiotic use in Shanghai – amongst the most intense in China – had come down dramatically since 2011, the year *The Campaign* commenced.

At the time of the study in late 2017, the main source of revenue for the hospital was a combination of service provision, pharmaceutical sales and funding from the district government. Financing of the hospital had been undergoing substantial changes in recent years. Far-reaching local reforms during, and especially after *The Campaign* had sought to change how healthcare was financed in the area studied, and it would likely impact on the extent to which the local government could influence hospital administration.

As a result of these strong crosswinds from reforms in hospital financing, growth in pharmaceutical use has plateaued in recent years, according to senior managers. On the one hand, contribution to revenue from pharmaceutical sale had been dwindling. During *The Campaign*, service provision and pharmaceutical sales

were a substantial part of the hospital's income. However, over the past five years – including the years contemporaneous with *The Campaign* – the mark-up of pharmaceuticals in general has been continuously adjusted downwards from 15% to 5%. It was expected that a new zero-mark-up policy that applies to all pharmaceuticals (as opposed to essential medicines only) would be rolled out in 2017, which would affect over half of the pharmaceuticals, which were non-essential medicines, available at the hospital.

On the other hand, contribution to revenue from government funding had been increasing. In an ensuing move to restructure the financing of secondary hospitals in the district, the district government was to implement a global budget system starting in 2018. Managers explained that by then, the hospital would have to turn over all the revenues to the district government, before the government reallocated the funding for covering the costs for operation, development and expansion based on its performance and the specific project needs. This new arrangement was similar to the financing reforms of primary care that sought to delink revenue generation from service provision, as described in Chapter 4 (Healthcare System Context). However, whereas performance was assessed in public health services in primary care, the volume of activities in service provision would reportedly still be one of the most important performance indicators for them when it came to budget allocation. They also claimed that the reform would affect all secondary hospitals in the district. It was unclear if similar arrangements would apply to tertiary hospitals in the district, or hospitals in other districts in Shanghai.

Whilst Shanghai overall could be ahead of the curve in terms of introducing healthcare reforms due to its municipal status, the aforementioned reforms were largely consistent with developments being rolled out in urban areas in China. In this context, the studied hospital – a typical secondary hospital in a suburban district away from the city centre in Shanghai – represented a modest healthcare setting much more typical to common urban areas in China than the markedly more affluent, *nouveau-riche* metropolis. Due to its designated size and scale, the hospital had a limited catchment area, and all of its patients came from the nearby community. On average it received about 500 – 600 patients per day. Besides local residents, the community was also occupied by a large number of migrant workers, who lived in this area for its cheaper housing. Non-clinical managers reported that over the past few years, the ratio of local and migrant residents had increased from 4:6 to 5:5 due to a crackdown on illegal

housing for migrants. The implication here was that the proportion of payments made through social health insurance were gaining on that through out-of-pocket payments, as the local residents were covered by insurance, but the migrants were not. Therefore, the stronger regulation of pharmaceutical use from social insurance payers was expected. Overall, however, the hospital claimed that they had been seeing a decrease in total patient visits as the hospital continued to adjust to the material changes in health financing and demographics in the district.

9.3 Administration and policy actors of the hospital

A simplified organisational structure of the hospital studied is represented in Figure 9-1 below. The department of medical affairs was the central hub for the overall administration, supervision and coordination of activities in the clinical departments. It reported to the director of the hospital, who was accountable to the district for ensuring all aspects of healthcare delivery at the hospital such as quality of healthcare and availability and safety of pharmaceuticals, but not directly involved in the day-to-day managerial affairs. Most of the managerial functions were performed by medical affairs with technical support on data collection and analysis from the Office for the Control of Hospital Infection and the Department of Pharmaceutical Affairs. Due to the small size of the hospital, medical affairs assumed a range of responsibilities that were normally associated with other departments in bigger hospitals, including intensive care management (which is usually done by the intensive care unit) and social health insurance management (which is usually done by the department of insurance reimbursement). Ultimately, medical affairs was accountable to the director of the hospital for fulfilling all these functions through various reporting lines.

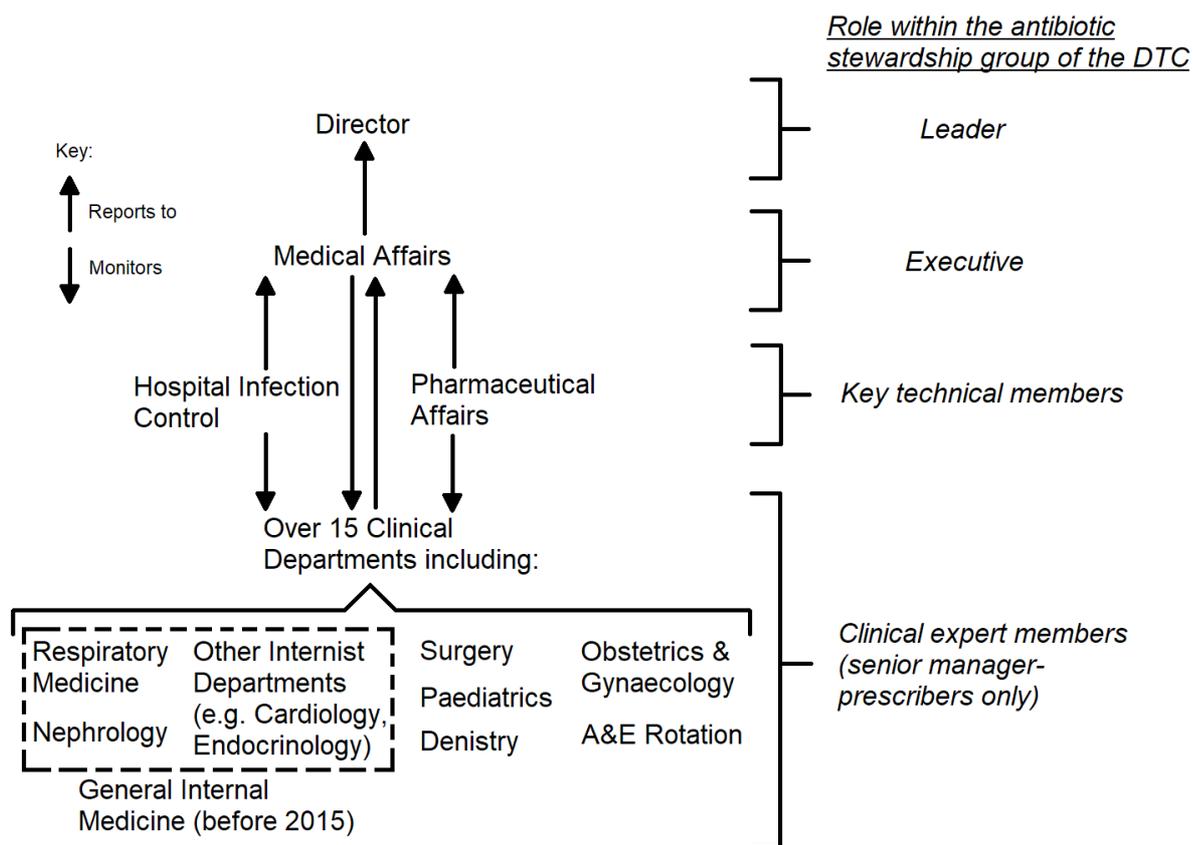


Figure 9-1 Organisational structure of the secondary hospital in Shanghai studied

The reporting line between medical affairs and the director in the case of antibiotic stewardship was through the antibiotic stewardship group, which was part of the more general drug and therapeutic committee (DTC) headed by the director. Groups under the DTC were led by medical affairs on different clinical areas, with pharmaceutical affairs being another crucial member. The make-up of the groups depended on the clinical setting of interest; for antibiotic stewardship, this included the office for hospital infection control and senior prescribers, usually manager-prescribers, with expertise in infectious diseases and antibiotic use. The director had the authority to make the most crucial decisions in antibiotic stewardship with the support from the work of the group, such as the selection of antibiotics to be procured by the hospital, but medical affairs oversaw most of the managerial-level decision making that concerned how specific activities should proceed and be delivered.

For the clinical departments where antibiotic prescribing took place, about 80 prescribers were divided into over 15 specialisations such as respiratory medicine,

gastroenterology, nephrology, surgery, orthopaedics, obstetrics, gynaecology, and paediatrics. Due to limitations in the size of the hospital and the number of prescribers available, these sizes of these clinical departments were small relative to those in large hospitals; on average each department contained about 5 prescribers. Administratively, each specialisation was led by a head of department, who functioned as a manager-prescriber who oversaw antibiotic stewardship at the departmental level as a manager and at the same time, carried out clinical duties as a senior prescriber. Leading their team of prescribers, the manager-prescribers of various clinical departments were directly accountable to medical affairs and were responsible for implementing the mandated activities through their own actions and through ensuring actions from their subordinate prescribers.

Prescribers at the “bottom” were directly accountable only to the line managers of their respective clinical specialisations, meaning that their performance was ultimately assessed only by their line managers. However, they also took instructions from ward leaders and senior prescribers in various clinical settings. One prominent example was the A&E section of the hospital. Again, due to limitations in resources, the hospital did not have a large and independent A&E section; the section comprised a manager-prescriber and rotating prescribers on duty drawn from various clinical departments. Even though the direct reporting managers for the prescribers remained the heads of their clinical specialisations, they were also under the supervision of the supervisor of the A&E section while they were on duty there. Similarly, they were supervised by ward supervisors when they worked in inpatient wards.

Although the specialisations were clearly defined, the clinical pathways for patients with minor complaints such as coughs and colds were less formalised in the past than in 2017. Prior to 2015, these patients had been given an appointment to see one of the prescribers from a generic “general internal medicine” grouping including respiratory medicine, gastroenterology, cardiology, neurology, endocrinology and nephrology. In the words of the non-clinical managers, prescribers in these specialisations had fulfilled a role similar to general practitioners at the primary care level. After better formalised clinical pathways were introduced in 2015, patients were diverted to specialisations more specific to their complaints.

9.4 Top-down features of implementation at the hospital

Similar to the tertiary hospital in Beijing, centralisation of administrative authority to the medical affairs and closer financial alignment between the hospital and the district government described in the foregoing sections significantly enabled top-down policy implementation as proposed by *The Campaign* at the hospital studied. First discussed in Chapter 2 (Theoretical Background), these top-down elements included a clear line of accountability, a target approach supported by numeric targets, ranking system and intelligence system, punitive measures and redundancy were all present in the hospital. These elements are to be discussed in turn in this section.

Clear line of accountability

To buttress the existing line of accountability that ran through the district government, the hospital, the manager-prescribers and the prescribers, specific responsibilities of the actors above departmental level were formalised during *The Campaign* in the context of antibiotic stewardship. Medical affairs acted as the focal point of liaison in this continuous line of accountability through its role in the antibiotic stewardship group, which was set up per the requirements of *The Campaign*. In addition, an explicit signed document detailed the expected tasks and performance was signed between medical affairs and each manager-prescriber, which clearly defined managerial responsibilities in antibiotic stewardship. As mentioned before, medical affairs took on a central role in representing the hospital, taking orders from and reporting to the district government on the one hand and giving order to prescribers in the hospital on the other. Centralised internal coordination within the hospital would prove crucial, as lines of accountability ran vertically, and departments refrained from directly interacting with each other under this model. The implication of this will be returned to later in the analysis of the demands for antibiotic use in different settings and specialisations, an organisational level factor that influences policy implementation.

Target approach

The accountability structure was driven by a target approach, where restrictive numeric targets, or permitted thresholds, were set for many prescribing indicators as demanded by *The Campaign*, such as prescribing rates for various clinical settings,

density of inpatient antibiotic consumption, timing and duration of prophylactic antibiotic use in surgeries and rate of prophylactic antibiotic use in clean surgeries. The hospital was given a set of overall targets by the district government, and managers from Medical Affairs then broke down these targets for each clinical department. Data on prescribing were analysed by a team of clinical pharmacists, who also conducted prescribing review to investigate the medical rationale for the prescriptions themselves.

The ranking system worked in accordance with the line of accountability. At the district level, performance of all hospitals within the district was ranked in annual meetings. At the hospital level, the results of the analysis were first discussed and ranked in monthly managerial meetings attended by non-clinical managers and senior manager-prescribers only, and the manager-prescribers then communicated the results to the prescribers in their departments afterwards. At the managerial meetings, every manager-prescriber could see how they were doing compared with others. Warnings for under-performing departments were issued by medical affairs, and subsequently the responsible manager-prescribers took actions to warn prescribers within the departments too.

To enable the collection of a vast amount of data and support coverage of more prescriptions in prescription reviews, the hospital switched from a dated data collection system that relied on manual collection of information to a computerised data system at the beginning of *The Campaign* and kept on improving it as it progressed. This data collection system was connected to that of the district government, and according to some of the managers, the same data system had been adopted by other hospitals in the district too. Level of access to the system within the hospital was commensurate with the levels of authorities of the policy actors. Whilst managers could access the full database, prescribers could only access their own data records.

Punitive measures

Punitive measures in relation to antibiotic stewardship were introduced during *The Campaign* in hand with the target approach along the line of accountability. Levels of antibiotic prescribing that exceeded the restrictive targets placed on the prescribing indicators specified by *The Campaign* (e.g. prescribing rates, consumption measured in DDD/100 bed-days) would result in the deduction of financial reimbursement in the performance assessment of the directors and non-clinical managers of the hospital by

the district government, and of manager-prescribers and junior prescribers by the hospital. Although manager-prescribers were line managers of their subordinate prescribers, they did not assess the prescribers directly; in fact, they had to take on responsibilities for their departments' performance as the hospital assessed their performance as manager-prescribers as well. As the assessments were points-based and negatively marked, failure to achieve prescribing targets would result in a deduction of points: for the hospital, a deduction in financing by the district government; for all the prescribers, a deduction in a performance-based bonus. However, it was difficult to gauge the extent of knowledge on the punitive measures possessed by the interviewees: non-clinical managers did not disclose how exactly points deduction correlated with a deduction on financial reimbursement, and manager-prescribers and prescribers claimed they did not have the details either. It was likely that manager-prescribers and prescribers were at least vaguely aware of how the system worked, as they suggested that the punitive measures were purely monetary in nature, and that they had never heard of any extreme punishments in other hospitals in these districts such as sacking of directors or prescribers as a result of failure to hit the administrative targets. But it would also make sense for these actors to be apprehensive about the system even if they did not fully know how the system functioned: having conspicuous punitive measures without giving away specifically how they translated into financial penalties would all but have made the system difficult to game. Consequently, manager-prescriber and prescribers reported that they were very cognizant of the possibility of getting fined for not hitting prescribing targets.

