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Evidence use for global health policy development:

a case study of malaria preventive treatment policy processes at the

World Health Organization

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I, Bianca Juliana D'Souza, 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.



Doctor of Public Health (DrPH) Integrating Statement

The DrPH programme aims to equip its graduates with the experience to deal with the particular challenges of understanding and adapting scientific knowledge in order to achieve public health gains, as well as the analytical and practical skills required by managers and leaders in public health.

When I first began working at the London School of Hygiene and Tropical Medicine (LSHTM) in 2008 to manage the Artemisinin-based Combination Therapy (ACT) Consortium, a \$40m Bill and Melinda Gates Foundation-funded global research consortium with the aim to develop and evaluate delivery mechanisms to improve ACT use in Africa and Asia, I viewed the programme primarily as a form of professional development. As a ‘staff student’ I wanted to benefit from the expertise of colleagues, as well as formally learn about and reflect on the relationship between evidence and policy, while working on ways to facilitate that process as part of my job. In this regard, the first part of the DrPH, the taught component, was well-timed to be particularly helpful.

The taught component consisted of two compulsory modules. In “Understanding Leadership, Management and Organisations”, taken in 2009, I explored a range of issues and theories relating to management, leadership, and organisations, and the application of these theories both to public health organisations, and my own management practice. “Evidence Based Public Health Policy”, taken in 2010, focused on key skills required for improving and shaping policy and practice, involving accessing, understanding, developing, disseminating, and facilitating the

use of evidence for better public health outcomes. At the time, I was attempting to juggle management issues within the ACT Consortium, while also trying to figure out how to best position and disseminate our study results in the future, so I found both modules to be full of theoretically-grounded practical advice.

It was during this taught component phase that I first heard of intermittent preventive treatment and the Intermittent Preventive Treatment for infants (IPTi) Consortium, which had involved many malaria researchers from LSHTM. LSHTM is well known worldwide for its innovative malaria research, among other areas of expertise. I became fascinated by the ‘from the trenches’ stories I heard from malaria colleagues about what policy making was like within the World Health Organization (WHO). As a result of my work with the ACT Consortium (I was tasked with developing a plan to maximise our policy uptake, without treading on the toes of the WHO Global Malaria Programme, WHO-GMP, whose then-director happened to be on our scientific board), I was able to secure a placement with WHO-GMP for my Organisational and Policy Analysis (OPA) project.

The OPA project – the second component of the DrPH programme – involves research that provides DrPH students with the opportunity to observe and analyse the workings of a public health organisation in its policy environment, in order to gain a better understanding of how to develop effective public health organisations and policy. WHO-GMP was the perfect place to observe and analyse public health policy making in action.

In 2011, WHO-GMP were in the process of embarking on a major review and re-design of its policy setting process in order to be more responsive to what was an increasingly dynamic and rapidly evolving malaria landscape. My OPA covered the behind-the-scenes period that led to the creation of the Malaria Policy Advisory Committee (MPAC), a newer, more agile, and transparent evidence advisory body for global malaria control and elimination, compared to the system that was in place during the time of the IPTi policy development process.

The aim of my OPA was to understand the organisational factors and forces that drove and restrained the change process for strengthening policy setting at WHO-GMP. Using the qualitative study methods of participant observation, semi-structured interviewing, and Kurt Lewin's force field analysis, my results showed that the strongest driving force for change at WHO-GMP appeared to be its leadership, specifically its director, and its organisational mandate to set health policy. Although the MPAC had yet to be constituted and convened, the driving forces identified that would most likely contribute to its success were the transparency and the timeliness of its policy recommendations. Many of my key informants used the example of the IPTi policy process (among others) as an example of what a policy process shouldn't be like. My interest in this topic was further peaked.

Following my OPA, and perhaps as a result of my by then deeper understanding of policy making within WHO, I was asked to stay on at WHO-GMP in the capacity of a consultant to help form the MPAC (its terms of reference, membership, and operating procedures), and help ensure it was "transparent, responsive, and credible"

as WHO-GMP intended. As I will later outline in this thesis, MPAC's first policy decision was for an intermittent preventive treatment, but for children (IPTc) instead of infants (IPTi). IPTc later became known as Seasonal Malaria Chemoprevention (SMC). In comparison to what I had heard about the IPTi policy process, the deliberations were relatively smooth during the discussion about SMC. Yes, not everyone in the room agreed on every aspect, but the debate was civil and the consensus to move forward was reached relatively quickly. As an observer of the process, I was curious about why this was happening. Was this 'normal'? Could it be replicated? Was this because of something the researchers did, or because of the evidence advisory committee, or both? Were there lessons to be learned from all of this?

It was during this experience of witnessing policy making in action that the seeds of what would later become my thesis – the final component of the DrPH – first began germinating. Comparing the policy process for SMC with the (what seemed to me) infamous IPTi process that preceded it, was a natural choice. If this were to have been a PhD thesis versus a DrPH thesis, I would have loved to also compare how the perceived differences between both intermittent preventive treatment evidence-to-policy processes affected their implementation. However, my supervisors and I felt it would have been too large a topic for a DrPH. It remains a question I would like to explore in future.

The ACT Consortium grant finally ended in the summer of 2016. Based on our original goals, we exceeded our expectations for results dissemination and knowledge transfer, and I am hopeful that one day in the not too distant future, we,

like IPTi and SMC before it, will feature as an LSHTM Research Excellence Framework (REF) impact case study. In the meantime, a welcome break from the consortium and the full-time world of global malaria politics finally allowed me the time, distance, and thinking space, to reflect and produce this piece of work.

Completing my thesis hasn't been an easy process, primarily because I have still continued to work part-time over the past two years, first on UK global outbreak preparedness and response, and at present on antimicrobial resistance, both fields where the good use of evidence in policy is essential. It has been necessary for me to work, but working part- versus full-time has been the only way I have been able to finish my thesis. Overall, the part-time DrPH programme has taken a long time (nine years), interspersed with lengthy periods of inactivity due to competing priorities, but I have finally managed to make it to this stage of the process, and am proud to say that I have.

I am looking forward to the coming months, where I plan to continue sharing my thesis results, and contributing to the practice of improving the public health policy process. So far I have presented papers on my thesis results at the International Conference on Public Policy in Milan in 2015 and in Singapore in 2017. Recently I contributed a paper, co-authored by my DrPH supervisor, Dr. Justin Parkhurst, which went through the peer-review process, before being published in a *Global Challenges* journal series special issue, coordinated by the Global Strategy Lab at the University of Ottawa, on "Optimising the Institutional Design of Scientific Advisory Committees for Quality, Salience, and Legitimacy". This article, together with a

previous article that was published in the *Malaria Journal* in 2012 following my DrPH OPA project, are included at the end of this thesis document for reference.

Although I am not sure what the future will hold for me in terms of a research career at LSHTM (at the time of submitting this thesis, my contract at LSHTM is due to end in September 2018), I have enjoyed the experience that working in an exciting and rich academic environment, and particularly on my own research project, has brought me.

As a public health practitioner, I remain interested in how and why policy decisions are made, and committed to how to improve that process in practice. I look forward to applying those lessons in my current and future leadership roles.

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Finally, I would like to thank my friends and family – Sarah, Felicity, Modi, Cristin, Kristin, Will, Natasha, Sujit, Venetia, Esther, Mei, Jo, Rob, David, Mum, Dad, Charlie, and many others, but most importantly, Bill, for never losing faith that I would eventually finish.

I dedicate my thesis to my late global malaria colleague and WHO Malaria Policy Advisory Committee member, Dr. Sylvia Meek, a positive influence who still serves as a source of inspiration for me that it is possible to balance life as a public health researcher and practitioner, and have fun at the same time.

Thank you all very much.

Thesis Abstract

Evidence, in its multiple forms, is often perceived as playing key roles in public health policy development, although how and why evidence is used and when, despite a wide range of research on the subject, is less clear. This thesis – the final component of the professional doctorate programme known as the Doctor of Public Health (DrPH), which is intended for leaders and future leaders in public health policy and practice – looked at the policy development processes of two different global malaria preventive treatment policies produced by the World Health Organization (WHO) known as ‘Intermittent Preventive Treatment in infants’ (IPTi) and ‘Seasonal Malaria Chemoprevention’ (SMC).

The aim of the DrPH research was to better understand the influences on the use of evidence in policy making in organisations such as the WHO, using a case study of the WHO’s malaria department – the Global Malaria Programme (WHO-GMP). Specifically, the thesis objectives are to: (a) explore the factors that influenced the consideration of particular evidence at WHO-GMP, i.e. determine what was considered ‘good evidence’ for policy (and why) in the case of IPTi and SMC; and (b) examine how factors associated with the policy process influenced eventual policy outcomes at WHO-GMP, i.e. determine what was considered ‘good use of evidence’ for policy (and why) in the case of IPTi and SMC. A more holistic understanding of what influences the use of evidence in policy making may help shed more light on the complexity of evidence use, and may help, in multidimensional ways, to increase and improve evidence use, which is the goal of many public health organisations, including the WHO.

By comparing the policy development processes for IPTi compared to SMC, the findings showed that forms of ‘good evidence’ often held up as high quality in terms of technical considerations, though important, were not sufficient to ensure universal agreement and uptake of recommendations, even within a highly technocratic body such as WHO-GMP. An analysis of 29 key informant interviews found that the perceived relevance of evidence to the policy question being asked mattered to expert actors, and that they also retained a concern over the legitimacy of the process by which technical evidence was brought to bear in the policy development process. Cash and colleagues’ (2003) findings from the field of sustainable development, that evidence must be credible, salient, and legitimate, to be accepted by the public, appears to equally apply within this evidence advisory body within WHO.

While the WHO has principally focused on technical criteria for evidence inclusion in its policy development processes, this study suggests that the design and functionality of its advisory bodies must also enable transparent, responsive, and credible processes of evidence review to ensure that these bodies are effective in producing advice that engenders change in policy and practice. The findings from this thesis contribute to the public health policy literature on evidence use in policy making, and will be of interest to scholars of health policy as well as public health policy makers and practitioners.

Table of contents	Page no.
DrPH Integrating statement	3
Acknowledgements	9
Thesis Abstract	10
Acronyms	17
Chapter 1: Introduction	19
1.1 Introduction	19
1.2 Background	20
1.3 Case study setting	27
1.4 Case study context	31
1.5 Aims and objectives	39
1.6 Summary and outline of thesis	40
Chapter 2: Existing reviews and theoretical perspectives	42
2.1 Introduction	42
2.2 Ways of perceiving evidence use in public health policy making	42
2.3 Influences on evidence use	48
2.4 Managing the political process of policy making	57
2.5 Reflective summary and analytical framework	66

Chapter 3: Methods	72
3.1 Introduction	72
3.2 Approach to the DrPH and case study	72
3.3 Case selection	78
3.4 Data collection	81
3.5 Coding and analysis	86
3.6 Ethics	88
Chapter 4: The global malaria context and the case of intermittent preventive treatment	89
4.1 Introduction	89
4.2 The fall and rise of malaria as a global health issue	90
4.3 Twists and turns in the policy journey of the IPTi Consortium	95
4.4 Strengthening the policy process for global malaria control and elimination, and the emergence of SMC as a policy success	101
4.5 Reflective summary	106
Chapter 5: The features of the evidence used to form global malaria intermittent preventive treatment policy	109
5.1 Introduction	109
5.2 Findings	110
5.2.1 Differences affecting credibility	110

i.	Protective efficacy	111
ii.	Repeatability, and reliability, of results	114
iii.	Drug resistance and safety issues	116
iv.	Rebound effect	118
v.	Strength and quality	119
5.2.2	Differences affecting salience	122
i.	Local applicability	123
ii.	Contextual relevance	125
iii.	Generalisability	126
iv.	Timing	129
5.3	Reflective summary	132

Chapter 6: The process of forming global malaria intermittent preventive treatment policy **135**

6.1	Introduction	135
6.2	Findings	137
6.2.1	Differences affecting legitimacy	137
i.	Structural differences	139
-	Research-related structures	139
-	Policy development process-related structures	141
ii.	Expectations and framing	142
iii.	Broken consensus	145
iv.	Conflicting agendas	147
-	Researchers as policy advocates	148

- Funders as consortium members	153
- WHO as consortium members	157
v. Consensus versus transparency	160
vi. Membership and representation	162
6.3 Reflective summary	164
Chapter 7: Discussion, conclusions, and lessons learned	167
7.1 Introduction	167
7.2 Discussion and concluding reflections	168
7.3 Limitations and areas for future research	175
7.4 Key lessons for public health researchers and policy professionals	180
7.5 Final thoughts	184
References	187
Tables	
1. Analytical framework – factors that may shape evidence use in IPT policy development at the WHO-GMP	70
2. General summary of Key Informant roles and their involvement in the IPTi and/or SMC policy processes	83

Figures

1. Target date for a WHO policy recommendation on IPTi, as projected by the IPTi Consortium to the BMGF 96
2. Schematic view of the interactions between the different institutional elements of the IPTi Consortium 97
3. Simplified timeline of the IPTi and SMC policy development processes 107

Appendices

1. Interview topic guide 201
2. Interview information sheet and consent form 202
3. Previous (pre-MPAC) WHO-GMP policy setting processes for malaria 203
4. Publication resulting from DrPH Organisational and Policy Analysis Project
D'Souza BJ, Newman RD. 2012. Strengthening the policy setting process for global malaria control and elimination. *Malaria Journal*, 11, 28.
<https://doi.org/10.1186/1475-2875-11-28> 205
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Acronyms

ACT	Artemisinin-based Combination Therapy
AQ+SP	Amodiaquine +SP (drug used for SMC)
BMGF	Bill and Melinda Gates Foundation
DrPH	Doctor of Public Health
EBP	Evidence-based Policy
EPI	Expanded Programme on Immunisation
GRADE	Grading of Recommendations Assessment, Development and Evaluation
GRC	Guidelines Review Committee
IOM	Institute of Medicine
IPTc	Intermittent Preventive Treatment in children (now SMC)
IPTi	Intermittent Preventive Treatment in infants
IPTp	Intermittent Preventive Treatment in pregnancy
IRS	Indoor Residual Spraying
ITN	Insecticide Treated Mosquito Nets
IVB	Immunology, Vaccines and Biologicals Unit
KI	Key Informant
KTE	Knowledge Transfer and Exchange
LMIC	Low and Middle Income Country
LSHTM	London School of Hygiene & Tropical Medicine
MPAC	Malaria Policy Advisory Committee
NICE	National Institute for Health and Care Excellence
OPA	Organisational and Policy Analysis

PIRU	Policy Innovation Research Unit
RCT	Randomised Controlled Trial
REF	Research Excellence Framework
SAGE	Strategic Advisory Group of Experts
SMC	Seasonal Malaria Chemoprevention (formerly IPTc)
SP	Sulfadoxine-Pyrimethamine (drug used for IPTi)
STAG	Strategic and Technical Advisory Group
TEG	Technical Expert Group
TRAC	Technical and Research Advisory Committee
UN	United Nations
UNICEF	United Nations Children's Fund
WHO	World Health Organization
WHO-GMP	WHO Global Malaria Programme

Chapter 1. Introduction

1.1 Introduction

This is a study investigating evidence use in global malaria policy development at the World Health Organization (WHO). Past work looking at decision making at WHO has engaged with topics such as its criteria for guideline development (Burda et al., 2014, Oxman et al., 2007) or critical reflection on the organisation's response to global health crises (Horton, 2006, Piot, 2014, Abeysinghe, 2015). In this study, however, the focus is not so much on the outcomes of decisions, but rather on the internal processes involved, observing what is sometimes referred to as the 'black box' of how evidence actually informs the policy process (Birkland, 2014), within the primary global health institution responsible for the production of normative guidance to 193 member states (WHO, 2007b).

Using interview data recorded between 2014 and 2015 when I was working part-time at WHO, and as part of my DrPH, I explore the factors that influenced the consideration of particular evidence, and examine how factors associated with the policy process influenced eventual policy outcomes for global malaria control and prevention.

In this introductory chapter, I explain how my interest in evidence use in public health policy making developed; describe the context of malaria and 'intermittent preventive treatment', which is a type of malaria intervention recommended as policy by WHO, the focus of my case study; outline my DrPH thesis aims and

objectives; ending with a brief summary of the remaining chapters that follow.

1.2 Background

‘Evidence-based public health policy and practice’ is a core component of the DrPH programme at LSHTM (LSHTM, 2017a), and as a staff member at LSHTM, there are constant reminders, e.g. via award news, the academic staff promotion process, and the school’s Research Excellence Framework (REF) ranking, of the importance placed on research that influences public health policy and practice, and the prestige impactful research bestows on both the researcher as an individual, and LSHTM as an institution (LSHTM, 2017b). Indeed, a central part of my previous job as the manager of a large global malaria research consortium led by LSHTM was to ensure that our ‘evidence’ was ‘policy-driven’ and ultimately influenced policy via high-impact journals and establishing a presence at high-level policy discussions. When I agreed to take on that role, I did not fully understand what this jargon meant. I have since come to learn that I am not alone; despite the discourse around evidence and its valuable role in forming policy, scratching below the surface reveals that there is little common agreement on what evidence is, let alone how and when it influences policy (Lin and Gibson, 2003, Nutley et al., 2007).

Yet the pervasive terminology of ‘evidence-based policy’ (EBP) is difficult to avoid, particularly when you work in public health. This is partly because the use of evidence has been a long-established part of the policy process, and within public health, research evidence is in some respects considered the necessary foundation for many health policy decisions (c.f. Lavis et al., 2009, Lomas and Brown, 2009,

Nutley et al., 2007). Whether in the form of peer validated research or defined more broadly as any type of knowledge that influences a decision, particular uses of evidence can help to project rationality about a decision or an outcome (Sanderson, 2006, Parsons, 2002, Berridge and Stanton, 1999).

Sanderson (2006) explains that one of the presumptions behind policy making bodies and institutions wanting to be evidence-based is that policies and decisions formally influenced by evidence are perceived to be better than they otherwise would have been without evidence. Relatedly, taking that presumption further, Saunders (2005) suggests that adopting a culture of evidence use within a policy making institution is seen to help, in theory, to mitigate the ideologies and biases that individuals bring to the processes within that organisation. Parsons' (2002) explanation of institutional cultures adopting evidence use is that evidence-based policy making has a hypothesised link between improved policy development and better policy delivery via the management of policy and decision processes.

The public health sector has particularly embraced the language of EBP, in part because of the increased emphasis and influence of evidence-based medicine, which has driven certain ways evidence has been used within the policy process, although sometimes without considering how medicine may be different from public health (Cookson, 2005, Berridge and Stanton, 1999).

For example, a commonly cited definition of evidence-based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients (Sackett et al., 1996). However, Eddy

(2005) points out that what is missing from this definition is the question of implementation and the many ways that applying evidence to practice might happen in a real-life setting. What he draws attention to in his conclusion is that evidence-based medicine is about “a set of principles and methods intended to ensure that to the greatest extent possible, medical decisions, guidelines, and other types of policies are based on and consistent with good evidence on effectiveness and benefit” (Eddy, 2005, p. 16). Essentially evidence-based medicine is a way of working that incorporates elements of rigour, rationality, and continuous learning, in order to keep up with the latest evidence advances and, unlike evidence-based public health policy that typically aims for population-level outcomes, it focuses on the outcomes of the individual (Berridge and Stanton, 1999). So despite the connections between evidence-based policy and evidence-based medicine, the models are not directly transferable. Evidence in a clinical setting is decidedly different from that in social policy, with the latter being more open to contestation, competing ‘right’ answers, and political expediency than the former (French et al., 2009, Klein, 2000), which some argue is as it should be (Parkhurst, 2017, Cairney, 2015).

Criticisms of how evidence-based medicine is applied in relation to its influence on EBP, do not dispute the desire to use evidence to make sure the best care possible in patients or populations is achieved, but rather focus on how some types of evidence become privileged over others (Greenhalgh et al., 2014, Greenhalgh and Russell, 2009). There is a need, some argue (for example, see Klein, 2000, Parkhurst, 2017), for more contextualisation when applying research findings from one situation to another. One of the reasons for this is because of how evidence is defined. Specifically that evidence will be defined differently by different users, according to

use, and that context will shape this (Klein, 2000, Nutley et al., 2007, Lin and Gibson, 2003, Dobrow et al., 2004).