Redundancy

Redundancy in the form of overlapping monitoring and reporting mechanisms and multiple assessments on prescribing helped amplify the regulatory effect of *The Campaign*. Firstly, there were specific monitoring and reporting activities for *The Campaign*. Some manager-prescribers recalled that specific forms were used to report prescribing targets to the district government at the very end of the year, and that district officials elected to visit some of the hospitals to examine implementation activities. Non-clinical managers with the information explained that the hospital studied was too small to be selected for inspection, which was why it did not take place there. Secondly, there were routine monitoring and reporting activities on antibiotic prescribing outside *The Campaign*. The hospital reported to the district government

twice a year on the delivery and quality of healthcare, of which antibiotic prescribing was a part. In addition, since the data collection network across hospitals in the district went live at the beginning of *The Campaign*, the district had been able to access and review prescribing data in real time throughout the year, and issue cautionary messages to the hospital when necessary. Thirdly, prescribing in general was an important item in assessments outside the specialist *Campaign*. As described earlier, prescribing was an important aspect of delivery and quality of healthcare. It was also part of the assessment for the hospital's rating, which took place less regularly. Additionally, it was also reviewed by social health insurance payers to ensure that prescriptions conformed to insurance policies and regulations. These assessments had financial implications. In addition to the deduction in financial reimbursement by the district government described earlier, social health insurance payers could fine the hospital for breaching insurance regulations if their prescribing was judged to be inappropriate. The centralisation of administrative duties to medical affairs was recognised by manager-prescribers to be crucial in coordinating policies and minimising potential confusion and duplication, as was the introduction of computerised data collection systems in significantly enhancing the efficiency of information retrieval.

9.5 Perception of top-down implementation

In order to understand how top-down policy demands from the government were translated into actions, it is crucial first to explore perception of policy implementation from the perspectives of all the actors, especially the frontline implementers including the manager-prescribers and prescribers. This section will describe the perception of *The Campaign* by all managers and prescribers at the hospital, including its contents, priorities, limitations, temporality and reported impact on behaviour change.

Overall, *The Campaign* seemed to be well-communicated across all levels of actors along the line of accountability at the mediation by medical affairs. All managers and prescribers reported that municipal and district governments organised policy briefing meetings for managers from various hospitals especially from medical affairs, who could “download all the materials online and organise training sessions for all the prescribers at the hospital afterwards” (Non-clinical Manager M9) and then “talk through the materials with prescribers and explain what to be done” (Prescriber P1).

Although all the actors were able to recall the introduction of activities related to antibiotic stewardship during the period of *The Campaign* a few years ago, not all of them responded with strong familiarity to the concept of *The Campaign*. Consistent with their exposure to the policy and management aspects of healthcare, all managers regarded *The Campaign* as a managerial exercise which introduced stricter and more specific requirements in the prescribing of antibiotics. They very specifically associated *The Campaign* with targets on antibiotic prescribing. On the contrary, prescribers were much more cognizant of the required changes in clinical practice than the managerial details that were introduced in training. They were less acquainted with *The Campaign* as a policy concept, but they were very conscious about the new restrictions they faced in prescribing antibiotics:

“From the perspective of management, The Campaign was about targets on antibiotic prescribing: the rates of prescribing, those rates in different clinical settings, and so on. And then we told prescribers about how exactly prescribing practices needed to change.” (Non-clinical Manager M5)

“You keep mentioning ‘The Campaign’, but I don’t actually have a great idea about this concept. I’m a prescriber, I don’t study policies. There were meetings about the policies, but as an implementer I only learned about those through doing my job. Over time, I realised antibiotic prescribing was made less convenient by the new rules, and some antibiotics even became locked in the system—I couldn’t prescribe them anymore.” (Prescriber P5)

Regardless of how they perceived, and how they came to perceive *The Campaign*, all the actors understood that they had to change prescribing practices in respect of antibiotics. Whilst some managers and prescribers appreciated the rationale of *The Campaign* in *“doing good to the patients by giving them fewer drugs”* (Manager-prescriber M1) and *“preventing the emergence of antimicrobial resistance”* (Prescriber P5) more than others, they all accepted that *The Campaign* was *“an administrative order”* (Non-clinical Manager M9), and its implementation was *“an involuntary mission: the hospital had to go through the motions, and prescribers had no choice but to move along”* (Prescriber P2).

Summarising the accounts from all the actors, it was clear that not all the policies delineated by *The Campaign* were equally well implemented. Some policies were prioritised and implemented right from the start; others went through a more

staggered and phased process; still others were even less progressed in implementation due to limitations in resources.

Understandably, top-down elements were prioritised, and their implementation penetrated thoroughly across all levels of actors. To constrain the accessibility of advanced antibiotics that could significantly influence prescribing targets, the hospital quickly moved to introduce formulary restriction in accordance with the line of accountability, stripping the rights of junior prescribers to prescribe more advanced antibiotics without consultation with their line managers or someone of their professional grade. Minor revisions to the hospital's antibiotic formulary were made to comply with the government's requirement that no more than 35 types of antibiotics could be made available. By contrast, patient education, which was a bottom-up approach to improving prescribing, was introduced in a more spontaneous way as implementation of top-down elements progressed, as manager-prescribers and prescribers stepped up their efforts to explain to and persuade patients during clinical consultation. Other efforts to educate patients were passive, including distribution of leaflets and displaying of posters.

Policies related to the building of capacity and multidisciplinary collaboration across prescribers, pharmacists and microbiologists were gradually rolled out by the non-clinical managers throughout *The Campaign* as complementary measures, but progress was uneven. The hospital organised training sessions on clinical practice and antibiotic stewardship by experts from tertiary hospitals during *The Campaign*, and at the time of the study introduced new examinations and qualification requirements on rational antibiotic use. Clinical pharmacists were given an increasingly key role in analysing and reviewing prescriptions in support of the target approach, but their relevance in overall clinical practice was still peripheral. Microbiologists provided basic support in diagnosis, but the range and quality of tests remained limited. Managers admitted that as a secondary hospital, their limited financial and human resources contributed to "*weaknesses in clinical pharmacology and microbiology*" (Non-clinical Manager M5); most of the attention had been directed at prescribers, who were "*key to antibiotic prescribing in clinical practice*" (Manager-prescriber M1). This limitation of resources resulted in the lack of implementation of tasks related to building surveillance of antimicrobial resistance in view of the regional surveillance network, as the hospital was "*not qualified for it*" due to its "*small size and lack of advanced equipment compared with tertiary hospitals*" (Non-clinical Manager M5).

Reflecting on the overall implementation process and especially the prioritisation of the top-down elements, all actors concurred with the perception that implementation was noticeably patchy prior to *The Campaign*. They stressed that the most essential policies of *The Campaign* did not suddenly come into existence, and they were highly conscious of the strong policy continuity from before *The Campaign*. Manager-prescribers were aware that similar policies, indicators, targets and clinical guidelines were already in place in Shanghai nearly 15 years ago, but hospitals were not insisting on them at that time. Meanwhile, prescribers had been told not to use antibiotics for common cold, and not to prescribe antibiotics if there were alternatives from before *The Campaign*, and lack of substantial actions was down to the lack of financial punishment for not implementing them.

From that, the actors felt that *The Campaign* was less of a “*dramatic overhauling process that instantly turned black to white*” (Prescriber P5) than of a “*gradual process that took effect over the three years it encompassed, and beyond*” (Manager-prescriber M1) in changing prescribing practices. Through a high degree of standardisation and fine-tuning of existing policies and enforcement of implementation, the process aimed to “*normalise antibiotic stewardship*” (Non-clinical Manager M9) beyond *The Campaign*. Rather than seeing *The Campaign* as a standalone and defined stretch of time, all managers and prescribers regarded it as a timepoint that divided the preceding and succeeding periods, in which the more far-reaching changes that could not be promptly implemented within the strict timeframe of *The Campaign* (such as building a comprehensive electronic prescription system with a full set of indicators built in that enabled thorough monitoring and reviewing of prescriptions) continued to evolve and be introduced in the ensuing years:

“During The Campaign, clinical pharmacists didn’t review all our prescription records, but now they look at every single one with the help of the computerised system. Every single one!” (Manager-prescriber M6)

“The government is still monitoring our prescribing like it was. So is the hospital. Personally, I feel that we’re even more closely watched on prescribing than the past. It’s not like rules are relaxed again after The Campaign was over, it’s not like that at all.” (Prescriber P1)

The implementation of the top-down policies experienced by all the actors at the hospital had led to changes in antibiotic prescribing behaviours. Firstly, prescribers

were more reluctant to prescribe antibiotics. Both manager-prescribers and prescribers saw themselves as *“gatekeepers to antibiotics”* (Manager-prescriber M1), who now *“proactively try to find ways not to prescribe antibiotics”* (Prescriber P4). The way that prescribers interacted with patients had also become more proactive and educational. They recognised that the most direct and effective way to educate patients about antibiotic use was through examples that came up during clinical consultations. Through explaining to patients *“how common cold progresses from viral to bacterial infections, and why antibiotics aren’t useful in the first stage”* (Prescriber P1) and why *“antibiotics can have harmful bad effects”* (Manager-prescriber M2), prescribers actively attempted to dissuade patients from demanding antibiotics, or at least delay prescribing.

Secondly, prescribers became more judicious in ensuring that their prescribing practices strictly followed existing recommendations, instructions and national treatment guidelines:

“I prescribed antibiotics on an empiric basis in the past. For instance, there’s an antibiotic that I used to administer once per day, in its full dosage. But we were then told to follow the recommended dosage schedule closely by the hospital. To comply with the rules, I’m administering the antibiotics thrice per day in smaller dosages.” (Manager-prescriber M1)

“Regulations on prophylactic use of antibiotics became so much more stringent. One of the biggest changes is the duration of administration. We used to administer antibiotics for patients with partially contaminated wounds for a good few days after their surgeries, but now we have to stop at 48 hours after surgeries.” (Prescriber P4)

One of the most prominent changes after *The Campaign* was that antibiotics can no longer be prescribed without sufficient indications. Whereas antibiotics were commonly prescribed to patients who had a fever in the past, prescribers must use blood test to examine indicators for bacterial infections such as levels of neutrophils and C-reactive protein, and observe other clinical presentations such as coughing and colour of sputum to distinguish between viral and bacterial infections before deciding whether antibiotics were needed post-*Campaign*.

9.6 Interaction between contextual factors and policy implementation in generating behaviour change from a bottom-up perspective

Even though the reported behavioural changes highlighted by the actors were consistent with the intentions and requirements of the implementation of well-communicated top-down policies, questions surrounding how the policies were implemented in practice, and how such behavioural changes were brought about by the policies remained. Any viable mechanism of change would have to be compatible with the actors' varied perspectives on *The Campaign*, the priorities and constraints for the implementation process and the temporal continuity of the policies. As outlined in Chapter 2 (Theoretical Background), the bottom-up approach to understanding implementation recognises that policy implementation and the problems therein occur through the interaction between the central-led *Campaign* and settings of the local hospital (Berman, 1978); top-down implementation of *The Campaign* at the hospital studied was therefore subjected to the influence of system-, organisation- and individual level contextual factors pertinent to the local context, and the interactions between *The Campaign* and these contextual factors were crucial to shaping and creating the necessary change in prescribing behaviour for policy implementation. This interaction went both ways: as the local context deflected *The Campaign* from its intended direction and imposed constraints, *The Campaign* in turn directly addressed some of these contextual factors and created better conditions for top-down implementation.

This section will demonstrate how behavioural change was engendered by the interaction between the actors' responses to the complexities and nuances pertinent to contextual factors and the top-down implementation activities associated with *The Campaign*. Drawing on the interviews, the influence of the contextual factors at system (perceivable differences in policy context), organisational (financial incentives to prescribe; relationship between manager-prescribers and prescribers; availability and selection of antibiotics; diagnostic technology; clinical needs in different specialisations) and individual levels (patients' expectations and demands; prescribers' knowledge and experience) on antibiotic prescribing will be described and discussed along with the relevant *Campaign* policies that most directly addressed or impacted on these factors. Each subsection will discuss one of the contextual factors described above and

examine the combinatorial impact of the contextual factor and implementation of the *Campaign* policies on behaviour change, unravelling the mechanisms of change.

System level factor: perceivable differences in policy context in respect of regions and levels of healthcare

All actors noted two conspicuous types of difference in the policy context of *The Campaign*: across regions, and across various tiers of hospitals. Both types of differences were present during policy implementation, and implementation of *The Campaign* in fact consciously reinforced policy differences across hospital tiers. This led to disparate experience of healthcare service provision for patients and difficulties in congruently upholding stewardship policies for prescribers.

In terms of geography, both the manager-prescribers and the prescribers consistently felt that antibiotic stewardship policies were much better implemented in Shanghai than in other provinces based on their personal experience and exchanges with colleagues in other regions; some even felt that there were district-level differences within Shanghai. For example, whereas antibiotics were readily available in retail pharmacies in other provinces, they could not be purchased without prescriptions in Shanghai, where strict regulations of antibiotic use “*goes back a long way, even before The Campaign took place*” (Prescriber P7). One of the reasons why Shanghai was subjected to “*great scrutiny*” in antibiotic stewardship was the city’s early adoption of electronic management platforms in hospitals, which enabled better surveillance of antibiotic use (Manager-prescriber M8).

In terms of hospital tiers, managers and prescribers were sufficiently aware of the key differences in stewardship policies between secondary and tertiary hospitals. Non-clinical managers pointed out that in addition to being permitted to have a bigger antibiotic formulary (50 types of antibiotics for a tertiary hospital versus 35 for a secondary hospital), tertiary hospitals reserved some of the most restricted and advanced antibiotics, which were not accessible to secondary hospitals. Manager-prescribers, and to some extent, a few prescribers, understood the intention behind the policy arrangement: whilst tertiary hospitals were “*more likely to encounter highly resistant bacterial infections*” and “*more equipped to managing use advanced agents*”, secondary hospitals such as the hospital studied “*served mostly patients from the community*” and managed “*not much more than minor illnesses and chronic diseases*”

(Non-clinical Manager M9). In this sense, manager-prescribers and prescribers felt that the 35 types of antibiotics were sufficient to address most, if not all, the cases they received. However, there were patient exchanges between secondary and tertiary hospitals through patients' self-referrals in China's ungated healthcare system, and through "increasing collaborations between tertiary and secondary hospitals set up by the district government to improve service quality in secondary hospitals" (Manager-prescriber M4).