For example in public health, most rankings or hierarchies of evidence place Randomised Controlled Trials (RCTs) at the top. The reason RCTs are often given priority is because of their rigour in ensuring internal validity, i.e. their ability to show an intervention effect with certainty (Petticrew and Roberts, 2003, Cartwright and Hardie, 2012). However, the internal and external validity of the evidence are confused in the assumed superiority of RCTs within public health, as there is a need for additional information for most social and politically relevant questions to understand whether an intervention tested in an RCT will produce similar results for a policy maker, i.e. whether or not something that worked ‘there’ will also work ‘here’ in their own country or context (Cartwright and Hardie, 2012, Parkhurst, 2017).

RCTs appear to be mainly useful to answer a subset of questions that a policy maker may be considering on a given issue, such as whether a medical intervention is effective (Cartwright and Hardie, 2012, Parkhurst, 2017). They tend to be less helpful in answering broader social questions such as whether that intervention would be accepted or appropriate (Parkhurst, 2017, Petticrew and Roberts, 2003).

Parkhurst (2017) notes that one reason evidence-based policy has been very effective in the field of clinical medicine is because of how RCT findings, testing new drug treatments for example, relate to and can be applied to human physiology. That is, because drug treatments work through biochemical and physiological mechanisms

that humans share, researchers and policy makers can assume some generalisability of drug RCT results across populations, even though local contextual elements may differ. However, he explains that this form of evidence application becomes much more difficult and complicated when it is applied to more complex policy questions and solutions related to clinical medicine interventions which have to (and should) reflect conflicting social values and norms. An example he provides is that for the use of the drug Viagra to treat erectile dysfunction, where the evidence (16 RCTs) clearly demonstrates that the drug is effective and ‘works’, but does not answer the question of whether a government should prioritise it as a form of public health intervention over other public health priorities that might appear to have a weaker evidence base according to the medical model of health (Parkhurst, 2017, p. 20).

It would appear that in some cases, promoting RCTs as the best type of evidence to guide policy in effect favours or promotes policy solutions towards those issues conducive to RCTs to begin with (Abeysinghe and Parkhurst, 2016, Barnes and Parkhurst, 2014, Petticrew and Roberts, 2003, Parkhurst, 2017), such as the therapeutic effect of short-term clinical treatments for diseases like malaria. Smith (2013) explains that this preference is compounded by the notion among many academic researchers, implicit in the evidence use literature, which assumes that *more* use of the ‘best’ evidence equals *better* use of evidence. Parkhurst (2017) and others have identified this evidence hierarchy approach as problematic due to the way it can work to de-politicise socially complex policy debates by prioritising technically effective solutions over socially or politically desirable ones (see also Cairney, 2015, Oliver et al., 2014b).

Therefore, as a public health practitioner with a research interest in evidence use, while one can appreciate the appeal of RCTs to public health policy makers in search of quantifiable solutions to certain measurable questions, one must also acknowledge that ‘evidence-based policy making’, when reflective of multiple competing social values, is not as straightforward or linear in the way the term ‘evidence-based’ policy implies it might be (Parkhurst, 2017, Smith, 2013, Cairney, 2015). In addition, the extent to which public health policies ‘use’ evidence in multiple forms, and how multiple competing tensions are eventually resolved by actors in the practice of policy development, is not always obvious and can sometimes be difficult to discern (c.f. Weiss, 1979, Black, 2001, Oliver et al., 2014b), not just for scholars of evidence use, but speaking from experience, for actors involved in the policy development process itself.

Smith (2013) recognises these challenges from the start, quoting Pawson (2006, p. viii) to say:

There is no such thing as evidence-based policy. Evidence is the six-stone weakling of the policy world. Even its most enthusiastic advocates are inclined to prefer the phrase ‘evidence-informed policy’ as a way of conveying a more authentic impression of research’s sway.... (Smith, 2013, p. 1).

This recognition aligns with my own experience as a public health practitioner tasked with increasing and improving the use of my global malaria research consortium’s ‘policy-driven’ evidence; it wasn’t clear to me how we could influence policy through our research, given the RCT-related limitations of internal versus external validity, let alone whether promoting our research results in a ‘policy-driven’ way was even the right thing to do. Some public health actors do attempt to

at least acknowledge the limits of and tensions within EBP in this way, so that the language they use to describe the influence of evidence in policy making still reflects the principle of, and their underlying good intention to use, evidence to improve the public health of a population (Fielding and Briss, 2006). Some scholars suggest that indeed it might be better to advocate for ‘evidence-informed’ rather than ‘evidence-based’ policy (see Young et al., 2002, Boaz et al., 2008, Head, 2016), although these authors, and others (see Smith, 2013, Pawson, 2006) also acknowledge that the term still has its limitations, given the continued emphasis on the role of evidence over other influencing factors.

Despite the residual limitations of the term, an example of a public health actor and global health institution preferring the use of the phrase ‘evidence-informed policy’ over that of EBP is the WHO Global Malaria Programme (WHO-GMP), which is the setting of my case study. The phrase is the preferred expression the WHO-GMP uses to describe the goal of its principal evidence advisory body, the Malaria Policy Advisory Committee (MPAC), in addition to some other interesting word choice. MPAC’s terms of reference from its creation in 2012 state (*italics added for emphasis*):

WHO-GMP, in keeping with its mandate to articulate ethical and *evidence-informed* policies for malaria control, established MPAC as a mechanism to increase the *timeliness, transparency, independence* and *relevance* of its recommendations to WHO Member States for malaria control and elimination (WHO, 2012b, p. 1).

Many years after the creation of MPAC and its terms of reference, the clear and deliberate use of these words within an organisation that internally (based on my observation and experience) prides itself on its evidence review processes, technical

authority, and normative function, still intrigues me, to the extent that I eventually decided to make evidence use for policy development within WHO-GMP the focus of my DrPH thesis.

1.3 Case study setting

I first began working at WHO-GMP in 2011 as part of my DrPH Organisational and Policy Analysis project (see D'Souza, 2014), documenting and analysing the drivers and constraints of WHO-GMP's efforts to strengthen its policy setting process via MPAC, and then again between 2012 and 2015 to support MPAC's biannual open-session evidence advisory meetings. It became clear to me over this period that the *process* of evidence-use mattered as much to WHO-GMP as the evidence itself, and I wanted to understand how and why this was the case.

Knowing that there was already a substantial body of work not only on the use of evidence in policy (c.f. Lin and Gibson, 2003, Nutley et al., 2007), but also on ways to overcome 'barriers' and increase 'knowledge transfer' (Contandriopoulos et al., 2010, Estabrooks et al., 2006, Innvaer et al., 2002, Mitton et al., 2007, Oliver et al., 2014a), as well as increasing attention to the shortcoming of these approaches (Cairney, 2015, Oliver et al., 2014b, Parkhurst, 2017, Smith, 2013) (see next chapter for review of this literature), I wished to further explore this type of discourse, but in a context which would satisfy my (and the DrPH programme's) preference for research which might eventually be of practical value for public health policy makers and practitioners.

For example, I became aware that “instead of repeating studies of perceptions of barriers and facilitators of use of research evidence, appropriate methods must be used to answer questions about when, why, how, and who finds what type of knowledge sound, timely, and relevant at different stages of the policy cycle” (Oliver et al., 2014b, p. 8). The notion is that a more holistic understanding of influencing factors, such as the role of different policy actors or their institutional structures, which have been acknowledged but are not well explored in the current applied literature (see Liverani et al., 2013, Mitton et al., 2007, Oliver et al., 2014b), could help shed some light on the complexity of evidence use in health policy making (Greenhalgh et al., 2014, Oliver et al., 2014b). As Weiss and Bucuvalas (1980) pointed out several decades ago:

However well we come to understand the nature, flow, and response to...research, if we are ever to discern its influence on public policy we will have to confront the realities of the decision-making process. Only with better awareness of the convoluted ways in which decisions take shape – and the complex interplay of situations, problems, opportunities, and actors – will we make headway in untangling the contributions of ... knowledge to the formation of policy” (Weiss and Bucuvalas, 1980, p. 274).

Many experts seem to agree with the notion that public health researchers and practitioners looking to improve evidence use in policy making should and/or are ready to move beyond the theoretically naive concepts of barriers and facilitators of a seemingly linear process, and into the messy complex social reality that is evidence-based policy making (Cairney, 2015, Oliver et al., 2014b, Parkhurst, 2017, Smith, 2013). Parkhurst (2017) for instance, argues that a shift is needed to engage with questions of what improved evidence use looks like by asking explicitly normative questions about how we might judge ‘good evidence’ in terms of policy

appropriateness, and the ‘good use of evidence’ from a perspective of the decision making process. He suggests that these considerations can then enable reflections on how to improve ‘evidence advisory systems’ over time, which he defines as the collection of structural bodies or groups, their rules, and norms of practice, which serve to govern the ways that evidence informs policy decisions (Parkhurst, 2017).

The ‘evidence advisory system’ that this thesis focuses on is on the role and function of evidence advisory bodies within WHO, an influential global health institution and archetypal technocratic agency that frames itself as a steward and promoter of evidence-based policy making (WHO, 2007b, p. 5), since its evidence advisory bodies are made up of experts that are explicitly tasked with the review of scientific information on behalf of WHO. In the case of the WHO-GMP, the focus of this study, evidence advisory body members are tasked with reviewing the evidence and advising WHO in their development of global policy recommendations to control and eliminate malaria (WHO, 2012b). The experiences, composition, and professional status of actors involved with these bodies are among the factors that interact and influence how evidence is interpreted and how recommendations are formed (Atkins et al., 2013). In the case of WHO-GMP, evidence advisory body members, such as those on its principal evidence advisory body, MPAC, tend to be clinicians (WHO, 2017a), who having been trained in the practice of evidence-based medicine described earlier in this chapter, tend to bring that experience and belief system with them into policy deliberation (Greenhalgh et al., 2014).

Other insights into the role and function of evidence advisory bodies in health are part of a slowly growing literature on how to improve their inner workings, for

example by including patient experience information (Campbell et al., 2010) or economic information (Eddama and Coast, 2009, Williams et al., 2007) in order to promote the integration of evidence into health policy and practice. Other literature has been concerned with exploring how such bodies deal with constructing or facilitating a process less prone to bias, for example by applying clear, comprehensive, and consistent evidence inclusion criteria (Schlander, 2008).