Implementation of *The Campaign* had a mixed effect on the differences in policy context: it reduced regional differences on the one hand and increased differences across the tiers of hospitals on the other. Non-clinical managers felt that regional differences became lessened, as provinces outside Shanghai were brought up to speed in implementing regulatory measures during *The Campaign*, creating an "equalising effect" (Non-clinical Manager M3) on the progress of antibiotic stewardship across the country. Nevertheless, *The Campaign* exacerbated the policy differences across secondary and tertiary hospitals at the same time, which led to difficulties in managing patient expectations. On the one hand, having experienced variation of prescribing practices at tertiary hospitals as a result of the tier-specific policies on antibiotic formulary, patients could find the limited range of antibiotics available at the hospital studied "disappointing and frustrating" (Non-clinical Manager M9), leading to complaints. On the other hand, patients transferred from tertiary hospitals often failed to respond to antibiotic treatment at the hospital studied due to their previous exposure to more advanced antibiotic treatments prior to the transfer.

Organisation level factor: financial incentives to prescribe

As explained in Chapter 4 (Healthcare System Background), financial incentives at the institutional (hospitals receiving financial benefits from pharmaceutical companies) and individual levels (prescribers receiving financial benefits from pharmaceutical companies) had been a major factor in driving prescribing in general in China. In the meantime, social insurance reforms also stimulated demand for healthcare, leading to increasing prescribing. Actions were therefore taken by the government and the hospital to rectify financial incentives to prescribe, aiding the implementation of *The Campaign*.

According to the non-clinical managers, pharmaceutical sales were one of the main sources of financing for the hospital studied during *The Campaign*, which was typical with secondary and tertiary hospitals in general. They also recognised the fact that the system existing at the time of *The Campaign* could encourage hospitals and prescribers to benefit financially from prescribing. Some of them described their previous observations about corrupt practices in hospitals in other provinces; but none of them recognised this to be a problem at the hospital studied. Although the overall reticence of the interviewees on this issue made it difficult to ascertain the extent to which the potential financial incentives influenced prescribing during *The Campaign*, it was clear that the continuous financial reforms that took place in the ensuing years of *The Campaign* were gradually removing the financial incentives to prescribe at the hospital level, creating an environment that enabled sustainable policy action on antibiotic stewardship after *The Campaign*. Introduction of zero-mark-up on all drugs and a global budget that would reduce the link between the hospital's revenue from the funding allocation would eventually lead to increasing reliance on performance-based funding allocated by the district government.

During *The Campaign*, when these financing reforms were not yet in place, three levels of top-down financial disincentives were employed strongly to discourage and reverse incentives to prescribe. On the first level, *The Campaign* as an integral part of the performance assessment by the government in the area of overall healthcare quality and expenditure included restrictions on the proportion of expenditure on antibiotics in total pharmaceutical expenditure, and how well *The Campaign* was implemented directly affected the size of funding from the government. Cost-control was such a potent criterion that restricted prescribing that prescribers felt their preferences for using cheaper generics where possible and avoiding using expensive branded antibiotics were effectively "*shaped and guided by the regulations*" (Manager-prescriber M8). On the second and third level, assessment of policy implementation by the district government was directly linked to the income of the hospital directors and of all prescribers (including manager-prescribers), respectively, so that "*everyone's pay was linked to The Campaign and its related assessments*" (Prescriber P1).

Furthermore, social health insurance imposed further restrictions on prescribing. Payment through social health insurance was substantial and it amounted to at least half of the total payments received by the hospital from the patients. Social

insurance payers imposed extra cost control parallel to that from the government. If a hospital was judged to be overspending on prescriptions, the hospital and its staff could face financial penalties in addition to not getting the commensurate reimbursement from the payer. Therefore, where antibiotics were necessary, prescribers favoured cheaper antibiotics and shorter treatment schedules where possible.

Consequently, all the prescribers were very conscious of the disincentives produced by the measures described above and were cautious about when and what to prescribe no matter a patient's insurance status. Prescribers with experience at tertiary hospitals felt that their hands were tied even more at the hospital studied, as tertiary hospitals were notably more relaxed with prescribing despite these restrictions, especially for uninsured patients. Some prescribers argued from their experience that this had to do with the fact that tertiary hospitals had more room for manoeuvre because of their large patient volume, greater case severity and much more diversified revenue sources; by contrast, small secondary hospitals like the hospital studied had a small patient base and could not afford financial penalties.

Organisation level factor: relationship between manager-prescribers and prescribers

Prescribers did not have the same level of clinical autonomy; which was commensurate to their position within the hierarchy of authority within the hospital, subordinate to non-clinical managers and manager-prescribers in the levels above. Further formalised by the line of command and accountability for antibiotic stewardship described earlier in the chapter, this hierarchy was reinforced by some of the top-down measures, most notably formulary restriction. Therefore, manager-prescribers had leading roles in steering behaviour change in junior prescribers.

As line-managers of the clinical departments, manager-prescribers had a close working relationship with their subordinate prescribers. The responses from the prescribers were sometimes similar to those from their line managers; often it was the case that the manager-prescribers were more outspoken than the prescribers, more willing to critique and engage in in-depth discussion. Power dynamics were likely to be at play; junior prescribers were less secure in status and could fear the repercussions of what they discussed. In the context of this research, it was difficult to determine and establish whether the prescribers were in genuine agreement with their superiors.

Manager-prescribers were supervisors of prescribers from an administrative point of view, and mentors from a professional development point of view. Prescribers were directly accountable to their line managers, and at the same time they were subjected to supervision by other senior manager-prescribers in their rotation across various work settings. Manager-prescribers could access and monitor prescribing records of all levels of prescribers, which enabled them to track the performance of prescribers in their departments in real time. They also attended monthly managerial meetings organised by Medical Affairs, where any potential problems in prescribing were discussed. Prescribers could only access their own records and were passively monitored; they were not eligible to attend managerial meetings, and feedback was delivered to them by their managers. Besides manager-prescribers, there were other senior supervisors responsible for overseeing all the treatment decisions within certain wards or for specific patient cases. As prescribers rotated their roles across various settings, they were required to report to the supervisors in charge of those settings and follow their strategies for patient management. However, manager-prescribers were more than just supervisors: they were effectively their mentors, whose practices they closely shadowed and imitated. Both manager-prescribers and prescribers acknowledged this influence and felt senior prescribers passing on their experience to junior ones was an indispensable part of how *“the trade was learned”* (Manager-prescriber M1, Prescriber P5). With antibiotic prescribing this was especially essential: as clinical indicators were often insufficient to fully support prescribing decisions, prescribers were often required to prescribe based on their experience.

The Campaign further rigidified this hierarchical structure. Managerial supervision became more intensified after the introduction of prescribing targets, and the authority of the manager-prescribers was reinforced after the introduction of IT-enabled formulary restriction, where authority to prescribe in the electronic system was linked to the seniority of the profession. Junior prescribers had even less scope for decision making, and they were increasingly reliant on the input and clearance from manager-prescribers in prescribing decisions. Power dynamics were still an important factor at play: whilst most prescribers did not discuss how they felt about the apparent hierarchical structure within the hospital, one prescriber noted that *“unless one wanted to lose their job, acting against the superior and the hospital was out of the question”* (Prescriber P2), and another confessed that *“prescribers perhaps have their own takes on things, but will never discuss disagreements openly”* (Prescriber P3).

Organisation level factor: diagnostic uncertainty

Due to limitations in existing diagnostic technology available at the hospital studied, prescribers very often relied more on their experience than clinical indications to prescribe antibiotics. As resource constraints limited the extent to which the hospitals could develop microbiological and diagnostic capabilities within the timeframe of *The Campaign* and beyond, lack of improvement in the reduction of diagnostic uncertainty proved to be a sticking point for prescribers in making prescribing decisions.

Diagnostic criteria for bacterial infections in the outpatient setting were based around results from blood tests, with key indications being rising levels of white blood cells, neutrophils and C-reactive proteins. Whilst some of the prescribers described how the use of these tests could clearly distinguish bacterial infections from viral ones, others recognised that they were useful but not definitive indicators for bacterial infections, at the end of the day empiric treatments are a norm. In this sense, rather than provide clear guidance to indicate antibiotic use, the use of blood tests – which only became a strict pre-requisite for antibiotic prescribing at the hospital after *The Campaign* – was more of a justification for delaying prescribing, as they showed patients why they were not given antibiotics despite their discomfort and symptoms. Prescribers claimed that these were common standards used across all levels of hospitals in the country for outpatients.

In the inpatient settings, microbiological specimens were sometime taken from inpatients for further culturing and investigation, which could provide prescribers with more information about the bacterial species concerned, and whether they were resistant to certain antibiotics. Prescribers complained – and manager-prescribers agreed – that this process took too long for meaningful results to be available in time to guide timely initial diagnosis and treatment: the process took 5 to 7 days after patients were admitted and specimens cultured. Therefore, prescribers again had to rely on empiric therapy, as there was “*no way for prescribers to delay and then act on that information in the first instance, as the patient’s infection may quickly aggravate without medication*” (Manager-prescriber M7), and “*results from the culture only served to inform revisions to later treatments*” (Prescriber P7). Again, prescribers felt the delay from doing bacterial cultures was common to “*many if not all hospitals in the country*” (Prescriber P6).

Although *The Campaign* expected both secondary and tertiary hospitals to improve the rate of microbiological culture-based diagnosis in inpatients and contribute to the expanding surveillance network of antibiotic resistance, non-clinical managers in the hospital were frank in acknowledging that they did not have the resources for some of those tasks as the hospital was small in size, and that the hospital was taking only *“limited initial steps”*, and *“had a certain level of insufficiency”* (non-clinical manager M5) in completing the tasks related to microbiology and surveillance in *The Campaign*.

As *The Campaign* did not necessarily lead to a change in the limited diagnostic technology and resources available in the country, prescribing behaviours at the even more resource-limited secondary hospital studied did not become more informed by diagnostic tests compared to before *The Campaign*. In the outpatient setting, prescribers frequently encountered situations where they were sitting on the fence about antibiotic prescribing. In these scenarios, patients presented relatively notable symptoms but limited indications from blood tests. Based on these indications, prescribers were not allowed to prescribe antibiotics, but the diagnostic uncertainties and the need to ensure patient satisfaction made it difficult for prescribers to decide whether to prescribe. Many prescribers recalled outpatient cases where the strategy of delaying prescribing based on clinical indications often prolonged patients' symptoms and ended in multiple visits by the patients and eventual antibiotic prescribing, at which point *“patients could blame prescribers for not prescribing in the first instance”* (Prescriber P5). Some prescribers suspected that blood indicators could be *“suppressed by widespread self-medication, which could mask patients' symptoms and complicating the diagnosis”* (Manager-prescriber M1). In the inpatient setting, prescribers described choosing initial empiric therapy before microbiological evidence was made available as *“an educated guess and an exercise of trial and error”* (Manager-prescriber M7). Despite the test results potentially showing a variety of results, they had to go ahead and attempt to control the infection as quickly as possible or risk worsening the infection at the patient's peril.

Organisation level factor: demands for antibiotic use in different settings and specialisations

Patient mix and the nature of clinical conditions determined the demands for antibiotic use and, consequently, the patterns of prescribing in different clinical

specialisations and settings, giving rise to highly heterogenous contexts of use and stewardship cases for antibiotics. Where antibiotic use was higher, the pressure to reduce and rationalise use was greater, and at the same time implementation of antibiotic stewardship – especially complying with prescribing targets – became more difficult. Despite providing some crude consideration for clinical settings by setting different targets for outpatient, inpatient and emergency settings, *The Campaign* as a policy by design largely presented itself as a one-size-fits-all solution, at least on paper. In contrast, how prescribing targets were operationalised across clinical settings and specialisations within a hospital proved to be anything but straightforward, and the resultant clinical and managerial complexities required the establishment of mutual understanding and coordination amongst managerial actors.

All managers and prescribers agreed that much antibiotic use was concentrated in the department of respiratory medicine. A great proportion of patients in the area came to the hospital for respiratory-related complaints, many of whom were aged residents with chronic obstructive pulmonary disorders and respiratory infections were a frequent and major concern; antibiotic use was thus indispensable. Similarly, paediatrics also had high level of antibiotic use, as paediatric patients had a narrow spectrum of disease mainly focused in respiratory problems. Significant antibiotic use also took place in departments that performed surgical procedures, including the departments of surgery, orthopaedics and obstetrics and gynaecology. The specific use case in these departments depended on the nature of the procedure and the level of contamination to the wounds concerned. Policy implementation benefited from the formalisation of clinical pathways that took place after *The Campaign*, which further stratified patients and patterns of antibiotic use. As described in Section 8.3, patients with minor health problems could visit any prescriber from a generic “general internal medicine” grouping that included prescribers from various specialisations before 2015, spanning the full duration of *The Campaign*. Common cold patients “could end up seeing an endocrinologist and could obtain antibiotics from any prescriber”. The more “leaky” clinical pathways, which enabled patients to see prescribers from a variety of clinical departments, in a way helped to dissipate pressure to prescribe from departments where antibiotic use was high (mainly respiratory medicine) to those where antibiotic use was low (such as cardiology and endocrinology). However, since clinical pathways became formalised in 2015, patients were “allocated to visit specialisations appropriate to their conditions by nurses at the reception”, as many patients had respiratory problems, this led to antibiotic use becoming “even more

concentrated in respiratory medicine” whilst *“negligible in some other departments”* (Non-clinical manager M3).

In terms of clinical settings, all managers and prescribers claimed that most antibiotics were consumed in inpatient wards, where patients were significantly sicker and had more severe infections. For example, several manager-prescribers estimated that close to 90% of inpatients referred to the Department of Respiratory Medicine required some form of antibiotic treatment. Accordingly, the most advanced and the more expensive antibiotics were reserved for inpatient use only and were not available at outpatient clinics. The A&E section was somewhere in between inpatient and outpatient settings in terms of antibiotic use. Although initial antibiotic treatments might be required to address the urgency and severity of symptoms in the visiting patients, the makeshift A&E section was not responsible for further disease management, and patients who required further treatment would have to be admitted to inpatient wards.