What many of these studies have in common, however, is their focus on advisory bodies serving national governments. In health care, an exemplar often referenced is the National Institute for Health and Care Excellence (NICE) in England and Wales (see Culyer and Rawlins, 2012, Culyer, 2006, Kelly et al., 2010), which serves a mandated role to develop guidelines and make decisions that can have direct influence over policy and practice for the National Health Service. Yet, few studies examine the processes and perceptions of global health evidence advisory bodies, such as MPAC, who advise technocratic agencies such as WHO, in this case WHO-GMP, on recommendations for global health policy, in this case global malaria control and elimination. This may be an important distinction, however, because global health governance systems are decidedly different to national bodies, given the lack of a supreme authority and much more indirect systems of accountability to population groups.

Exploring the influences on the use of evidence in policy making within a global health evidence advisory body (MPAC) within a global health policy institution (WHO) might be useful to help address some of the limitations highlighted by Oliver and colleagues (2014b), by understanding the ways in which evidence and policy

interact, and how these factors influence policy outcomes for a global health priority (malaria). In particular, I will compare two different policy development processes for malaria control and prevention that took place within the department between 2006 and 2012 (these are outlined in brief in the next section to set up my research question, but are discussed in more detail in Chapter 4 to provide the full context for my case study). Both the policies I refer to relate to what is known within the global malaria community as ‘intermittent preventive treatment’, or IPT, which is the delivery of a treatment dose of an anti-malarial drug given at pre-specified times for the prevention of malaria, regardless of the presence of symptoms or confirmed malaria infection.

The findings from this comparison may contribute to a growing body of literature on evidence use and evidence advisory bodies in global public health. More importantly perhaps, in the context of the DrPH programme and the overarching goals of public health (to promote population health), the results may contribute to the understanding by public health policy makers and practitioners of how ‘good evidence’ and ‘good use of evidence’ to build better ‘evidence advisory systems’ can more effectively contribute to solving complex public health problems, of which preventing malaria infection, and sustaining that prevention, is just one prime example.

1.4 Case study context

Malaria is a complex, mosquito-borne, infectious disease and a major global public health problem. In 2015 there were over 200 million new cases of malaria and nearly

500,000 deaths (WHO, 2016). An estimated 90% of malaria cases and 92% of malaria deaths occur in Africa, the majority among children below five years of age (WHO, 2016). This makes this particular age group, in this particular geographical location, an important target for global health policy makers and funders of public health research and programmes, who have a vested interest in reducing the global burden of malaria for moral, economic, and global health security reasons (WHO, 2015).

The global malaria community, which is comprised of funders, researchers, policy makers, and other stakeholders, state that they are strongly committed to finding ways of addressing the consequences of malaria for vulnerable populations (RBM, 2015, Malaria Summit, 2018). One of the ways they do this is through the development and implementation of public health interventions to try to reduce the number (burden) of malaria cases (morbidity) and malaria deaths (mortality). Intermittent preventive treatment (IPT) is one such public health intervention aimed at treating and preventing malaria episodes in certain at-risk populations such as infants (IPTi), children (IPTc/SMC), and pregnant women (IPTp), whether they are known to be infected with malaria or not, through pre-specified drug treatment doses at pre-specified times separated by 'intermittent' periods without drug treatment (both the ideal choice of drug treatment and the dose timing(s) will vary, depending on the at-risk target population).

The way the IPT intervention works is two-fold: (a) it clears existing malaria parasites from the human body through treatment with effective anti-malarial drugs, and (b) it helps prevent new infections by maintaining therapeutic levels of that anti-

malarial drug in the human body over a sustained period of time when the person is considered to be most ‘at risk’, through repeated dosing (WHO, 2015, Greenwood, 2006). Because IPT is a form of mass drug administration, where the purpose is primarily to *prevent* malaria infection and by extension death, whether or not the intervention ‘works’ is measured by the length and extent of its ‘protective efficacy’, which in plain language, is a percentage calculation of the amount of reduced clinical malaria episodes in infants (or children, or pregnant women, depending on the form of IPT) as a result of that particular IPT intervention (WHO, 2010, WHO, 2012c, WHO, 2012a). In meta-analysis or other situations where a body of evidence (several IPT RCTs for example) is considered, protective efficacy is often ‘pooled’ to give an average measure of protective effect. It should be noted that as with other forms of mass drug administration, recommending IPT as a preventive treatment for malaria is not based on protective efficacy alone; researchers and policy makers also consider other relevant (but mostly technical) information in balancing potential good versus harm, such as measures of drug safety, the possibility of a ‘rebound’ effect once naturally built immunity in malaria-endemic populations is lost, and the impact on drug resistance of an increasingly limited array of effective anti-malarial drugs (WHO, 2010, WHO, 2012c, WHO, 2012a).

In 2001, the results of a RCT in Tanzania using Intermittent Preventive Treatment in infants, or IPTi, using the anti-malarial drug *Sulfadoxine–Pyrimethamine* (SP), delivered through the Expanded Programme on Immunisation (EPI), which is the WHO’s standardised essential vaccine schedule for infants, showed that IPTi could be a useful public health intervention as it reduced clinical malaria episodes in infants by 59% (Schellenberg et al., 2001). Subsequently, a global research

partnership, funded by the Bill and Melinda Gates Foundation (BMGF), was established in 2003 called the IPTi Consortium whose goal was to build the evidence base for IPTi, that would then lead to a policy recommendation for IPTi by the WHO (IPTi Consortium, 2003). In fact, a ‘Policy Platform’ within WHO was established in 2006 by the Consortium specifically for the purpose of facilitating a WHO IPTi policy recommendation.

I will explore the timeline of the IPTi policy development in more detail in my contextual chapter (Chapter 4), but to summarise, following repeated stalling of the policy process, for numerous reasons, despite a seeming wealth of evidence on IPTi, it took until April 2009, eight years after the first IPTi study was published, for WHO, via its policy setting process at the time, to finally issue a global policy recommendation on IPTi to its member states in 2010 (see WHO, 2010).

Shortly after this, in 2011, WHO-GMP embarked on the policy setting strengthening exercise I became involved with as part of my DrPH. Its goal was to increase the ‘timeliness’, ‘transparency’, ‘independence’, and ‘relevance’ of its recommendations to WHO member states in relation to malaria control and elimination (D’Souza, 2014). The result of that exercise was the evidence advisory body, MPAC, which was first convened in 2012 (D’Souza and Newman, 2012).

The first body of evidence to come under MPAC review was for Seasonal Malaria Chemoprevention (SMC), formerly known as IPTc, which like IPTi is a form of intermittent preventive treatment, but for children (between one to five years of age) instead of infants (under one years old). SMC is officially defined as the intermittent

administration (once a month, up to four months) of full treatment courses of the anti-malarial drug (*Amodiaquine* + *SP*) during the malaria season to prevent malarial illness by maintaining therapeutic anti-malarial drug concentrations in the blood throughout the period of greatest malarial risk (WHO, 2012c), which for SMC-relevant countries is essentially the rainy season.

Here, similar to IPTi, there was a promising RCT showing high (86%) protective efficacy (Cisse et al., 2006), but unlike with IPTi, an official consortium with overt policy goals via a ‘Policy Platform’ was never formed. Again, I will explore the timeline of the SMC policy development in more detail in Chapter 4, but in short, a series of non-controversial SMC studies culminated in a formal meeting of a single WHO evidence advisory body (the Chemotherapy Technical Expert Group, or TEG) to review the evidence for SMC in May 2011, which resulted in a positive policy recommendation for the intervention (see WHO, 2011c). The recommendation was reviewed by the newly formed MPAC in February 2012, and by March, WHO-GMP issued a policy recommendation for SMC (WHO, 2012c).

Within a year of the announcement and accompanying policy document from WHO recommending SMC, an implementation guide was published, nine countries included SMC in their strategic plans for malaria control, and SMC was implemented in southern Senegal, in parts of Mali, Chad, and Niger, and in a pilot scheme in northern Nigeria (Bhasin et al., 2014). In comparison, for IPTi, it took several years for an implementation guide to be published, and only one African country has implemented IPTi as a policy (Greenwood, 2018).

Although there are some commonalities between the two policies (both are forms of IPT for malaria), there are also differences, for example in target age group and implementation mechanism (WHO, 2010, WHO, 2012c). In addition, although there was some overlap in the timeline between both policy processes, the system of evidence advice had changed within WHO-GMP by the time of the SMC policy decision. Therefore, although comparisons can be made between the two policy processes, they are not directly comparable; my unit of study is WHO-GMP rather than the two policy processes themselves.

One aspect about the two policy development processes that allows for comparison however, is that they resulted in two very different perceptions by the same stakeholders about what they viewed as the ‘success’ of those processes. Perhaps this is to be expected given WHO-GMP’s attempts to strengthen its policy setting processes by the time of SMC (see D'Souza and Newman, 2012), but it does not explain how and why the SMC policy development process is perceived to have been somehow better according to the actors involved.

I will expand on these aspects in greater detail in the following contextual and results chapters, but in summary, for IPTi, the process through which evidence was used to inform policy was seen as contentious and problematic to those who were involved, in comparison to the process for SMC (LSHTM, 2014a, LSHTM, 2014b). For example, many of the researchers for both IPTi and SMC were from LSHTM, where I am currently employed. LSHTM, like most other institutes of higher education in the UK, takes part in the UK government’s Research Excellence Framework (REF) exercise that ranks them on the measure of their research impact, which is a

reflection of “the extent to which [their] research has influenced policy and the wider world” (LSHTM, 2014c).

REF scores are considered to be especially important to research-focused, graduate-only institutions like LSHTM, which get no additional income through fees from undergraduates, since The Higher Education Funding Council for England uses REF outcomes to calculate each institution's annual research funding allocation. As a result, LSHTM spends a lot of time (several years based on my experience) choosing, and then carefully crafting, optimal individual impact case studies, in the hopes that they will be judged as outstanding, which in turn improves LSHTM's ranking in the REF tables of excellence. During the last REF exercise in 2014, LSHTM, which was eventually ranked no. 10 overall out of all universities in the UK, and no. 2 on the specific measure of impact, submitted a total of 27 individual impact case studies for REF consideration, including one each on IPTi and SMC (LSHTM, 2014c).