There were significant challenges to implementing stewardship policies in all these settings. For the outpatient setting and, to a lesser degree, the A&E section, patients *“had a major and active role in shaping the consultation process that is not within a prescriber’s control”*, making it very difficult for prescribers to achieve outpatient prescribing targets even though the limited choice of antibiotics was *“straightforward and easy to manage”* (Manager-prescriber M1). For the inpatient setting, prescribers, especially senior prescribers, were *“in control of antibiotic use”* and patients *“were happy to follow orders due to the complexity of the situation”* (Prescriber P4), and determining the appropriate types of antibiotics to use and dosage schedules were the main challenges.

As described in Chapter 5 (National Policy Context), *The Campaign* recognised the necessary variability of antibiotic prescribing across clinical settings in drawing up targets for prescribing rates and consumption for different clinical settings, but only to a limited extent. Consistent with the content of the policy documents, non-clinical managers described that target prescribing rates for outpatient, A&E and inpatient settings during *The Campaign* were 20%, 40% and 60% respectively. They remarked that these targets, along with other targets in inpatient antibiotic consumption and surgical antibiotic use, formed *“a strict redline”* (Manager-prescriber M1) that the hospital as a whole must not cross. As described in Section 8.4, these targets – as the core parts of the top-down measures – were monitored by the district government and assessed at the end of each year; failure to stay below the target levels would result in

financial penalties for the hospital. However, *The Campaign* did not specify exactly how the targets were to be implemented. How the targets were broken down and allocated to various clinical departments – the tangible units of administrative accountability – was up to the senior non-clinical managers at the hospital. Manager-prescribers and prescribers were all aware of the fact that medical affairs was responsible for coordinating, determining and allocating department-specific target levels appropriate to their demands for antibiotic use, so that hospital as a whole could “*even them out between the quotas*” and “*stay below the overall red line set out by the government*” (Manager-prescriber M2). To exemplify this, whereas the target levels on outpatient prescribing rate were as high as 70% for heavy users of antibiotics like respiratory medicines and paediatrics, they were as low as 5% for infrequent users such as orthopaedics.

These department-specific targets were said to be flexible and were subjected to change over time. In the first instance, medical affairs continuously evaluated and revised these targets based on each department’s patient volume, service provision, case mix and demands for antibiotic use. Most importantly, manager-prescribers had an active role to play in proactively negotiating for larger target levels in contingencies where they were likely to exceed the target levels:

“If manager-prescribers are going to go over the targets they’ll tell medical affairs about it well in advance. Medical affairs then needs to investigate and discuss with the antibiotic stewardship group, including the director of the hospital, about whether possible revision of targets for that department in this instance can be justified, whether there’s room for downward adjustment in other departments, and whether the hospital as a whole can clear the targets at the end of the year.” (Non-clinical Manager M9)

“Orthopaedics were well below their targets in the past, and their cases mostly had clean wounds and they were not too busy. But recently they started to work with a large hospital, which transferred a large volume of patients that had complex and dirty wounds to their department. Now that they don’t have as much time to disinfect the operating theatre between cases and are dealing with contaminated wounds, they have to use more antibiotics during surgery and, as a result, requires relaxation of their original targets.” (Prescriber P7)

Therefore, to keep the overall target level constant, target revision for one department inevitably involved reallocations for other departments at the same time. In this sense, the centralised role of medical affairs in the chain of command above all other clinical departments made it an effective coordination and communication mechanism to avoid possible inter-departmental frictions. Even though manager-prescribers would be well-aware of levels of antibiotic prescribing and consumption in other departments due to their attendance of month managerial meetings, they all communicated their positions and opinions to medical affairs rather than to each other:

“It’s about balancing each department’s target and make sure everyone can do their jobs. Medical affairs knows where the extra room can be made, and where there’s no scope for the slightest changes.” (Non-clinical Manager M9)

“Obviously every head of department has a tough job to do and feels there’s little we’re willing to give to help out other departments, and no one wants to make others’ jobs more difficult, knowing that our targets are already not easy to work with. But then sometimes the only way forward is to get a share from others, and others are not necessarily happy to give up their share. So the only way is to let medical affairs know; they rank above us and they can coordinate.” (Manager-prescriber M7)

Although the pressure to negotiate for revision of targets might well have stemmed from the potential financial punishment for failure to achieve existing ones, it remained unclear whether the points-based system of performance assessment on antibiotic stewardship was deployed continuously by the hospital, so that any breach of the departmental targets could incur penalties, even if these breaches were internal to the hospital and came before the year-end assessment by the government. Interestingly, both the manager-prescribers and prescribers had differing accounts about their experience with financial punishments, with some claiming that the penalties were strictly enforced, whilst others unsure whether and how it took place. This could imply a certain level of discretion from the hospital (to manager-prescribers) and from the manager-prescribers (to prescribers). What they had strongly in common was their understanding of what would be deemed as *“reasonable and acceptable prescribing practices”* (Prescriber P5) from the perspective of a medical professional, and recognition of the importance to adhere to this understanding in prescribing and do what they thought to be *“the right thing to do for the patients”* (Prescriber P1) regardless of the target requirements:

“Prescribers in our department are all on the same page: we all know sometimes how difficult it is to decide whether or not to prescribe. As a head of department, I’m more than sympathetic to my colleagues. As long as they fully explain their medical rationale for why they had to prescribe when the indications are not necessarily clear, then I’ll go along with that, because I know I’d probably do the same in their shoes.” (Manager-prescriber M1)

“If we go over the targets the hospital may well fine us. But what do we do — we’ve got to use antibiotics when the patients really need it. We want patients to get better.” (Manager-prescriber M8)

“Our head of department never really fines us. Maybe there’ll be a word or two, but if our diagnosis and explanation make sense then they’ll say it’s fine; when it comes to flu season everyone is a bit over. After all we’re not here not to prescribe; we’re here to treat patients.” (Prescriber P1)

...And what would be deemed as unacceptable:

“We do try our best to stay below the targets. Our prescribing rates fluctuate around the targets, but we’re never too far. But if the target rate is say, 10%, and a department comes up with 50%, then no one would accept that, that would be highly irrational prescribing.” (Prescriber P5)

In summary, the clinical demand for antibiotics in a clinical department remained the biggest factor that influenced whether antibiotic prescribing could be kept below target levels but going over the target did not necessarily indicate irrational prescribing behaviour per se, as manager-prescribers and prescribers already shared a heightened awareness of the targets and consensus around rational antibiotic use. At a departmental level, effective policy implementation was made possible by the crucial coordination by the Medical Affairs, which ensured that implementation process duly reflected prescribers’ common understanding and allowed flexibility in antibiotic use out of clinical consideration.

Individual level factor: prescribers’ knowledge and experience

Crucial as the system- and organisation-level factors were, the most immediate factors that influenced prescribing behaviours were individual level factors. For manager-prescribers and prescribers at the hospital, deficiencies in knowledge and established patterns in practice were in the way of behaviour change, hindering policy

implementation. Some of the policies in *The Campaign* attempted to improve knowledge and experience of prescribers, and as top-down policies initiated by the senior management of the hospital, they were implemented to good effect.

Manager-prescribers and prescribers admitted that their patterns in prescribing behaviours were largely shaped by entrenched personal preferences that every prescriber developed over their career. Examples of its manifestations include a tendency to prescribe a certain type of drug more than others, or a preferred approach to managing a condition. As explained in a previous section, these preferences were reinforced by the reliance on empiric therapy in the absence of diagnostic certainties, and they were easily passed on to junior prescribers in their apprenticeship with senior manager-prescribers. Crucially, knowledge also played a key role in shaping prescribing behaviours; filling the knowledge gaps in antibiotic prescribing was seen to be essential in changing the personal preferences of prescribers by non-clinical managers.

To ensure implementation of the target-driven antibiotic stewardship policies, *The Campaign* also introduced measures to monitor and rectify prescribing behaviours and to create the necessary behaviour change. A comprehensive review of prescription records was conducted by pharmaceutical affairs, who were also tasked with monitoring inpatients along with prescribers and providing advice on case management since *The Campaign*. The less frequent, but far more detailed, patient history review, which permitted much closer scrutinization of prescribing behaviours, was conducted by Medical Affairs to “*reveal every detail about antibiotic use especially during surgery*” and “*identify where improvements could be made over the prescribing process and inform prescribers what specifically they could do differently*”, complementing prescribing reviews by “*revealing specific behaviour change required*” (Non-clinical manager M9). It created “*huge pressure for prescribers to be more careful with prescribing*” (Prescriber P6).

Plenty of training by health officials and experts from large tertiary hospitals was organised by medical affairs for prescribers. Whereas training tended to focus on theoretical and practical knowledge about antibiotic prescribing prior to *The Campaign*, more sessions were devoted to explaining behaviour change in relation to *The Campaign* and prescribing targets after its commencement. Examinations were introduced after *The Campaign* ended as a means to assess and maintain prescribers’ qualifications and authority to prescribe antibiotics. However, knowledge alone was

insufficient to drive behaviour change, as prescribers and especially patients were most concerned about treatment results. Therefore, illustrating the impact of the stewardship policies being proposed through data and evidence became crucial. In this case, evidence and prescribing behaviour formed a positive feedback loop that reinforced behaviour change: better adherence to guidelines was understood by manager-prescribers and prescribers from all the specialisations as good practice, because the guidelines were “*standardised and evidence-based and supported by national statistics and data*” (Prescriber P7). In the meantime, the hospital’s own data during *The Campaign* reassured prescribers of their fear of lack of effectiveness in infection control and patient dissatisfaction:

“We all know the theories, but it’s all about the data showing whether it works. At the beginning everyone was apprehensive about not using antibiotics, but we had to do it because the policies were to be obeyed. When the data showed that using fewer antibiotics didn’t impact on key outcome indicators such as duration of hospital stay, duration of symptoms, rate of infection or complications, prescribers became confident and nothing more needed to be said. Prescribers accept and embrace the concept of antibiotic stewardship willingly.” (Manager-prescriber M6)

“Patients only want to see effective treatment outcomes. They don’t actually care about what or how much antibiotics they’re given. If the treatment plans can ensure that pains and infections go away as we expect, then prescribers’ authority remain intact and patients are happy. Plus its great for their health because they’re exposed to fewer antibiotics.” (Prescriber P7)

Individual level factor: patients’ expectations and demands

As patient-facing service providers, one of the biggest challenges for prescribers was juggling between policy requirements, work pressure and patients’ expectations and demands. As highlighted earlier in the discussion of the impact of differences in policy context on patients’ reception of differential treatment, patients’ expectations and demands were difficult to manage; however, this was not something that *The Campaign* sympathised with, and prescribers often had to find ways to cope with pressure from patients, which was reported to be sometimes extreme. Importantly though, the nationwide implementation of *The Campaign* helped diffuse the tension

between prescribers and patients by establishing formal rules for antibiotic stewardship that prescribers could defer to. On top of that, greater attention to patient education through mass media and clinical consultation helped to create new social norms.

Prescribers observed that older patients, parents and migrant workers tended to be more adamant in insisting on antibiotic treatments and their opinions were often less malleable. Their expectation of antibiotics stemmed from their understanding about antibiotics being anti-inflammatories that were effective against common cold, and they came up with an expectation of getting antibiotics to improve their symptoms. The younger generation, however, were perceived to be better educated and had adequate exposure to science through internet and social media, and hence were much better versed in rational antibiotic use and antibiotic resistance.

In the outpatient setting, where patients were an active part of the consultation process, tensions between prescribers and patients were said to frequently arise during *The Campaign* as a result of patients' expectation for antibiotics not being met:

"Parents and grandparents are highly protective of their kids, and if they don't see instant improvement in their kids' conditions and the prescriber still refuses to use antibiotics, they would gang up on the prescriber to demand it. It's too much pressure on the prescriber." (Non-clinical Manager M3)

"Once there was a patient who came here and demanded antibiotics. We said we couldn't prescribe them. He then said, I won't leave without antibiotics. In the end the impasse lasted for hours; we kept telling him we couldn't prescribe antibiotics, and he just sat there protesting." (Manager-prescriber M8)

To appease the patients, the prescribers were more willing to prescribe antibiotics than educating patients before *The Campaign* due to their very high work load and the limited time they had for each patient:

"In the past, prescribers would try to be efficient and keep everyone happy by prescribing antibiotics; patients were happy to get what they wanted, and prescribers themselves were happy as they could then move on to the next 1000 things. A prescriber sees about 60 patients a day in outpatient clinics and up to 120 patients a day if they're on A&E rotation. There's little time to communicate with patients more." (Manager-prescriber M1)

This tension also led to defensive prescribing in surgical departments, where it was the most intense. This was due to patients associating perceived lack of antibiotic use with a prescriber's negligence in cases of post-operative infections:

"Before The Campaign I'd say overuse of antibiotics in surgeries was normal. Surgeons especially were really worried about post-operative infections and the potential attacks from patients because of that: we've already seen critical incidents where knife-wielding, gasoline-soaked patients threatened and nearly managed to cause prescribers substantial bodily harm." (Manager-prescriber M7)

In this sense, manager-prescribers and prescribers felt that *The Campaign* helped dissipate the tension by introducing education at the societal level and initiating widespread implementation of antibiotic stewardship that formalised and equalised prescribing practices. Mass media education about antibiotic use and antibiotic resistance became prevalent, which significantly helped buttressing the hospital's own messaging through patient seminars and health posters and shifted the public's perception of antibiotic use at a fundamental level. Extensive implementation reduced overall differences in policy context, so that when *"patients found out they weren't getting antibiotics easily from anywhere and were asked by every prescriber to take a blood test instead, they realised this was the new norm and gradually came to accept it"* (Manager-prescriber M10). This led to prescribers being more proactive and successful at educating patients during clinical consultation, as patients were more willing to listen to prescribers during *The Campaign*. However, patient demand occasionally was *"too ingrained"* and prescribers felt they had little choice but to satisfy their requests. More importantly, stronger emphasis from the government and the hospital on guideline adherence, exemplified by multiple instances where the hospital *"supported prescribers' decisions of not to prescribe antibiotics and argued for prescribers when patients sought explanation from senior management"* (Manager-prescriber M7) encouraged prescribers to see stewardship practices and rational prescribing as a new form of defensive medicine:

"True, these policies and rules are very constraining for the prescriber, but then it's also about managing risk. We prescribers need to protect ourselves. if a patient is saying no to something I propose, I'd ask them to sign their refusal." (Manager-prescriber M6)

“If extensive post-operative infections occurred under these new guidelines, then we would simply report them and not worry about them like before. We’re now doing everything by the book and all the records are here. If patients were to sue us, we have sufficient evidence to show we’re simply doing our job as told by the rules and committed no wrongdoings.” (Prescriber P7)

“All the tests that we run, all the detailed electronic records that we spend a lot of time to write is worthwhile: all of these are our best protection against potential litigation.” (Prescriber P5)

The desire to obtain antibiotics on the part of the patient and the prescriber-patient tension reported by prescribers above did not come through in the patient interviews, which were conducted in the outpatient waiting areas after patients were approached and recruited on the day of fieldwork. Overall, the 11 patients interviewed were not particularly engaged with the interviewer. Within this patient sample, there seemed to be a stark disconnect between the common cold tracer and a patient’s reported use of antibiotics. None of the patients felt that it was necessary to go to a hospital because of common cold unless they were subjected to persistent and notably severe symptoms, and none of them reported antibiotic use for mild common cold, with over-the-counter symptomatic medications being their first choice.

This reluctance to visit hospitals for minor diseases was in part due to patients being put off by what they perceived to be *“protracted diagnostic procedures”* before getting treatments if they did choose to go to a hospital, which they deemed to be *“unnecessary”*, *“bothersome”* and *“costing extra money”*. Some patients observed increasing use of more diagnostic tests in hospitals in Shanghai. Whereas in the past prescribers would *“prescribe even if we were not that ill”*, now they instead *“order patients to do blood tests for minor things like common cold and won’t prescribe without test results”*. The contrast in practice between Shanghai and other provinces were stark according to patients from outside Shanghai, where the consultation process for common cold was *“straightforward, where prescribers look at the symptoms and proceed to prescribing”*. Aside from the need to obtain molecular evidence from blood tests, some patients felt that prescribers increasingly *“do things by the book and get a trail of evidence to protect themselves”* as they were *“afraid of getting sued by patients”*. This increase in use of diagnostic blood tests accompanied a decrease in antibiotic prescribing, according to 5 of the patients. In their experience, prescribers in Shanghai were *“much less ready to prescribe antibiotics than before”*.

Most patients did not expand on the reason why that was so, with only one patient suggesting that prescribers' hands were *"tied by the social insurance regulators, so that they in turn restrict provision of pharmaceuticals to patients"*.

Patients had limited understanding about antibiotics, but at the same time they were clearly aware of the negative impact of antibiotic use. When pressed about antibiotic use, all patients responded that there was no need to take antibiotics unless one had *"serious and unbearable discomfort"*, which did not include *"self-limiting diseases like common cold"*, or at least when its symptoms were mild. However, their understanding about antibiotics notably varied, and some was highly questionable. Although all patients claimed to know of antibiotics as a class of pharmaceuticals, 5 out of 11 patients said they did not know anything antibiotics apart from the name. Of the remaining 6 patients who claimed to know something about antibiotics, their descriptions of how antibiotics worked were considerably inaccurate regardless of their background: all of them mentioned antibiotics were used to suppressed inflammation of some kind (including a medical school student), and only 3 of them talked about their actions on pathogenic bacteria.

Interestingly at the same time, this inadequate level of understanding was juxtaposed with heightened awareness of risk associated with antibiotic use. Most of the patients – 8 of them – were conscious about the *"harmful side effects"* of antibiotics, positing that overuse of antibiotics when *"one is not too ill"* would *"destroy balance in the immunity"*, *"kill good and bad bacteria altogether"*, *"lead to resisting bodies"*, and *"eliminate effectiveness of antibiotics so that they don't work in severe diseases"*, which they reported to have read and learned about through mass media including TV, internet and newspaper, targeted health promotion posters in the community or word of mouth from prescribers, relatives and friends. Even though the full scientific insight was clearly not effectively conveyed, the central message of "antibiotics are bad" as well as some of the terms and discourse around the issue of rational antibiotic use did seem to have reached the public through educational measures in *The Campaign*.

However, it was difficult to gauge the extent to which patient demands played a role in the prescribing process. Only 1 patient explicitly acknowledged that they would actively request antibiotics from the prescriber when they did visit the hospital for severe common cold, with the rest saying that they would listen to whatever the prescriber said and take whatever they prescribed; however, that may not be the case, as patients could mask their opinions about interaction with prescribers. There was a

risk of social desirability bias in the patients' responses; although this bias could apply to other areas of the enquiry involving reported behaviours of antibiotic use, patients were likely to be much more conscious about their social image as portrayed by interpersonal interaction than their choice of commonly available pharmaceuticals.

The potentially significant role of patient demand and expectations was underlined by two things. Firstly, all patients claimed that they would only opt to visit hospitals when they felt sufficiently ill, at which point their demands for pharmaceutical treatments were more likely to be strong than weak. Secondly, even though patients readily talked about the harms of antibiotics, 3 of them expressed special concern for children, who they considered to be physically weaker and less resilient, and thus more likely requiring timely treatments by antibiotics than adults.

9.7 Conclusion

In capturing the perspectives of all levels of actors – non-clinical managers, manager-prescribers, prescriber and patients – within a single hospital typical to an urban healthcare setting in China, the case study presented in this chapter thoroughly analysed the implementation of *The Campaign* through a bottom-up approach that focused on the perceptions and experience of frontline implementers. As “street-level bureaucrats”, manager-prescribers and prescribers had to cope with the demands of the top-down policies of the *Campaign*, and reconcile requirements of *The Campaign* to reduce antibiotic prescribing with the demand that arose from their clinical work (Winter, 2006: 153). As the activities of the street-level bureaucrats would effectively become the policies that they were charged to implement (Hill and Hupe, 2002: 52), how the prescribers reacted to and addressed with gaps between policy expectation and constraints imposed by contextual factors became crucial to effective policy implementation.

The case study demonstrated that contextual factors at system, hospital and individual levels heavily influence policy implementation at the secondary hospital studied. Some contextual factors – such as the existing and incoming policies to rectify financial incentives to prescribe, and the mentor-mentee relationship between senior and junior prescribers – were helpful in generating necessitating changes in prescribing behaviours for policy implementation. Other contextual factors – exemplified by perceivable differences in policy context in respect of regions and levels of healthcare,

and diagnostic uncertainty that complicated prescribing decisions – could impede effective policy implementation.

The case study also analysed how *The Campaign* itself interacted with those contextual factors to generate changes in prescribing behaviours. Overall, implementation *The Campaign* had a positive effect on aligning contextual factors to better enable rational prescribing behaviours. *The Campaign* helped to reinforced contextual factors that were beneficial for policy implementation: punitive measures and financial penalties further deterred incentives to prescribe; target management further strengthened the authority of senior prescribers in regulating the prescribing practices of junior prescribers. To some extent, it also helped to reconfigure contextual factors that were not originally favourable for driving rational prescribing: nationwide implementation promoted better antibiotic stewardship across geographic regions and reduced differences in policy context; effective monitoring of prescribing and resistance patterns contributed to an evidence-based approach to training and capacity building, which improved prescribers' knowledge and understanding of rational prescribing.

Notably, *The Campaign* did not fundamentally change other contextual factors. In some cases, contextual factors were sufficiently entrenched to be immune from the effect of *The Campaign*. *The Campaign* did not introduce resources or technology to improve diagnostic uncertainty, creating challenges for prescribers to adhere to rational prescribing guidelines as they had to rely on their judgement and experience instead. Despite contributing to shifting public opinions about antibiotics, *The Campaign* was unable to tackle the deeper social and cultural causes for patients' expectation and demand for antibiotics.

In other cases, the interactions between *The Campaign* and contextual factors were complex, making it difficult to determine whether *The Campaign* was an appropriate approach to encouraging rational prescribing. One prominent case in point was the need to balance top-down policy requirements of *The Campaign* with the specialised and dynamic needs for antibiotics in various clinical departments. Without clear instructions to adapt the target approach for different clinical settings and the evidence required to support them, *The Campaign* could risk negatively affecting established clinical practices.

In this light, it can be argued that the role of the internal negotiation process for redistributing quota for antibiotic prescribing across departments was crucial in helping

to bridge the gap between central policy requirements and local clinical needs. On the one hand, this internal flexibility was managed and coordinated by Medical Affairs from the top within the hospital, which ensured an orderly communication process across all clinical departments. On the other hand, it provided crucial grounds for manager-prescribers to feed frontline concerns into the implementation process from the bottom, which further enabled all prescribers to build a common understanding about *The Campaign* at an operational level that closely related to their daily work and needs.

Having examined the implementation of *The Campaign* at central and hospital levels in Chapters 7, 8 and 9, the next chapter will bring together findings from those chapters and draw conclusions.

Chapter 10. Conclusion

10.1 Introduction

This thesis has studied the subject of policy implementation through a case study of the implementation of *The Campaign*, a set of antibiotic stewardship policies enforced in China between 2011 and 2013. In this chapter, the findings and conclusions of the empirical research, which were presented in Chapters 7 (Policy Implementation at the Central Level), 8 and 9 (Policy Implementation at the Hospital Level Parts 1 and 2), are summarised in relation to the research aim and objectives set out at the very beginning. The strengths and limitations of the research methodology employed as described in Chapter 6 (Study Design and Methods) are scrutinised. The research findings are then discussed in relation to their contribution to, and relationship with the existing knowledge, which was described in chapters 1 (Introduction), 2 (Theoretical Background), 3 (Literature Review), 4 (Healthcare System Background) and 5 (National Policy Context). Finally, implications for policy and future research are discussed.

10.2 Summary of findings in relation to research aim and objectives

The subject of this thesis was policy implementation. Specifically, the overall aim of this research was to explore and analyse the implementation of *The Campaign* in China from 2011 and 2013 at the central and the hospital levels. In order to achieve this aim, this thesis set out three objectives and commensurate questions to be addressed under each of them:

Objective 1: to understand the national policy context of antibiotic stewardship policies in China

- a. What reasons led to actions on antibiotic use in hospitals?
- b. What were the antibiotic stewardship policies to date?
- c. Who were the key actors at the central and the hospital levels?
- d. How did *The Campaign* relate to the overall policy context?

Objective 2: to understand the context in which the implementation of *The Campaign* took place

- a. What did the system level context comprise?
- b. What did the hospital level context comprise?
- c. What did the individual level context comprise?

Objective 3: to explore and analyse the implementation process of *The Campaign*

- a. How was *The Campaign* implemented at the central level?
- b. How was *The Campaign* implemented at the hospital level?

These objectives were addressed through reviews of literature on policy implementation (Chapter 2), the tentative impact of *The Campaign* and the background of China's healthcare system (Chapter 4), review of literature and policy documents on the national policy context (Chapter 5), and empirical research on the implementation of *The Campaign* concerning and policy implementation at the central (Chapter 7) and the hospital levels (Chapters 8 and 9).

This thesis has argued that the mandatory nature of *The Campaign* was conditioned by the national policy context, which saw its conception as a way to strengthen the implementation of previous iterations of antibiotic stewardship policies. Inevitably, context and process were deeply intertwined: contextual factors at the levels of healthcare system, hospital and individual strongly influenced the scope and capacity for policy actions at both the central and the hospital levels, so that the implementation strategies had to be adjusted accordingly either to accommodate or counteract the influence of these factors. Different elements contributed to the implementation process at the central and the hospital levels respectively. Whereas vital aspects of policy implementation at the central level were dictated by the central government through measures that helped exerting and reinforcing central control, many aspects of policy implementation at the hospital level were products of a mixture between the alignment with the central government and the coordination and leadership by the management of the hospital, instead of being faithful mirrors or simple extensions of the activities led by the central government.

The first objective of the research was to understand the national policy context of antibiotic stewardship policies in China. Through a retrospective review of literature and policy documents, it was found that antibiotic stewardship had become a major aspect of health policy in China in the early 2000s due to concerns about the impact of irrational antibiotic use on rising antibiotic resistance inside and outside the country, which subsequently stimulated a series of policy responses under the policy areas of

healthcare quality and safety, and control of hospital-associated infections. Continuous policy actions had been set out to improve surveillance, technical capacity of medical professionals, rational antibiotic use, and legal institutions for antibiotic stewardship. At the central level, these actions were initiated and carried out by the central government, in conjunction with government-affiliated research and expert groups and academic and professional associations. At the hospital level in the national tertiary hospital, they were followed through by the managerial actors and interdisciplinary teams of prescribers, clinical pharmacists and microbiologists that they led. However, hindered by the gradual progress of policy development and a lack of mandatory enforcement, the implementation of the early policies was unsatisfactory. As a result, *The Campaign* was introduced to inject urgency and impetus into strengthening policy implementation. This set a top-down tone in the overall implementation of *The Campaign*.

The second and third research objectives sought to understand the context and process of policy implementation, and they were addressed through two phases of fieldwork: Phase 1 fieldwork explored the perspectives of multiple actors at central and hospital levels on policy implementation; Phase 2 fieldwork employed the case study method to study the implementation of *The Campaign* at an ordinary secondary hospital in urban Shanghai, and examined how top-down and bottom-up implementation took place and how context and process of implementation were intertwined within a single hospital setting from the perspectives of all the actors concerned. Findings from both phases of fieldwork in relation to objectives 2 and 3 will be discussed below.

Contextual factors influencing policy implementation

At the system level, impacts of the existing healthcare reforms on rational antibiotic use, the patterns in healthcare service delivery in the tiered hospital system, and the capacity of different levels of healthcare providers to implement antibiotic stewardship policies were crucial factors that shaped the policy approach of *The Campaign* from the perspective of the central level, which, in response, took a justifiable focus on secondary and tertiary hospitals for several reasons. Firstly, at the primary care level, access to antibiotics became limited, and the financial incentives to prescribe antibiotics became nullified due to the implementation of the Essential

Medicines policy package, which stipulated that pharmaceuticals were to be sold at zero-mark-up, and commensurate government subsidy for primary care providers were to be introduced. Secondly, most of the healthcare services in China were provided by secondary and tertiary hospitals, in which pharmaceutical sales remained a main source of revenue. Thirdly, only higher-level hospitals were equipped with the human and technological resources that met the requirements for implementing antibiotic stewardship policies. However, enabled by the successful expansion of social health insurance coverage in China, exacerbated by the lack of alternative options to hospital-based healthcare delivery and reinforced by patients' strong preference for better prescribers and technology available in higher-level hospitals but not in primary care providers, secondary and especially tertiary hospitals became severely overcrowded, and their capacity became highly overstretched, which posed significant challenges to policy implementation at the hospital level. In order to counter the huge healthcare demand, the national tertiary hospital introduced several measures to divert patients with minor conditions or inquiries away from hospital-based care, including cancellation of provision of intravenous infusion services in the outpatient department, and introduction of prescription consultation services in parallel to clinical consultations.