The LSHTM REF impact case study on SMC states:

The way in which SMC has progressed rapidly from pilot research studies to early implementation is widely regarded as a model of how this process should be conducted. Staff from LSHTM, working together with their partners in Africa, have played a key role in all stages of this process. (LSHTM, 2014a, p. 3)

In comparison, for IPTi, the LSHTM REF impact case study (LSHTM, 2014b), which could not claim for IPTi to be as emphatic a success, cautiously concludes:

The complexities of the policy-making process provided a learning opportunity helping groups (including the ACT Consortium) to engage better with policy-makers. (LSHTM, 2014b, p. 3)

It should be noted that it isn't just LSHTM researchers who use IPTi as an example of a 'learning opportunity' instead of a policy success. For example, researchers at the Barcelona Institute for Global Health, also heavily involved as part of the IPTi Consortium, whose operations were led by their institute, uses the case of 'What went wrong with IPTi?' as one of the core case studies during teaching on its masters-level global health courses (ISGlobal, 2014).

In terms of the formal academic literature however, and excluding my own subsequent work later either published or presented from these thesis findings, only one analysis of 'what went wrong' exists – which was work done by Valeria Oliveira Cruz and Gill Walt, who were funded by the IPTi Consortium prior to its ending in 2009, to understand what lessons could be learnt from the IPTi policy development process, if any. Using a framework of interests, institutions, and ideas, Cruz and Walt (2013) suggest that the varying tensions in the IPTi policy process were primarily the result of actors transgressing the 'delicate' boundaries between research and advocacy, and that in future, actor demands and expectations of knowledge translation need to be better understood.

Although the IPTi policy development process preceded my own time at WHO, and to a large extent LSHTM, I was nevertheless familiar with the case and perceptions of it based on my work in malaria research at LSHTM, where many of the IPTi, and SMC, researchers were based, including Cruz and Walt who later studied the IPTi process. In comparison, I noticed during my work at WHO, that SMC was, and still

is, viewed by my colleagues (both at WHO and LSHTM) as a model process due to its seeming efficiency (LSHTM, 2014a, Greenwood, 2018). I wanted to understand in my global malaria colleagues' own words, outside of neutrally presented academic journal articles or carefully crafted LSHTM REF impact case studies, why they felt this was the case, and what the reasons were behind it, according to them.

In looking at the negative assessment of one policy process in relation to the positive assessment of the other, according to those individuals involved, this case study allows for the exploration of the influencing factors that affected the use of evidence in the two IPT policy processes within WHO-GMP, during a period of organisational self-improvement related to evidence review. In studying the process of WHO global malaria policy development, there may be lessons about the institutionalisation of practices to improve evidence use, and why that matters, that can be learned by the public health and global malaria community from this case, as well as by researchers of evidence use in public health policy making.

1.5 Aims and objectives

This study investigates the use of evidence in global malaria policy development, with a focus on the WHO-GMP and its evidence advisory bodies. In particular, I aim to:

1. Explore the factors that influenced the consideration of particular evidence at WHO-GMP, i.e. determine what was considered 'good evidence' for policy (and why) in the case of IPTi and SMC.

2. Examine how factors associated with the policy process influenced eventual policy outcomes at WHO-GMP, i.e. determine what was considered ‘good use of evidence’ for policy (and why) in the case of IPTi and SMC.

1.6 Summary and outline of thesis

In this chapter, I have:

- outlined the development of my interest in evidence use in policy making, particularly global malaria policy, within WHO-GMP;
- provided background information about intermittent preventive malaria treatment and a brief timeline of the global policy development for IPTi and SMC;
- indicated what I set out to achieve in this study, and why.

The remaining chapters are organised as follows:

- Chapter 2 contextualises the study in the relevant literature briefly mentioned in this introductory chapter, and illustrates how I arrived at my framework for analysis.
- Chapter 3 is an account of the research methodology and method.
- Chapter 4 provides the global malaria contextual background and introduces the journeys of the two global malaria policies (IPTi and SMC) I will be comparing in more detail.
- Chapters 5 and 6 – my two main results chapters – focus, in turn, on comparing the evidence base (what is ‘good evidence’) and the policy process (what is ‘good use of evidence’) for each policy.

- Finally, Chapter 7 focuses on the discussion, conclusions, and key lessons for public health researchers, policy makers, and practitioners that wish to promote or sustain practices and processes that increase evidence use in policy and decision making.

Chapter 2. Existing reviews and theoretical perspectives

2.1 Introduction

The aim of this chapter is to review select literature on evidence use in public health policy making, and some of the factors that might influence its use as they might apply to my research question. As mentioned in the previous introductory chapter, there is already a substantial body of work on evidence use in policy, and not just on ways to overcome ‘barriers’ and increase ‘knowledge transfer’, but increasingly, and of relevance to my thesis, on the shortcomings of these approaches and ways in which the field of ‘evidence use in policy making’ might move forward.

As such, in the following sections I provide brief overviews of key texts on evidence use in public health policy making, including on some of the influences on evidence use, as well as the politics of evidence-based policy making, before discussing how current debates and gaps in the literature helped inform my research question and analytical framework, and where I see my thesis contributing to this revived and growing field of study.

2.2 Ways of perceiving evidence use in public health policy making

The use of evidence has been a long established part of the policy process (c.f. Cartwright and Hardie, 2012, Lin and Gibson, 2003), and within public health, research evidence is widely considered in some respects the necessary foundation for many health policy decisions (Lavis et al., 2009, Lomas and Brown, 2009, Nutley et

al., 2007). As a public health practitioner, one can understand the appeal of ‘evidence-based policy’ (EBP) and all the positive and logical connotations associated with it; after all, it is intuitive to many working in public health, who strive to improve public health outcomes, to wish to transform evidence into action. However, what emerged during the course of my literature review, and following further reflection of my own experience, is the consideration that the multiple steps involved in assessing and utilising research evidence within policy making is in fact not necessarily as straightforward as what many of us who work in public health might naively assume.

To begin with, that there are multiple uses of research was emphasised by Weiss (1979) in her research on the different meanings of (social) research utilisation which classifies seven distinct models, summarised as follows:

1. Knowledge-driven – derived from the natural sciences and seemingly linear, applied research follows from basic research to develop policy solutions to identified problems;
2. Problem-solving – similarly linear but more decision-driven, involving the direct application of results from specific studies to a pending policy decision that is in need of a solution;
3. Interactive – less linear and more disorderly, with an interconnected and back-and-forth process of solution-searching between policy developers and a variety of sources of information, including, but not limited to, researchers;
4. Political – where research is used strategically as a form of ‘ammunition’ for pre-determined policy positions;

5. Tactical – used, in other words, as a tactic by policy makers, and often unrelated to the substance of the research itself, mainly as proof of responsiveness, an excuse to delay action, and/or to pre-empt or deflect criticism;
6. Enlightenment – the indirect process of permeation through which research (social science research in particular) influences policy thinking more broadly;
7. Part of the intellectual enterprise – social science research and policy, as responding to, and being influenced by, both each other, as well as the changing interests of society more generally.

For example, basic research or specific studies are the predominant form of evidence in the “knowledge-driven” and “problem-solving” models she proposes, but it is a form of evidence that can be used in different ways or that might be more or less relevant in different models of use (Weiss, 1979). In other words, research evidence can be adapted (versus simply adopted or transferred) according to the need or in response to a particular situation, and the factors that influence its use can vary (c.f. Lin and Gibson, 2003, Nutley et al., 2007, Weiss, 1979). Evidence use is in actuality far more dynamic, complex, and contingent than the traditional EBP instrumental views of research use imply (Nutley et al., 2007).

The body of evidence on the complex and contingent use of research leads Nutley and colleagues (2007) to suggest that an interactive and dialogical model, that balances positivist and interpretivist framings of research use, offers the most insight and potential to improving research use. They offer that these interactive model mechanisms could encompass a range of methods, such as formal partnerships between relevant actors, as well as more informal workshops and seminars to

enhance discussion and debate, in order to accommodate uncertainties in research, which are inherent and accepted as part of more reflexive social research approaches (Nutley et al., 2007).

Another relevant work on evidence use, but specific to health rather than public services more generally, describes health policy as the product of three competing rationalities (Lin and Gibson, 2003, p. 14): (a) cultural rationality, which is defined as “values, ethics, what (perceived) societal opinions feel is right in relation to health policy”; (b) political rationality, which relates to the process through which power is exercised and decisions are made, including such factors as “the willingness of policy makers to have transparent processes and be accountable, the ability of interest groups to participate ... and the role of commentators (be it media, experts, or lobbyists)”; and finally, (c) technical rationality, which is described as the knowledge produced by researchers, which can include diverse forms of evidence, such as epidemiology and economic data. Lin and Gibson describe this technical form of rationality as “the weakest link in the chain” (p. 14) because it is dominated by positivist science that aims for universality, when policy making is often context-specific. They argue that these rationalities (and the health policies that they create) are shaped by “historical political legacies” and reflect “ongoing processes of social learning” which collectively reflect the contestability, power, interests, heterogeneous voices, and complexity that is inherent in health policy making (Lin and Gibson, 2003, p. 15).

Smith (2013) offers an alternative view, that the relationship between how evidence is used in policy might be best understood as a “continual exchange and translation

of ideas” (p. 75). She proposes a four-genre ideas-related typology for analysing the relationship between evidence and policy: *institutionalised* ideas which have become ‘unchallengeable’ and embedded in policy and discourse; *critical* and *charismatic* ideas, which in different ways may challenge institutionalised ideas; and *chameleonic* ideas, which can transform to simultaneously appeal and be acceptable to a variety of policy actors, but also challenge existing policy (see Smith, 2013, ch. 3). Smith (2013) suggests that ‘ideas’ are potentially a more acceptable and accurate descriptor of how evidence informs policy in practice, as the notion “allows space to acknowledge the normative, political, and empirical dimensions of public health debates”, while also acknowledging “the malleable nature of knowledge which is translated as it moves between actors and across contexts” (Smith, 2013, p. 213).

Nutley and colleagues (2007) offer that more attention ought to be paid to group and collective research use in informing public policy decisions such as at the organisational level. They point out that most evidence use literature focuses on the individual, but that focusing on research use at the systems or ‘meso-organisational’ level can help find ways of better incorporating research into procedures, standards, and other practice tools and processes, and that this is an important research gap for future work within the field of evidence use (Nutley et al., 2007).