At the hospital level, the determining influence of both the external environment and internal structures, including financing arrangements, hospital settings and clinical specialties, over the scope and means of policy interventions meant that adaptation of policy in local implementation was necessary if not unavoidable. In the national tertiary hospital, corresponding measures were set out to address some of these hospital level factors. Some of the key policies of *The Campaign* were adjusted and relaxed according to the specific needs of different clinical specialties where stringent regulations might not be in the best interest of the patients, such as in emergency medicines. Furthermore, the characteristics of the national tertiary hospital proved to provide an enabling environment for policy implementation, as its income generation largely depended on high-tech services rather than prescribing, and its traditional ethos had a strong emphasis in upholding medical ethics and pursuing international excellence.

At the individual level, the importance of prescribers' and patients' understanding of rational antibiotic use to effective policy implementation was overshadowed by the influence of deteriorating prescriber-patient relationships, in which prescribers often had to yield to patients' demands. By offering solutions outside

conventional medicines, local alternative medicines exemplified by TCM could offer a useful buffer for patients' demand for pharmaceuticals in cases where the conditions and symptoms were not severe. However, the practice of polypharmacy involving TCM could raise another concern about its appropriateness in terms of rational use of medicines in general. In the national tertiary hospital, continuous training for prescribers was helpful in improving antibiotic use. Particularly, the introduction of an information technology system in the management of antibiotic prescribing offered an interface to validate prescribers' prescribing decisions and ensuring equal standards for all the patients, which was instrumental in reducing the tensions between prescribers and patients due to the discrepancies between prescribers' prescribing decisions and patients' demands.

Policy implementation at the central and hospital levels

At the central level, data from interviews with key informants representing the actors at the central level revealed strong characteristics of top-down implementation, most conspicuously marked by the dominance of the central government during the implementation of *The Campaign*. The perceived necessity of such a hands-on approach by the actors at the central level was a direct response to the lack of progress in the implementation of the preceding policies. In this process, a new legal mandate was created to further assert central dominance. Despite extensive engagement with, and reliance on other state and non-state actors such as government-affiliated research groups and professional associations in carrying out training, building networks and gathering resources required for policy implementation, the dominant role of the central government was indubitably unchallenged. Effective coordination and collaboration of multiple actors were achieved through the central government retaining its control over all the relevant actors concerned, as some branches of the government-affiliated research groups had dual functions within professional associations. The line of accountability between central level and hospital level actors in policy implementation was reinforced by the target approach and the use of multiple "redundant" independent regulatory mechanisms on antibiotic use. The target approach, which introduced numeric targets, ranking and intelligence systems to track key indicators and measure them against desired thresholds, was associated with a strong punitive aspect in the event of failure, effectively raising awareness of antibiotic stewardship at the same time. Multiple regulatory mechanisms, such as by

social insurance payers and hospital accreditation auditors, also regulated antibiotic use in their own right in parallel to *The Campaign*, further diversifying the forms of accountability reinforcement. At the same time, decentralisation in policy implementation was deemed both to be necessary and unavoidable in China due to the huge size of the country and the high levels of heterogeneity at local level. A level of autonomy was therefore appropriately delegated to the local actors, which raised questions about the level of control that the central actors could retain in the long term after *The Campaign*.

At the hospital level, policy implementation was first studied at the national tertiary hospital, a leading hospital in China. Besides taking the initiative to address the contextual factors that influenced policy implementation, the managerial actors at the national tertiary hospital also focused on several organisational elements vital to effective policy implementation. Despite recognising the positive influence of *The Campaign* in helping legitimising and formalising antibiotic stewardship and creating an enabling implementation environment, the actors in the national tertiary hospital constantly stressed the vital importance of the continuity of antibiotic stewardship policies prior to *The Campaign* in leading to early prioritisation of rational antibiotic use, and the development of the necessary human resources for antibiotic stewardship – particularly clinical pharmacists – long before *The Campaign* commenced. Much time and resources were also dedicated to building trust and collaborative relationships between clinical pharmacists and prescribers. The strong leadership of the managerial actors in early policy implementation also showed that there was a level of top-down implementation at the hospital level, which preceded *The Campaign* and its associated target approach. This was reflected in the organisational structure, in which the Department of Medical Affairs was given a leading role over other departments in overseeing antibiotic stewardship policies, and the Drug and Therapeutic Committee was formed to coordinate experts and working groups of different clinical specialties and disciplines.

With a focus on managerial perspectives of policy implementation at central and hospital levels, phase 1 fieldwork showed that if the essential premises of sustained policy development, a responsive healthcare system constantly adapting to contextual challenges, a competent and collaborative central government, and effective decentralisation supported by capable and resourceful local actors (such as the national tertiary hospital) were fulfilled to the extent described by the actors

interviewed, top-down measures that emphasised accountability using the target approach and harnessing multiple existing regulatory mechanisms could create the necessary impetus for effective implementation of *The Campaign* in China. However, as policy implementation took place within a complex and dynamic healthcare system, effective top-down implementation required a refined and realistic policy scope, and the necessitating change in prescribing behaviour had to effect through the fundamental drivers of antibiotic prescribing by frontline implementers. In other words, an understanding of the bottom-up process of policy implementation, especially how frontline implementer perceived and experienced the interactions between top-down measures, contextual factors and changes in prescribing behaviours would be essential to analysing top-down implementation.

Therefore, in order to explore the bottom-up perspective further and analyse the interaction between top-down and bottom-up forces of policy implementation, phase 2 fieldwork focused on an ordinary secondary hospital in Shanghai, where all the actors involved in policy implementation – from managers to prescribers and patients – were sampled and interviewed.

At the hospital in Shanghai, exemplar features top-down features of implementation including clear line of accountability, target approach, punitive measures and redundancy – all consistent with those at central level implementation – were salient, and they were implemented by the department of medical affairs, which was central to all managerial activities within the hospital. From the perspectives of the interviewees, these measures were faithfully followed and largely worked as intended by the policy, although ambiguities remained amongst the interviewees with respect to the extent to which punitive measures were enforced. The enhancement, accentuation and prioritisation of these top-down measures in their stringency and enforcement, rather than these measure per se, were perceived by the interviewees to be the direct product and legacy of *The Campaign*. However, the perceived changes in antibiotic prescribing practices were the result of the interaction between top-down policies and local contextual circumstances rather than a linear consequence of the implementation of *The Campaign*. Local implementers were faced with challenges pertinent to system, organisational and individual levels.

At the system level, varied regional and healthcare policy context created difficulties for managers and prescribers to manage the same prescribing patterns vis-à-vis hospitals in other regions or of higher tiers when patients were free to move

across different hospitals and expected similar treatments throughout. At the organisation level, prescribing behaviours could be exposed to and influenced by entrenched financial incentives, which were not removed on a systemic level during *The Campaign*. In addition, prescribing behaviours were also shaped by the mentoring relationship between manager-prescribers and prescribers, where senior prescribers passed on their knowledge and experience. Furthermore, diagnostic limitations and uncertainties gave rise to cases where prescribers inevitably had to rely on their experience and judgement rather than wait for definitive evidence. Finally, varied demands for antibiotic use across drastically different clinical scenarios meant that manager-prescribers, in representing their own department's interest in achieving prescribing targets, had to liaise with one another indirectly through the mediation of medical affairs in a dynamic exercise that led to redistribution and harmonisation of targets at the departmental level within the hospital. At the individual level, prescribers' knowledge and experience mattered as much as patients' expectations and demands, and the sometimes volatile and brittle relationship between prescribers and patients in the society at large laid ground for occasional but potentially heated and acrimonious disputes that could overshadow a prescriber's decision whether to prescribe.

Implementation of *The Campaign* addressed and mostly positively influenced some of these contextual factors to create a better environment to encourage rational antibiotic use. At the system level, managers and prescribers felt that *The Campaign* created a more even policy context across China on antibiotic use and strengthened implementation in previously, even though differences in regional and healthcare policy context remained. At the organisation level, *The Campaign* introduced measures that aimed to counteract financial incentives to prescribe and solidified the authority of senior prescribers in order to create fundamental changes in prescribing practices. At the individual level, training of prescribers and improved collaboration between prescribers and other healthcare professionals, especially clinical pharmacists, were vital to improving prescribers' understanding of the theory, evidence and practice of rational antibiotic use. Public education since *The Campaign* on rational antibiotic use helped recalibrating patients' expectation, which was further boosted by proactive education from the prescribers especially during clinical consultations.

However, structural challenges engendered by contextual factors at central and hospital levels described in the earlier part of the research, which led to *The Campaign's* policy approach to focus only on the more resourceful and capable higher-

tier hospitals, had also constrained policy implementation at the secondary hospital in Shanghai. Although capable of providing a range of healthcare services for the local community, the secondary hospital studied was not a match to the national tertiary hospital in Beijing – or any other tertiary hospital – in terms of capabilities and resources. Despite having a strong focus on the top-down activities to regulate antibiotic use and prescribing, the secondary hospital lacked the necessary resources to contribute to wider surveillance activities, engage clinical pharmacists to the extent seen at the national hospital in Beijing, or vastly improve limitations in their microbiology capabilities. In highlighting the complexities in policy implementation at a fairly typical hospital in urban China, findings of the case study also underline the importance of drawing attentions away from “the Centre” in order to have a grounded and functional understanding of the process and challenges of policy implementation in a dynamic healthcare system such as China’s, and illustrates the necessity for even top-down implementation to consider its impact on contextual factors and subsequent behaviours for it to be a success.

10.3 Critique of the methodology

The major limitation of phase 1 fieldwork mainly concerned the selection of study sites and the recruitment of interviewees. Firstly, despite the fact that other key informants including academics and a former specialist in the pharmaceutical industry provided supportive accounts of government policy, analysis of policy implementation at the central level heavily relied on the accounts from a few government officials from the central government. Although their accounts could be triangulated with policy documents to a limited extent, there were no other empirical data sources that could permit triangulation to further establish the validity of the qualitative data as discussed in Chapter 6 (Study Design and Methods). Whilst this could be considered an inevitable issue due to lack of existing research, triangulation could be established based on the counter narratives about central level implementation from nested subgroups that were focused on hospital level implementation, and from existing policy literature on policy implementation at the central level in general. Furthermore, the researcher’s role in international meetings on antibiotic policies in China provided unique insight about policy actors at the central level, and opportunities to establish access to high-level officials and officers directly and very closely involved in the implementation of *The*

Campaign. In this regard, data collection at the central level in this research could be considered a strength.

Secondly, policy implementation at the local level was represented only by the hospital level; most conspicuously, the lack of representation of local government created a significant disconnect between the central and the hospital levels. The only reason for not including a local government in the study of this level was the lack of access. In order to mitigate the impact of this limitation, the researcher took measures to enhance the connection between the central level and the hospital level through careful selection of study sites. A step to reduce the disconnect in the administrative hierarchy was sampling hospitals from Beijing, where the central government was located. Although none of the hospitals sampled were directly owned by the central NHFPC (again due to lack of access), they were more closely located and more heavily influenced by the centre due to their proximity to the epicentre of national policies. Another crucial step to establish direct connections between the central and the hospital levels was selecting a leading hospital in China that had worked with the central government and international organisations in antibiotic stewardship policies to study implementation at the hospital level.

This can also lead to criticism about the selection of the national tertiary hospital. Even though the rationale for its selection was to establish a connection between the study of implementation at the central and the hospital levels, the national tertiary hospital was one of the least typical hospitals in China in terms of available resources, technological capabilities and national and international reputation. Given that it was unlikely that other hospitals would have similar levels of resources, capability and close relationship with the central actors, implementation of antibiotic stewardship policies in other cases would be less optimal in comparison, putting in serious question whether policy implementation at this hospital represented an example of policy implementation at a typical hospital in China.

Thirdly, the sampling of managerial-level actors, which took place in the national tertiary hospital, became separated from the sampling of prescribing-level actors, which took place in other hospitals in Beijing. Again, this issue arose because of lack of access to prescribing-level actors in the national tertiary hospital. The immediate consequence of the disconnect between the two levels of actors was that the study of implementation processes in the national tertiary hospital relied only on the accounts from the managerial actors. This in itself was not necessarily problematic, as

a number of existing studies at the hospital level also focused on managerial actors only; after all, antibiotic stewardship was a specialist activity organised by higher levels of the hierarchy within a hospital. From a bottom-up perspective that sought to encompass patients' experience, it could have been beneficial to include prescribing-level actors in the analysis of implementation in the national tertiary hospital. Since that was not possible, the researcher went for the next-best alternative, seeking instead to substantially enrich the analysis of the wider implementation context in China and Beijing by ensuring that the sampling hospitals and prescribing-level actors – prescribers and patients – reflected a wide range of characteristics commonly seen in urban Beijing. In doing so, it became possible to situate implementation in the national tertiary hospital in a description of the wider healthcare system context that was comparable and compatible with the descriptions in Chapter 4 (Healthcare System Background).

Another criticism of this research may concern the ways through which the policy of interest was analysed. As described in Chapter 5 (National Policy Context), the subject of interest in this research – *The Campaign* – comprised a list of Key Policies on antibiotic stewardship. In this research, *The Campaign* was analysed as a whole, and regarded as a representation of all the major and recent antibiotic stewardship policies in China. Individual policy components, such as restricting the antibiotic formulary and formulary restriction, were not used as individual tracer policies. It is worth noting that both approaches to analysing implementation – treating antibiotic stewardship as a single concept covering a specified range of policies and activities, or focusing on one or several individual policy components – were equally viable and not in conflict with each other, as demonstrated by existing studies summarised in Chapter 3 (Literature Review). Whilst each approach had its own merits, this research favoured the broad-brushed approach over the tracer policy approach out of practical need. On one level, there was a lack of detailed description of the policy context of antibiotic stewardship in China in the existing literature, so that exploratory research was required at a more fundamental level. On another level, the researcher's background and experience in policy analysis, health systems research and biological sciences could be better utilised in the more general approach to understanding policy implementation, which was comparatively less demanding in the understanding of clinical issues vital to the analysis of individual policy components.

Some of the major methodological shortcomings in the analysis of hospital level implementation in phase 1 fieldwork were addressed and rectified in the case study in phase 2 fieldwork. Overall, the case study achieved a thorough investigation of a relatively small hospital by sampling a significant number of hospital actors from clinical and non-clinical departments that were highly relevant to antibiotic prescribing and implementation of *The Campaign*.

The key improvement of the case study was that it sampled all levels of actors involved in the implementation of *The Campaign* at the secondary hospital in Shanghai, including senior non-clinical managers who performed key managerial functions, manager-prescribers that were senior departmental leads, more junior prescribers, and patients. All these actors were sampled from the same healthcare setting, which enabled a more comprehensive analysis of policy implementation than the study conducted at the national hospital in Beijing. More importantly, the secondary hospital studied represented an example of a much more ordinary and typical healthcare setting in urban China, and lessons learned from the case study here were likely to be applicable to many more hospitals of similarly modest scale.

Furthermore, the case study improved on the way qualitative data was collected. As opposed to phase 1 fieldwork, where more than 1 types of interviews for data collection were employed, the case study in phase 2 fieldwork consistently made use of the semi-structured interview as the only instrument. The instruments for each type of interviewee – non-clinical managers, manager-prescribers, prescribers and patients – were designed to match one another in themes and questions. This resulted in a more controlled and systematic approach in data collection and ensured that data collection was not biased by process disparities, and also resulted in a more systematic examination of key themes.

The way the themes and the overall enquiry was designed was another significant area of improvement. Whereas *The Campaign* as an overarching concept was used in a vague manner to extract data in the interviewees conducted in phase 1 fieldwork, the instrument for the case study in phase 2 fieldwork was purposefully designed to enable systematic examination of the individual policy components of *The Campaign*; fine details of those policies were discussed with all levels actors from the hospital, including managers, manager-prescribers, prescribers and patients. The redesigned instrument was therefore instrumental to the bottom-up analysis in the case study.

But there was still room for even further improvement in the case study. The major setback faced by the case study was the lack of sufficiently in-depth patient interviews, which had been a problem in earlier fieldwork. It could be concluded that sampling and interviewing patients in the waiting area of a hospital was not an effective strategy to obtain in-depth data. Overall, the willingness and ability of patients to engage with the research topic was modest without prior recruitment and debriefing. Bias in data was an unavoidable issue, as patients were likely to be more prone to having social desirability bias when interviewed in an open setting.

Besides the limited use of patient data, the case study also suffered from the lack of means to triangulate qualitative data in general. As quantitative data on antibiotic prescribing could not be obtained from the secondary hospital in Shanghai, the case study relied solely on actors' retrospective accounts in understanding changes in antibiotic use and prescribing behaviour during *The Campaign*. Although relevant literature on the quantitative trends in antibiotic prescribing in Shanghai provided a very useful context (Lin *et al.*, 2016), the absence of descriptive data from the primary data source meant that conclusions from the case study had to be seen in a more critical light, especially in considering how it informed the existing understanding of the hypothesised role of *The Campaign* in reducing antibiotic use or the lack thereof described in Chapter 3 (Literature Review). However, the findings of this research were ultimately situated amongst a wide range of existing literature; as demonstrated by the discussion section of this chapter, their high compatibility with existing knowledge could be easily established through comparison with literature on implementation of antibiotic stewardship policies in different parts of the world, prescribing behaviours, healthcare system reforms and health policy implementation in China.

10.3 Contribution of the thesis

Whilst antibiotic stewardship is becoming a subject of increasingly intense interest against a background of alarming levels of antibiotic resistance in China and across the world, there has been little research addressing the implementation of antibiotic stewardship policies. Considering the gaps in research as described in Chapters 1 (Introduction) and 2 (Theoretical Background and Literature Review), this thesis has made three original contributions.

Firstly, this thesis has made a unique contribution to the understanding of implementation of antibiotic stewardship policies in China. By analysing policy documents and describing in detail how antibiotic stewardship policies in China were aligned with the actors responsible for carrying out policy actions, the thesis enriches existing reviews of national policy context (Xiao & Li, 2015; Cui *et al.*, 2017). Having examined existing evidence of the impact of *The Campaign* at national, regional and hospital levels described in Chapter 3 (Literature Review), the thesis establishes that there is an inadequate level of understanding of whether and how *The Campaign* reduces antibiotic use in hospitals in China. Despite evidence from evaluative studies and studies of prescribing trends suggesting a decrease in antibiotic prescribing, these studies' attempts to correlate the observed trends with the implementation of *The Campaign* between 2011 and 2013 failed to attribute clear causality in the proposed relationship. Furthermore, none of these studies examined how the proposed effect of *The Campaign* might have been achieved due to policy implementation. To address this gap in knowledge and provide an in-depth analysis of the implementation of *The Campaign*, this thesis drew on a wide range of empirical data sources, from government officials to prescribers and patients at the central and the hospital levels, adding significantly to the scarce existing research in this area (Wang *et al.*, 2016; Jin *et al.*, 2011) by providing a detailed account of how policy implementation interacted with contextual drivers of antibiotic prescribing described in Chapter 4 (Healthcare System Background).

Secondly, this thesis has made a unique contribution to the understanding of implementation of antibiotic stewardship policies in general. Building on the insight from existing cross-sectional studies (Hersh *et al.*, 2009; Pope *et al.*, 2009; Johannsson *et al.*, 2011; Doron *et al.*, 2013; James *et al.*, 2013; Howard *et al.*, 2015; Bryant, 2015; Enani, 2016; Wolf *et al.*, 2016) and qualitative case studies (Charani *et al.*, 2013; James *et al.*, 2015; Jeffs *et al.*, 2015; Cotta *et al.*, 2015; Bailey, Tully & Cooke, 2015; Liu *et al.*, 2011a; Li *et al.*, 2014b), which mostly focused on important factors, especially barriers, to the implementation of antibiotic stewardship policies at the hospital level, this research explored and analysed factors crucial to the implementation of antibiotic stewardship policies at both the central and the hospital levels through a detailed case study. In providing a cogent analysis of context, process and their interactions, this research was one of the first to apply a framework based on implementation theory in the analysis of antibiotic stewardship policies. In so doing, this research presented an ambitious attempt to bridge the literature on several different

topics, including policy implementation, antibiotic stewardship, healthcare system and reform, and prescribing behaviours, and demonstrated a viable approach to analysing the implementation of antibiotic stewardship policies and a way to make clear sense of a wide range of existing research in relation to policy implementation.

Thirdly, this thesis has made a contribution to the understanding of implementation of health policies in China. Echoing existing studies (Duckett, 2001; Tolhurst *et al.*, 2004; Schwartz & Evans, 2007; Dong, Christensen & Painter, 2014; Xiao *et al.*, 2013b), this research provided further examples and evidence to understand the governance of healthcare and the implementation of health policies at different levels in China, which took place in a dynamic background of healthcare reforms and diverse local contexts. Whilst antibiotic prescribing has been frequently used as a tracer to understanding healthcare service provision and healthcare reforms in China (Reynolds & McKee, 2009), this research presented policy implementation as another angle to further reveal the complexities in the interplay between context and process in China's healthcare system and reform.

10.4 Discussion and implications of the findings

This section discusses findings with respect to the conceptual map set out in Table 6-11 in Chapter 6 (Study Design and Methods). Drawing on existing theoretical and empirical literature on policy implementation reviewed in Chapters 2 (Theoretical background), 3 (Literature review), 4 (Healthcare System Background) and 5 (National Policy Context), this section first reflects on the fundamental theoretical framework upon which the thesis is established and examines critically the use of implementation theory in this research. It then discusses the strengths and weaknesses of *The Campaign* in relation to the drivers of inappropriate antibiotic use at system, organisation and individual levels. Finally, implications of the findings for policy and future research are outlined.

Use of implementation theory in the research

In order to conduct the analysis, this thesis has applied implementation theory – particularly, top-down and bottom-up approaches to understanding policy implementation – in the analysis of implementation of antibiotic stewardship policies.

The theoretical framework set out in Table 2-1 in Chapter 2 (Theoretical Background) was in general highly useful for the analysis in this research for several reasons.

Firstly, the fundamental assumptions associated with the top-down and the bottom-up perspectives of policy implementation were useful for conceptualising the two levels of implementation examined in this research – the central and the hospital levels – in which the assumptions of the two contrasting perspectives were met to different degrees. Whilst key assumptions for the top-down perspective including the processual view of policy implementation, the linear and rational model for implementation and the dominance of “the Centre” were strongly echoed at the central level, they were much less conspicuously reflected at the hospital level. In part, this also highlighted the contrasting ways that the actors at the two different levels viewed *The Campaign*: whereas the central actors saw *The Campaign* as a special segment of antibiotic stewardship policies, the hospital actors saw it as part of a long list of their daily work.

Secondly, theoretical elements associated with both perspectives provided helpful insight in the design and analysis of the research. Consistent with the description in Chapter 2 (Theoretical Background), elements associated with the top-down perspective, exemplified by the concepts of control, accountability, target approach and redundancy, provided significant explanatory power in the analysis of policy implementation. Themes emerged from the empirical data lent themselves conveniently to these elements not only at the central level, but also at the hospital level, where they were manifested in a smaller and more confined scale. Elements that were pertinent to the bottom-up perspective informed the identification of interviewees, and helped uncovering their relationships and perspectives based on their accounts as frontline implementers rather than formal descriptions.

Thirdly, the theoretical framework offered a cogent framework to describe the complex interaction between context and process across different levels of implementation, which previous research did not achieve. By clarifying the theoretical treatment of context and process, it became possible to make clear distinction between influential elements that were outside and inside of the range of activities intrinsic to policy implementation, and how these elements interacted. An example to demonstrate the usefulness of this approach was the analysis of policy implementation at the hospital level, in which the implementation process was shown to include measures that directly addressed contextual factors. Furthermore, the conceptualisation of

different levels of contextual factors was crucial to the understanding of the interaction between context and process at different levels of implementation. At the central level, policy implementation was influenced by macro level contextual factors only, including the national policy context and system level contextual factors pertinent to China's healthcare system. This contrasted with the case of policy implementation at the hospital level, which was influenced by micro level contextual factors including hospital level and individual level contextual factors as well as the macro level factors.

To observe characteristics of top-down and bottom-up implementation separately, this thesis opted to combine the use of both perspectives in a comparative way rather than employ synthetic theoretical approaches. Doing so inevitably created tension within the theoretical framework, as the two theoretical perspectives seemingly opposes each other. Given their varying assumptions, emphases and affinities to different levels of implementation, the application of the top-down approach was not in total harmony with that of the bottom-up approach in this research, and combining these theoretical approaches without mediation and resolution of the inherent tension could have resulted in a disjointed analysis.

The top-down approach focused on the central level implementation and had an intrinsic inclination for analysing the expected policy process and outcomes; this being the point of reference, deviations from the intended paths of implementation were judged to be less than ideal. The preconditions for "perfect" implementation (Hogwood & Gunn, 1984) were a paragon of this angle to analysis. This perspective was undeniably useful for this research due to the fact that *The Campaign* was centrally conceived from the beginning with the purpose to set new standards for antibiotic use, and that its mechanism of implementation was largely reliant on the power differential in administrative authority between the central and the local actors; nevertheless, analysing how context and process might not lend itself to the ideal top-down implementation could provide an opening for the analysis of how policy implementation took place in a "messy" real world environment, and Chapter 7 (Policy implementation at the Central Level) showed that even effective top-down implementation could be at variance with what the theory judged to be ideal. The strong normative stance associated with the top-down approach could in effect hinder the exploration of fine details in implementation activities.

The bottom-up approach complemented the limitations of the top-down approach by providing a much needed focus on the more microscopic issues in policy

implementation. Its starting point from the perspectives of individuals guided the research process: the sampling of suitable interviewees relied on gatekeepers, especially those at the hospital level, to identify relevant actors based on understanding of the networks and relationships within the organisation from their experience instead of directly from the formal structure outlined in official sources (Hjern & Porter, 1981). Moreover, by placing emphasis on the perceptions and experience of frontline implementers in how things worked on the ground rather than dwell on the concerns of the central actors on how the policies were meant to play out, the bottom-up approach was critical to making sense of how the interplay between dynamic contextual factors and the top-down implementation process dictated by *The Campaign* influenced each other, and how they combined to influence behaviours in antibiotic use and prescribing. However, even though the bottom-up approach facilitated a thorough analysis of the heterogeneity and idiosyncrasy in decentralised implementation of central policies at the hospital level (particularly demonstrated by the case study in Chapter 9, Policy Implementation at the Hospital Level, Part II), its emphasis on individual incentives and behaviours could easily stray away from the analysis of high-level policy structures such as *The Campaign*, which was the central frame of reference for this policy analysis.

Therefore, a conceptual framework or theory was therefore highly necessary to bridge the between top-down and bottom-up perspectives and between context and process of policy implementation in an explanatory framework of the influencing factors of antibiotic use in hospitals at the system, organisation and individual levels, which was first described in Chapter 4 (Healthcare System Background) and will be described again in the next section. By providing a focal point of analysis in the influence on prescribing behaviours, the framework provided a bridge in the theory-driven thematic analysis to allow top-down characteristics and bottom-up themes to reconcile and combine, and directed the two seemingly opposing perspectives towards a meaningful and critical analysis of and for *The Campaign*.

The strengths and weaknesses of *The Campaign*

As the influencing factors of antibiotic use in hospital were also levers of behaviour change, the use of a conceptual framework describing the determinants of antibiotic use in hospitals at system, organisation and individual levels became central

to the discussion of the strengths and weaknesses of the policy implementation in relation to the extent they mobilised and changed some of these factors. This framework, which was first described in Chapter 4 (Healthcare System Background), is enhanced by findings of the research in the form below in Table 10-1. Using the framework as a reference, some of the major strengths and weaknesses of the policies of *The Campaign*, which were detailed in Chapter 5 (National policy context), will be discussed with respect to the drivers of antibiotic use from the perspectives of healthcare providers and users at different levels.