In summary, it would appear that there are multiple uses of evidence, depending on the circumstances, motivations, and context of the actors involved, which may all change over time, in different ways, and which may reflect individual as well as institutional, or even societal, learning and views. While these various constructs and perceptions of evidence use in public health policy making are helpful for beginning

to illustrate and appreciate the ‘dynamic, complex, and contingent’ uses of evidence, and although there is also a distinct body of literature focused on ways of better incorporating research into procedures, standards, and other practice tools and processes at the practitioner and systems levels (Dopson et al., 2002, Ferlie et al., 2000, Dopson et al., 2003, Ferlie et al., 1999, Locock and Boaz, 2004, Dopson et al., 2001), advice or lessons are often framed in ways of improving individual (and uni-directional) ‘knowledge transfer’ (see next section), and in the language of ‘brokering boundaries’ and the ‘gaps’ between science, policy, and practice (Cash et al., 2002, Cruz and Walt, 2013, Cash et al., 2003). That is to say, that although the complexity of evidence use in public health, in particular in clinical settings, is often acknowledged, including certain social and political implications (for example, see Ferlie et al., 2000, Ferlie et al., 1999), not all influences on evidence use (whether in policy or practice) are necessarily given full research consideration. This is acknowledged in the ‘evidence into healthcare practice’ literature as due in part to the dominance of the medical profession and the strong influence of their biomedical science model on what is considered credible and legitimate evidence in public health (Cammer et al., 2013, Fitzgerald et al., 2003, Dopson et al., 2003, Dopson et al., 2002; see also background section in Chapter 1 of this thesis for more on the influence of evidence-based medicine on evidence-based public health policy).

Cash and colleagues’ (2002, 2003) work on influences on evidence use for sustainable development policy acknowledge that the boundaries between science and policy are essentially socially constructed and negotiated, but can serve important functions, such as helping to organise and allocate authority within ‘knowledge systems’. However, Cruz and Walt’s (2013) work on influences on

evidence use in the IPTi process (described in Chapter 1), which does also acknowledge complexity in policy development, reinforces the notion of boundaries, and illustrates how deeply embedded the concepts of ‘two worlds’, and ‘knowledge translation’ are in the public health policy literature, and based on their findings, within the global malaria community itself.

2.3 Influences on evidence use

As Lin and Gibson (2003) critique early on in their book, the idea that there is a ‘gap’ at all between the ‘two communities’ of researchers and policy makers – a theory originally developed by Caplan (1979) – that can and should be bridged has been the key driver behind a large volume of work dedicated to some form of ‘knowledge transfer and exchange’. This, in turn, has led to a number of reviews to distil lessons on ‘what works’, often framed, as described in my introductory chapter, in the language of common ‘barriers’ or ‘facilitators’ to improve evidence use (Davies et al., 2015, Langer et al., 2016, Oliver et al., 2014a, Mitton et al., 2007, Contandriopoulos et al., 2010, Court and Young, 2003).

Although I have already alluded to what many scholars view as the shortcomings of perceiving evidence use in this simplistic and linear way, nevertheless, summarising some of the reviews on the influencing roles of ‘barriers’ and ‘facilitators’, as they might relate to my study, before then discussing the shortcomings in more detail, is necessary because the notions of ‘two communities’ and the ways to improve ‘knowledge transfer’ between them, is so pervasive within the discourse of the

public health practitioner community to which I belong, including among my global malaria research colleagues at LSHTM.

For one thing, much of the knowledge transfer literature implies that evidence/knowledge *should* be taken up into policy (Smith, 2013). This could be considered a reflection of actor values and their expectations (both of themselves, but also from the point of view of other actors). For example, in Court and Young's (2003) review of 50 cases of evidence use in development policy, all the cases included showed some impact on policy or practice. They explain that sometimes this impact was immediate, while at other times it required what they describe as "strenuous advocacy efforts" (see p. vii). Narrowing the focus of knowledge transfer to such cases at least implicitly appears to equate the success of knowledge transfer with the ability of actors to enact change in policy and practice. Indeed, much of this body of literature distils suggestions to actors on how to enact such change.

Mostly written from the researcher versus policy maker point of view, much of the 'knowledge transfer' literature explores numerous methods for increasing evidence use through influencing individual actions, with conclusions that there is more that can be done by all actors in the process – including both policy makers and researchers – to increase knowledge transfer. For example, some common themes are to call for knowledge outputs to be framed as relevant to policy maker needs, such as fitting outputs to policy makers' timescales and agendas, and ensuring that the information output is relevant to the problem (Contandriopoulos et al., 2010, Court and Young, 2003). Many papers also discuss the importance of presenting information in an accessible, understandable, and useable way, with Court and

Young (2003) highlighting the need to develop clear narratives in order to improve actor engagement (see also Contandriopoulos et al., 2010, Jones, 2009, Mitton et al., 2007, Nutley et al., 2002, Ward et al., 2009).

However, the credibility of the research itself matters too (Court and Young, 2003, Nutley et al., 2007, Cash et al., 2003). Nutley and colleagues (2007) summarise that aside from technical validity, research is more likely to be accessed and used when it comes from credible and trusted individuals and organisations, or where it is supported by experts in the field. In this sense, the neutral reputation of the source of the research is important and influential, and may even in some cases be more important than the technical quality of the research itself (Nutley et al., 2007).

Another seemingly controllable – and trust and reputation-building/beneficial – step was ongoing collaborative relationships between the key stakeholders in the policy development process. Both Mitton and colleagues (2007) and Court and Young (2003) reported that involving policy makers from an early stage, including in the research design process, increased their engagement in the policy process, and the likelihood that the outputs would be incorporated into policy. Instead, other papers point to the importance of knowledge brokers, rather than the original producers of research findings, to link, network, and facilitate evidence use (Contandriopoulos et al., 2010, Davison et al., 2015, Jones, 2009, Shaxson et al., 2012). In addition, Innvaer and colleagues (2002) highlight the widely held view of ‘two worlds’ of researchers and policy makers, noting the frustrations of both researchers and policy makers with their counterparts on the other side. In looking to identify what might better predict or influence evidence use, they conclude that the most commonly

identified facilitator of evidence use was personal contact between researchers and policy makers (Innvaer et al., 2002).

Smith (2013) similarly distils common lessons from existing reviews (p. 20-21) and highlights the implication that the disconnect between researchers and policy makers can be overcome by simply improving communication and trust between these two groups. However, she also notes that various attempts to increase the use of particular pieces of research is distinct from actually improving the use of research in policy (Smith, 2013, p.23).

Oliver and colleagues (2014b), as another example of an existing review of the evidence use literature, conclude that “[m]uch of the research in this area is theoretically naive, focusing primarily on the uptake of research evidence as opposed to evidence defined more broadly, and privileging academics’ research priorities over those of policy makers” (p. 1). They call for a new research agenda, which focuses on the “influences on and processes of policy” through in-depth, empirical descriptions of how evidence “fits with the other drivers and triggers that affect policy” (Oliver et al., 2014b, p. 7).

As Oliver and colleagues (2014b) suggest, another way to understand influences on evidence use in policy and decision making is to look at the processes and environment that facilitate the policy process, and the capacity that exists at the individual and organisational level to seek, analyse, and use evidence (see also Bowen and Zwi, 2005, Lachman et al., 1994).

In one of the few ‘knowledge transfer’ reviews to consider political science literature in its examination of knowledge exchange interventions at the organisational and policy level, Contandriopoulos and colleagues (2010) found that context “dictates the realm of the possible for knowledge exchange strategies aimed at influencing policy making or organisational behaviour. If a given issue’s salience and prioritisation are high enough for users to initiate knowledge exchange efforts and invest resources in them, then the probability of its use and impact can, from the outset, be presumed to be high” (p. 465).

Contandriopoulos and colleagues (2010) suggest that in technically-focused decision making, there is generally a perceived low level of contestation of the evidence. In such cases, technically-focused debate could be resolved through rational dialogues and arguments, based upon a similar worldview amongst actors. In contrast, high contestation of the evidence was found to lead to political debates and a strategic approach towards knowledge use. In other words, in minimally polarised contexts, evidence use more likely resembles Weiss’s (1979) earlier-described problem-driven model, whereas evidence use more likely resembles Weiss’s (1979) political model in highly polarised contexts where there is high contestation of the evidence (Contandriopoulos et al., 2010).

Court and Young (2003) and Contandriopoulos and colleagues (2010) also note that whether the evidence fit with perceived logic and pre-established ideas affected the weight that the evidence was likely to be given, and that this in turn affected whether or not it would be used in policy. Contandriopoulos and colleagues (2010) concluded that the external validity, that is the generalisability or local applicability, and

perceived alignment with existing knowledge, was awarded far greater weight than internal validity and scientific rigour when considering which information was likely to be used in policy making. This is an interesting finding, because it recognises that policy makers may think differently from public health researchers in how they approach evidence use. These various aspects of timeliness and relevance are sometimes referred to as ‘salience’ by some authors (for example, Cash et al., 2002) and ‘generalisable’ or ‘context-based’ decision making by others (for example, Dobrow et al., 2004) but in general refer to the local applicability of the evidence at that particular point in time of evidence consideration and policy decision making.

Much of the ‘knowledge transfer’ literature also discusses the role of a perceived crisis in shaping the policy process, and the timing of policy decisions. Court and Young (2003) and Jones and colleagues (2009) argue that in times of crisis, ‘policy windows’ open, in which policy makers are more open to the uptake of knowledge, especially if it offers them specific solutions to their problems. Jones and colleagues (2009) examined the policy opportunities in post-conflict states, and noted that the knowledge gap created a ‘blank state’ in policy making which policy makers were often keen to fill with ‘problem-solving’ research, although they acknowledged that this approach may end up prioritising short-term gains at the expense of long-term goals.

Analysing what influences the use of evidence in policy making also requires consideration of how issues rise to the top to become subjects of policy action. The importance of agenda setting and prioritisation was noted by Murphy and Fafard (2012), who discussed that unless something was considered an issue of importance,

there was little movement to make it a priority. This was also reflected in Contandriopoulos and colleagues' (2010) finding that where there was low agreement among actors around the problem definition, the issue was more politicised, with subsequent implications for evidence use i.e. high politicisation was seen to drive the 'political' uses of evidence mentioned earlier, whereas in contexts of low politicisation (high agreement about the policy issue), it was found that there was more likely to be neutral debate.

The seemingly implied inverse relationship between politicisation and evidence use in the 'knowledge transfer' literature can be contrasted with the political science literature which tends, in comparison, to conceptualise policy decisions as choices between competing sets of outcomes that require consideration of multiple social values, and not just purely as judgements based on evidence alone (Parkhurst, 2017, Cairney, 2015). Parkhurst (2017) and Cairney (2015) explain that in political science, politicisation is not seen as a problem that impedes effective or successful knowledge transfer. Rather it is recognised that politicisation is part of a bigger series of considerations. Similar to best practice described in the public health literature, they suggest that evidence may need to be systematically and rigorously reviewed according to the standards of the scientific community, but evidence is not considered to be the sole criteria in determining the social desirability of a policy outcome (Parkhurst, 2017, Cairney, 2015).

Political values, which can change over time and across contexts, affect not just the politicisation and perception of a policy issue, but also the politicisation and perception of the evidence used to answer the policy question. For example, RCTs

and the 'hierarchy of evidence' that developed out of the evidence-based medicine movement, are, rightly or wrongly, often seen by the public health community to provide guidelines for the effective use of evidence in policy (see Chapter 1). Barnes and Parkhurst (2014) explain that simply appealing to rigorous evidence (typically in the form of RCTs) to guide policy is a de facto political position, because it biases policy decisions to align with those issues conducive to RCT design, and away from complex social issues which are harder to evaluate with such methods.

While Parkhurst (2017), and others (Parkhurst and Abeysinghe, 2016, Petticrew and Roberts, 2003, Cartwright and Hardie, 2012), have noted the limitations of hierarchies of evidence in terms of policy usefulness, some say there still needs to be critical reflection of where evidence hierarchies can be useful, and what 'good evidence for policy' would have to look like if single hierarchies do not meet evidence use needs for policy making (Parkhurst, 2017, Berridge and Stanton, 1999). Parkhurst (2017), based on the work of Cash and colleagues (2003), suggests using the concept of policy 'appropriateness'. Rather than promoting one hierarchy relevant to a single consideration, Parkhurst (2017) defines appropriate evidence as that collection of high quality evidence which addresses multiple relevant political concerns, which is created to best serve policy needs, and which is applicable in the local context. He defines high quality evidence as that which is applied systematically, inclusively, and with integrity to scientific principles, as well as using methodological criteria relevant to the data type (clinical interventions evaluated through RCTs for example). In other words, appropriate evidence is evidence that is technically valid and credible, in addition to being politically relevant, and locally applicable.

Regardless of where they might eventually fall in the hierarchy of evidence and its associated projections of technical validity and credibility, Barnes and Parkhurst (2014) also note that bodies of evidence are not developed in a vacuum, and that actors will spend considerable resources to generate bodies of evidence in areas of interest to them. Calling for policy to follow established bodies of evidence serves a political position which in turn affects the context, as it aligns policy decisions with those issues that funders have decided to fund and researchers have decided (or are forced as a result of funding availability) to research.

Related to this point, and as part of her exploration of chameleonic ideas, Smith (2013, ch. 6) found that academics framed their research proposals to funding councils based on what they felt funders ‘wanted to hear’, which was seen to limit the potential for critical or challenging research, in the case of health inequalities research. In addition, policy-makers’ own institutional hierarchies, for example between junior and senior civil servants and their ministers, impacted on the journey that research evidence took in both her case studies (health inequalities and tobacco control). Smith (2013) suggests that the success of chameleonic ideas lies in being able to negotiate these expectations and simultaneously appeal to, yet also challenge, existing policy ideas. However, a potential downfall, Smith (2013) explains, is that the path of chameleonic ideas is far more unpredictable and risky, and can therefore end up having unintended negative consequences, such as a loss of credibility depending on how one’s funding source(s) is seen to influence research findings.

One of the four key lessons that Smith (2013) offers through the comparisons of both her case studies, and within her ideas-typology mentioned earlier in this chapter, is that politics is “a central component of public health” and shouldn’t been seen as a barrier to the use of research in policy (Smith, 2013, p.216). Smith (2013) suggests that the political nature of evidence, and its influence on evidence use, is just one demonstration of the complexities of the two-way interactive relationship between research and policy.

It would appear that it isn’t just the perceived credibility of the research, and the potential political factors that help shape it, that can influence evidence use (Court and Young, 2003, Cash et al., 2003, Nutley et al., 2007, Parkhurst, 2017), but the perceived credibility of the actors, through individual behavior and institutional processes, which are inherently political themselves, although not always explicitly so, that may play an influencing role in how evidence is used as well (Smith, 2013, Nutley et al., 2007, Parkhurst, 2017, Cash et al., 2003).

2.4 Managing the political process of policy making

Other scholars of evidence use have also drawn attention to the shortcomings of traditional ‘knowledge transfer’ approaches to improving the use of evidence, that have a tendency to gloss over political considerations from policy decision making (Cairney, 2015, Oliver et al., 2014b, Liverani et al., 2013). In incorporating theories from policy studies in their explanations of health policy processes, they argue that the public health community must consider the non-linear relationship between input (e.g. evidence) and output (e.g. policy decisions) by depicting policy making as a

nuanced craft process, which can face many challenges, not just simple notions of barriers and facilitators (Cairney, 2015, Oliver et al., 2014b, Parkhurst, 2017, Smith, 2013).

In his book, *The Politics of Evidence-Based Policymaking*, Cairney (2015), using the case studies of tobacco control and climate change adaptation, identifies practical consequences and advice for researchers trying to maximise the use of scientific evidence. He illustrates how policy makers cannot consider all evidence relevant to policy problems (known as ‘bounded rationality’), but instead use two ‘shortcuts’: ‘rational’ ways to gather enough evidence, and what seems like ‘irrational’ decision making, which draws on emotions, beliefs, and habits (see Cairney, 2015, ch. 2). Cairney (2015) goes on to describe how most scientists focus on the rational approach to evidence use, by identifying uncertainty when policy makers have incomplete evidence, and trying to solve that uncertainty by improving the supply of information, which unsurprisingly, according to his policy theory arguments, then tends to have little impact on policy making decisions. This is because policy making, he explains, is both rational and irrational; it takes place within a complex policy environment (or context), that needs to be better understood and actively engaged with, and not in a vacuum where scientific evidence alone matters over other considerations (Cairney, 2015).

Cairney (2015) advises that perhaps a better strategy for scientists, given policy makers tend to use evidence in a limited way before making major decisions, is to employ some level of engagement with politics and advocacy in order to be more persuasive, such as by forming coalitions with like-minded actors, exploiting

windows of opportunity when policy solutions are feasible, and accompanying evidence with, for example, simple stories to appeal to the emotional or ideological biases of policy makers – all of which involve framing issues in a way that provides relative competitive advantage in a world of increasingly limited attention spans (see Cairney, 2015, ch. 5). Cairney suggests that scientists basically have a choice: (a) to produce information and accept it will have a limited impact, but still maintain their professional ideals of objectivity; or his offered solution, (b) to go beyond their comfort zone to increase evidence impact ‘in the real world’ (versus an idealised world where scientists often bemoan politics as getting in the way of ‘evidence-based policy making’), by playing ‘the rules of the game’ by using advocacy, which will come at the expense of objectivity (Cairney, 2015).

Cairney is not alone in his encouragement of researcher advocacy and engagement with the political process of policy making. Chapman (2001) and colleagues (Chapman and Wakefield, 2001, Haynes et al., 2011) use decades of advocacy experience on public health issues such as tobacco control in Australia to reflect on the important roles and challenges of advocacy in public health, although most of their cases involve researcher engagement with the media and the public as the means to engage with policy makers to advance their issue agendas. In a primer-focused article on using advocacy in public health, Chapman (2004) further iterates the strategic use of news media to advance public health policy initiatives, although he suggests first seeing if a ‘win-win’ outcome can be ‘engineered’ with policy makers first, before influencing them via the constituents they are accountable to.

Freudenberg (2005) too uses the example of tobacco control activists to promote advocacy as a public health tool to counter the ‘science and politics of disease promotion’, but expands on his examples to include other types of ‘disease promoting’ corporations besides tobacco companies, such as environmental activists targeting the automobile industry regarding pollution, and consumer activists targeting the food industry for its contributions to obesity and diabetes (see also Freudenberg et al., 2011). However, in the cases presented by Chapman and Freudenberg and their respective colleagues, the researchers/advocates were working in the face of some form of opposition (namely, the tobacco, automobile, and food industries), rather than for the same public health goals, which makes the lessons they provide context-specific and not necessarily transferable for researchers presenting findings to government or global health evidence advisory committees for example, where one can assume they ultimately share the same common objective, to preserve and promote health.

In any case, the call for increased engagement with the media to advocate for a range of public health policy issues is not new (Boaz and Gough, 2016), although it appears there has also been a concurrent debate about how appropriate overt advocacy is (Lackey, 2007, Scott et al., 2007, Smith and Stewart, 2017, Cruz and Walt, 2013), regardless of media engagement. For example, Lackey explains that in his opinion, it is completely inappropriate “to let our [researcher] personal policy preferences colour our science” (Lackey, 2007, p. 12), whereas Scott and colleagues (2007) and Cruz and Walt (2013) present a more nuanced view, reflecting on the existing tension between science and advocacy, and how perhaps some form of

‘contribution’ to policy debates may be appropriate depending on the political environment.

Most recently, Smith and Stewart (2017) present findings from a literature review on public health advocacy (which also captures some of examples highlighted above, among others), which was supplemented with qualitative data in the form of interviews and focus group discussions. They present the current state of the debate as a complex “continuum between ‘ivory tower’ academia and fully fledged (often self-identified) advocacy and activism, in which the role of research is secondary to the advocacy aims” (Smith and Stewart, 2017, p. 42), within which lies overlapping activities for the dissemination of findings, knowledge exchange, work to support evidence-based policy, and evidence-informed advocacy. Smith and Stewart (2017) suggest that some of the tension and conflict regarding public health advocacy may be due to two deeply contrasting conceptualisations within the public health community, where advocacy is either seen as a ‘selling’ strategy, as opposed to being more ‘facilitational’ (particularly in the context of community groups, as described in the original paper by Carlisle, 2000), which was relatively more desirable and acceptable, perhaps because it doesn’t necessarily run counter to what is viewed within the public health community as being good personal and professional practice.