Level of determinants	Factors that mainly influence providers	Factors that influence both users and providers
System	Governance, organisation, financing and delivery of healthcare in the health system; major policies and regulations in healthcare and pharmaceutical sectors; role and influence of the pharmaceutical sector	Cultures, beliefs, values and medical universes in different societies; availability, accessibility and quality of healthcare services and medicines
Organisation	Governance, organisation, financing and delivery of healthcare in hospitals; organisational policies and regulations specific to hospitals; interactions with the pharmaceutical sector	Availability, accessibility and quality of healthcare services and medicines local to patients
Provider-user interpersonal		Interactions and relationships between doctors and patients
Individual		Personal background, experience, and socioeconomic characteristics; interactions with other actors in the health system; level of medical knowledge; attitudes and expectations towards healthcare and medicine use

Table 10-1 Expanded table of influencing factors of hospital antibiotic use (Hanson *et al.*, 2018)

Overall, it was clear that *The Campaign* in itself aimed at mainly addressing the drivers of antibiotic use that mainly influence providers in the healthcare system at the level of organisation (hospitals) and individual (healthcare professionals, particularly prescribers). First described in Table 5-4 in Chapter 5 (National policy context), these policies sought to reinforce accountability through using restrictive prescribing targets and financial penalties for failure to meet these targets on the part of both the hospital and the prescribers, where the target system of numeric thresholds was enabled by an intelligence system for gathering surveillance data on antibiotic use and resistance, was the basis for a ranking system created to shame low-performing actors. These measures were supported by restrictive measures that constrained the availability and accessibility of antibiotics in procurement and prescribing authority, and capacity building measures aimed at improving knowledge, capability and collaboration across

all the relevant healthcare professionals, especially prescribers. These policy elements indeed addressed the crucial challenges in implementing antibiotic stewardship policies identified through Chapter 3 (Literature Review) and summarised in Table 3-1. Not only were these policies in line with mainstream antibiotic stewardship policies, the tentative effectiveness of some of the individual policy elements of *The Campaign* such as public reporting, multidisciplinary involvement in antibiotic stewardship and formulary restriction were also described (Hua, 2016; Zhou *et al.*, 2015; Jiang *et al.*, 2014; Wang *et al.*, 2014b; Yang *et al.*, 2014; Bao *et al.*, 2013).

However, the fact that the policies of *The Campaign* were fine in principle did not necessarily mean that the policy design or implementation were fully informed by evidence. For a start, it was unclear whether the policy approach to target higher-level hospitals, especially tertiary hospitals, was a product of thorough research or simply based on an intuitive understanding about the working of China's tiered healthcare system like the high-level informants described. Additionally, it was also unclear how the specific target prescribing levels, or the numbers of antibiotics allowed in the formularies in hospitals specified in *The Campaign* were derived, or how they were justified. Furthermore, it was unclear whether sufficient considerations and instructions had been given for policy implementation in different clinical contexts, where hospital actors coped with ambiguities in the policy and necessity to deal with clinical challenges through operating with a level of permitted discretion. Ultimately, without proper evaluative studies, it was unclear whether the policies really worked as intended in containing antibiotic resistance in hospitals and in communities, and how well they worked.

More importantly, it is crucial to assess the role of *The Campaign* in influencing drivers of antibiotic use by placing it in the broader healthcare reform context in China. Though it was worth noting that many actors did perceive *The Campaign* to be an influential driving force in shaping a more standardised policy environment around prescribing practices across the country, it would be farfetched to consider *The Campaign* to be an instigator of those sweeping changes that the actors so palpably perceived. Just as antibiotic prescribing was merely a symptom of some of the ills of China's healthcare system, *The Campaign* as a single-issue policy solution that sought to regulate only one aspect of healthcare provision in antibiotic use in hospitals was no more than a part of the government's overall agenda to facilitate fundamental healthcare reforms, as its policies did not intend to change the contextual factors that

shaped and influenced prescribing behaviours. This is considered to be the main weakness of *The Campaign*.

It was fortuitous that in some cases, policy implementation was helped by some of those contextual characteristics; in other cases, it gravitated towards problems that were entrenched in the healthcare system and succumbed to those forces. In terms of governance, implementation of *The Campaign* largely relied on the fact that hospitals in China were public institutions subjected to the government's administrative control, evaluation and management. Even though the extent of dominance of the state exemplified by China's political system was not a necessary condition for top-down implementation per se, the presence of it was undoubtedly very helpful to *The Campaign*, where this central dominance was effectively translated into a force for changing specific areas of healthcare practices to good effect. Additionally, the participation of non-state actors such as professional bodies provided an alternative venue for channelling state policies.

However, despite the power held by the Centre, effective implementation of *The Campaign* was not a given, as it largely rested upon other factors being aligned with its aims. These factors were responsible for the policy approach of *The Campaign* to focus only on higher-level hospitals, the highly heterogeneous and decentralised policy contexts faced by different hospitals, and the plurality in policy implementation.

In terms of organisation and delivery, the chasm between primary care and higher-level hospitals persisted, so did the uneven distribution of resources across social, economic and geographical divides in the country. The insufficiencies here are addressed by ongoing initiatives to build a more functional primary care system and more effective gatekeeping and referral systems. However, the deeper structural issues that led to the divide between primary care and higher-level hospitals – including imbalances in capacity building, workforce generation and healthcare resource distribution – will require drastic improvement over a long term. Furthermore, the impact of well-intentioned health reform policies on antibiotic prescribing was unknown. The essential medicines policy severely capped the types of pharmaceuticals available at the primary level and could prove to be counter-productive to the effective provision of healthcare, as it restricted access to antibiotics without actively encouraging rational use of antibiotics per se. Increasing purposeful exchanges and referrals of patients between different level hospitals for surgical treatments could have significant implications for both infection control and antibiotic use.

Similarly, in terms of financing, the rooting out of financial incentives to prescribe needed time. On the one hand, policy implementation was buoyed by the implementation of synergistic prior reforms like the zero-mark-up policy, and assisted by stringent cost-controlling regulations rolled out both by social insurance payers and assessors of healthcare quality. On the other hand, malpractices by prescribers at a personal level became targets of a wider anti-corruption reform. The continual rolling out healthcare reforms to de-escalate the importance of pharmaceutical sales in revenue generation in hospitals and to dissociate revenue generation from healthcare provision in the healthcare system as a whole since *The Campaign* began, and the high-profile action against multi-national pharmaceuticals for their involvement in corrupting prescribers showed the government's resolution to tackle one of the most fundamental and difficult challenge in China's healthcare system in the financial incentives to prescribe. As these measures progressed, the jury was out.

Finally, at the individual level, *The Campaign's* overwhelming focus on healthcare professionals, especially prescribers, would not have shifted prescribing patterns without relevant health promotional campaigns that gradually changed the perception of antibiotics by the general public. The intended rectifying effect of *The Campaign* on prescribers came from four fronts: improvement in knowledge and understanding; frequent reviews of prescribing; career and financial disincentives to prescribe; and reinforcement of the hierarchical managerial culture and its impact on building new behavioural patterns. But from the prescriber's perspective, one the biggest incentives to follow through antibiotic stewardship was that of self-protection against potential dissent from patients. Whilst *The Campaign* in itself did nothing to tackle the persistent issue of deteriorating prescriber and patient relationships in China, the highly publicised nationwide operation to set a new healthcare standard across the whole country offered prescribers a new line of defence in adhering to the government's order.

At the same time, relevant but unrelated public media campaigns started to change patients' understanding of antibiotics but not the social constructs that governed patient expectation. Even as patients' self-perceived demand for healthcare services and pharmaceuticals remained high, their attention began to shift from antibiotics to other alternatives as they started to become aware of the "negative effects" of antibiotics which, in some cases, became even more accentuated in comparison to alternatives, especially TCMs. Whilst the media promotion no doubt

played a strong part in shaping new public opinions that helped relieved pressure on antibiotic use, the extent to which patients truly grappled with the medical understanding was questionable: patients who held hold negative opinions about antibiotics did not necessarily know anything about antibiotics at all. Therefore, at a deeper level, the fundamental expectation of antibiotics by patients largely remained unchanged in less clear-cut cases where they experienced strong symptoms, and where diagnoses were less certain and alternatives were not available; for prescribers, this could spell trouble as they faced many cases that were not clear-cut on a daily basis.

Implications for policy and research

The implications of the findings will be described in three areas: implications for the implementation of antibiotic stewardship policies; for broader healthcare reforms and policies in China; and for future research.

Implications for the implementation of antibiotic stewardship policies

The implementation gap remained one of the biggest challenges in an effective national and international response against antimicrobial resistance, and lessons from *The Campaign* have shed light on how this gap may be addressed.

Even the most top-down form of central-led implementation should be based on sustained development of national antibiotic stewardship policies, and healthcare reforms that seeks to improve healthcare quality and safety whilst continuously improving and balancing access, affordability and resource distribution. Given sufficient progress in achieving the necessary conditions, central government should play a crucial role in revitalising policy implementation. Top-down national campaigns using the target approach can be effective in providing the decisive impetus and momentum for initiating actions and driving progress in the short term. However, not all countries share China's political and health administrative systems, which are especially adept in delivering top-down implementation and mobilising civil organisations to that effect; whether China's experience could be replicated elsewhere will also depend on the extent to which similar top-down activities are politically feasible in a given country setting. Regardless of the political system, concerted actions across multiple

departments would be needed to ensure an effective response against the multisectoral problem of antibiotic resistance.

In addition, reiterating what has been widely noted, synergy will be required between healthcare system strengthening and reinforcement of operational aspects and resources available at the local level. Much as implementation of antibiotic stewardship at the hospital level is a technical exercise that required prioritisation and planning, capacity and team building, coordination and execution, hospitals should respond proactively to the challenges in implementation in a similar way to how they respond to challenges in healthcare service provision. Crucially, responsibility for antibiotic stewardship should not solely rest on prescribers: strengthening of clinical pharmacology and microbiology, especially diagnostic technology, is highly necessary to build an effective multidisciplinary team to jointly ensure rational antibiotic use. After all, implementation of antibiotic stewardship policies is part of service provision itself.

From a bottom-up perspective, frontline implementers of antibiotic stewardship, especially prescribers, should be given a bigger say in antibiotic stewardship at the organisational level, so that policy implementation is not reduced to a numbers exercise at the peril of endangering clinical practice. As national policies tend to be broad and directional and consequently could be lacking in consideration of nuances in hospital settings, insights from, and effective mechanisms established by hospital actors are vital in overcoming implementation challenges and maintaining standards of clinical practice. Moreover, it would be worth considering whether prescribing behaviour could be better incentivised, and the target approach better achieved through the use of a combination of rewards and punishments than the use of punishments alone. Whilst the negative marking system associated with *The Campaign* and other hospital audit exercises created sharp awareness amongst hospital actors to reduce antibiotic use, having all sticks but no carrots could have implications on the overall morale of healthcare workforce in the long term.

As patient-related factors continue to influence antibiotic prescribing, much more attention is needed to shift the perceived demand of antibiotics from patients. Despite the primacy of education, the impact of social and media campaigns in changing patients' perceptions should not be underestimated: if patients could be genuinely persuaded that taking antibiotics without doctors' instructions is a very bad idea, the extent to which they are versed with the scientific explanations may not matter as much.

Last but not least, the lack of understanding of *The Campaign's* impact on antibiotic use and the epidemiological and economic burden of antibiotic resistance can only be addressed by methodologically rigorous evaluations based on official data. To permit better understanding and enable the sharing of China's experience in implementing antibiotic stewardship to other countries, greater transparency in the policy process and better availability of data is required.

Implications for the broader healthcare policies and reforms in China

In this research, *The Campaign* also acted as a lens to understand policy implementation in the healthcare system in China. It was clear that standalone measures to change prescribing would be futile without the support from fundamental reforms in health systems to change influencing factors of antibiotic use at all levels, and *The Campaign's* perceived success in implementation was linked to previous and ongoing reforms in healthcare financing and delivery, which continue to move in a positive direction.

In the post-*Campaign* period, adjustments to the central-led strategy for policy implementation and the focus on higher-level hospitals will be necessary, especially because of the dynamics present in its complex and decentralised healthcare system. For secondary and tertiary hospitals, the substantial influence of local actors on policy implementation and the determining role of healthcare financing in defining the scope means that further reforms to strengthen healthcare financing will be indispensable in order to guarantee effective implementation in the longer term. At the same time, continuous efforts will be required to reduce the role of the prescription of pharmaceuticals in the provision of healthcare through, most fundamentally, dissociating prescribing from revenue generation. Furthermore, much work will be required at the primary care level in the near future as primary care providers, which are not the main subjects of *The Campaign* and are much less equipped to implement antibiotic stewardship, becomes enrolled in upcoming plans for policy implementation. Besides the difficulties in putting in place a viable plan for the surveillance of antibiotic use and resistance in resource-limited settings, a major challenge for policy implementation at the primary care level concerns the on the challenges in the ongoing primary care reform in China. Aimed at improving and redefining primary care, the reform has been a work in progress. On the one hand, existing policies, exemplified by the policy package of essential medicines, have restricted the services at the primary

care level by limiting pharmaceuticals available at this level and replacing the focus on healthcare service provision with public health service provision, on the basis that more expensive and advanced pharmaceuticals and services were not necessary at this level. On the other hand, measures are being introduced to improve the capacity of primary care providers in an attempt to persuade patients to utilise primary care instead of higher levels of healthcare where possible. This effectively creates a persistent paradox, as the most capable prescribers are still much more attracted to the career prospects at higher-level hospitals, and patients are attracted to the better prescribers. A fundamental solution to this paradox and establishing a functional tiered-healthcare system in China will be needed.

Implications for future research

The findings of this research shed light on two aspects of future research. In terms of research on the implementation of antibiotic stewardship policies in China, it will be useful to examine policy implementation in more typical settings in the country. Comparative case studies within China will be needed to further illuminate the influence of context on process at both the central and the hospital levels, and establish other crucial factors to policy implementation. Thorough understanding of these factors can inform methodological studies, as the development of process indicators for the implementation of antibiotic stewardship policies is in demand at the moment. In order to support this type of study, in-depth studies of individual policy, and proper theoretical-based studies in other countries will be required. To enable measurement of policy implementation, which is fundamental to introducing the target approach and monitoring and evaluation of policy in general, it will be highly necessary to find ways to improve surveillance of antibiotic use and resistance, especially in resource-poor settings. As highlighted in the discussion about use of theory, the use of a conceptual framework can effectively bridge top-down and bottom-up perspectives in future studies and bring focus to the organisational level processes.

This work also has more general application to healthcare system research. Much research is needed to better understand the interaction between healthcare policies and antibiotic stewardship, and their impact on antibiotic use. In particular, the potential unintentional consequences of healthcare and antibiotic stewardship policies on antibiotic use have largely gone undetected. Whilst past reforms encourage overuse, new reforms could push antibiotic use to another extreme by discouraging

prescribers from making the best decisions in the patient's interest. For example, cost containment in social insurance reimbursement could lead to undertreatment; increasing collaboration across secondary and tertiary hospitals could strain the tighter policy restrictions on antibiotic use in secondary hospitals; restricting antibiotic access at primary level could drive more patients towards higher-level hospitals, where they were more likely to be exposed to antibiotic resistance; strengthening of existing bureaucracy and hierarchy within the hospital and across government and hospitals could lead to loss of physician autonomy; one-dimensional assessment of the outcomes of complex medical practices could create uniform use patterns that do not reflect local epidemiological needs; and over-simplification of the message for antibiotic stewardship could lead to patients' misunderstanding of antibiotics.

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