What much of the literature on public health advocacy has in common with the literature that incorporates elements from policy studies is that they both emphasise that the ‘real world’ of policy making is a less ordered and more unpredictable environment than the commonly used visual of a perfectly circular policy cycle

might suggest. It has multiple actors, within multiple organisations, influencing policy at multiple levels, and through multiple ways. In order to help successfully navigate this complexity, Cairney (2015) and others (Boaz et al., 2008, Boaz and Hayden, 2002, Ferlie et al., 2011) highlight the value of developing networks between actors, which sometimes makes them difficult to access if they are close-knit to begin with, and well as the tendency for certain beliefs – what Smith (2013) terms as institutionalised ideas – to be commonly held and expressed within policy discussions within groups, which makes major policy changes by policy makers (and the ability of scientists to influence such change) perhaps difficult to accomplish, but in their eyes still worthy of pursuit.

In a multidisciplinary special collection in *Palgrave Communications*, titled “The politics of evidence-based policy making: maximising the use of evidence in policy”, led and edited by Cairney (2017), the practical lessons from two commissioned articles stand out as being particularly helpful to public health practitioners. Taking lessons from psychology and policy studies to produce a three-step strategy on communicating effectively with policy makers, Cairney and Kwiatkowski (2017) advise: (a) against bombarding policy makers with too much evidence. They explain that people in general have too much information to process, and so they often use heuristics to filter information in order to make decisions quickly; (b) that timing is everything, as it matters during key individuals’ patterns of thinking and the alignment of conditions in political systems; and finally, (c) to engage with real world policy making rather than waiting for a ‘rational’ and orderly process to appear. In fact, Cairney and Kwiatkowski (2017) advise that to present evidence

during the romanticised ‘policy cycle’ is misguided, and that without establishing legitimacy and building trust it may even be counterproductive.

In the second article within the same special issue, one by Oliver and Pearce (2017), they also offer three key lessons, but for policy practitioners, that have been learned from evidence-based medicine instead of psychology. They suggest that those looking to improve evidence-based policy: (a) be more transparent about the processes and structures used to find and use evidence; (b) consider how to balance evidence and other interests in assembling the ‘evidence jigsaw’; and (c) and this is a lesson they suggest for those in evidence-based medicine too – that understanding power is vital, particularly how it shapes how knowledge is produced and used (Oliver and Pearce, 2017).

Also continuing in the same vein of embracing, versus denying or blocking, the politics of evidence, and attempting to move the debates on improving evidence use forward, albeit moving away from the more advocacy-oriented approach proposed by Cairney (2015), is Parkhurst (2017) with his book *The Politics of Evidence: From Evidence-based Policy to the Good Governance of Evidence*.

Like with previous scholars reviewed in this chapter, in particular Cairney (2015) and Smith (2013), Parkhurst (2017) makes the assertion that politics is an intrinsic part of the policy process, which will inevitably involve tradeoffs, and that evidence rarely truly ‘speaks for itself’ (Parkhurst, 2017, ch. 1). However, due to its nature and its emphasis on measurement, scientific health evidence “can help identify who will benefit from different choices or how much different benefits will accrue to

different groups” (Parkhurst, 2017, p. 9), which makes reviews of technical evidence useful for addressing ‘who’ and ‘how’ questions, while being less useful at addressing whether the policy decision is the right choice to make to begin with (Parkhurst, 2017).

Of particular relevance to my own research question, Parkhurst notes that “in the evidence based policy world, almost no attention has been paid to the legitimacy of the process through which evidence is applied” (Parkhurst, 2017, p. 30). He argues that “from a policy studies perspective, the process by which public policy decisions are made and social outcomes are achieved must be accepted as legitimate by the population” (Parkhurst, 2017, p. 30). The concern so far, he and others (Oliver et al., 2014a, Oliver et al., 2014b) argue, has been over competing political or cultural considerations being classified as ‘barriers’ to be overcome. Parkhurst (2017) argues that democratic debate is not a barrier, but rather is necessary, and reflects the understanding that the process by which decisions are made matters to ensure that the final policy decisions will be respected. He suggests that an alternative approach to the heavy focus on individuals as the driving force to improving evidence use in policy making, is to focus on the institutionalisation of changes that serve to improve evidence use (that is, improving the ‘systems of evidence advice’ mentioned in the last chapter).

What the authors referenced in this section emphasise is that the process of policy making matters too, and that this process is inherently political, which doesn’t preclude it from also being fair and inclusive of multiple considerations and values, via better governance systems for example. These systems may affect how evidence

and the policy development process is perceived by audiences and actors within the process, which may in turn influence how evidence is used in those processes. For example, Parkhurst (2017) suggests building toward a comprehensive framework that aims to promote the good governance of appropriate evidence within policy decision making processes through ‘good evidence for policy’ and the ‘good use of evidence for policy’ (Parkhurst, 2017, p. 163).

Good governance includes taking multiple steps to create, select, and interpret evidence in the service of good policy making, and principles such as the use of appropriate evidence, accountability in evidence use, transparency, and accepting and allowing contestability of evidence, to ensure that there is room for sufficient debate (Parkhurst, 2017, p. 160). These principles reflect different facets of legitimacy, which Cash and colleagues refer to as “whether an actor perceives the process in a system as unbiased and meeting standards of political and procedural fairness....based on who participated and who did not, the processes for making those [policy] choices, and how information is produced, vetted, and disseminated” (Cash et al., 2002, p.5).

The reason these legitimacy-enhancing principles are needed, Parkhurst (2017) explains in his book’s chapters 3-5, is in order for ‘good evidence’ and the ‘good use of evidence’ to overcome two critical biases in the creation, selection, and interpretation of evidence: technical bias, in which evidence is misused or manipulated in various ways producing suboptimal social outcomes, and issue bias, in which appeals to evidence serve to obscure key social values towards issues that

have or are conducive to measurement; both forms of which can be affected by unintentional cognitive biases, or by more intentional political choices.

2.5 Reflective summary and analytical framework

This exploration of recent and select existing reviews and theoretical perspectives, together with the introduction in Chapter 1, has highlighted some of the tensions between the technocratic desire to promote expert knowledge and evidence use, and the political realities of policy making. While the embrace of evidence-based policy, growing from its origins in evidence-based medicine, through to recent and repeated attempts to distil lessons for ‘what works’, has been valuable for evidence use in public health policy making in order to improve public health outcomes and better serve society, it is clear that it also has its shortcomings, and much of the recent literature in the field of evidence use vocally identifies this.

As noted by Smith (2013), the evidence-based policy movement has tended towards the notion that more use of certain types of evidence equates to better use. However, Parkhurst (2017) and others (Cairney, 2015, Oliver et al., 2014b) have pointed out that prioritising technical effectiveness at the expense of competing valid social concerns, depoliticises policy debates that need to reflect those concerns as part of the policy process, and that a more explicit recognition of the nature of politics is needed in future work to promote evidence use in policy, recognising that social goals can and should be contested, given our naturally biased uses of evidence.

Parkhurst (2017) also argues that a shift is needed to engage with questions of what

improved evidence use might look like by asking explicitly normative questions about how we might judge ‘good evidence’ in terms of policy appropriateness, and the ‘good use of evidence’ from the perspective of the decision making process. These two elements are an integral part of ‘systems’ of evidence use – what Cash and colleagues (2003) alternatively refer to as ‘knowledge systems’ – and enabling reflections on how to improve these evidence advisory systems over time, rather than simply focusing on uptake of single pieces of research, could serve as an alternative way to thinking about how to improve evidence use.

However, as outlined in the introduction to this thesis (see previous chapter), and as evidenced within the key texts reviewed for this chapter, much of the evidence use literature tend to be based on systematic reviews of ‘what works’, and many case studies tend to be at the country level and government focused; there are few empirical case studies that look specifically at, and provide lessons for, what good evidence and the good use of evidence mean to those actors involved in public health policy making processes, particularly within global institutions, and their specific evidence advisory systems. Of note, few studies examine the processes and perceptions of global health evidence advisory bodies, within the context of their broader environment, and interactions with other actors within their institutional networks.

Therefore, exploring the influences on the use of evidence in policy making within a global health evidence advisory body (MPAC), within a global health policy institution (WHO), and in the context of a particular case study (the development of global malaria intermittent preventive treatment policies by WHO-GMP) that I had

insider knowledge of and access to, might be useful to help understand the complex ways in which evidence and policy interact with each other, and how these factors intentionally and unintentionally influence policy outcomes for a global health priority (malaria). The results will hopefully contribute to a growing body of literature on evidence use, and on evidence advisory bodies in global public health, as well as the various types of factors that influence them. In particular, I'd like to explore the questions and understandings of what constitutes 'good evidence' and 'good use of evidence' in the complex processes around gathering and interpreting the evidence for IPTi and SMC, and to understand and draw lessons from the attempts by different sets of actors to introduce and use evidence in both policy development processes, in addition to the implications and unintended consequences of those efforts. A more holistic understanding of what influences the use of evidence in policy making may help shed more light on the complexity of evidence use, and may help, in multidimensional ways, to increase and improve evidence use, which is the goal of many public health organisations, including the WHO.

Although there are clearly several frameworks to draw on based on the existing reviews and theoretical perspectives summarised within this chapter, I found that the framework that best helped classify and capture features of evidence (what is good evidence) and aspects of the political process of policy making (what is good use of evidence), based on my review of the literature (for example, elements of work by Cairney, 2015, Contandriopoulos et al., 2010, Cruz and Walt, 2013, Lin and Gibson, 2003, Nutley et al., 2007, Oliver et al., 2014a, Parkhurst, 2017, Smith, 2013, among others), while still leaving room for what these concepts might mean to the actors in my particular context, was the work by Cash and colleagues (2003) referenced

throughout this chapter. They analysed environmental sustainability across a range of countries and found that the effectiveness of science to inform policy (that was acceptable to the public, versus within evidence advisory bodies in my case) rested on three key factors: (a) credibility, which refers to the scientific adequacy of the evidence; (b) salience, which refers to the relevance of the science to the needs of decision-makers; and (c) legitimacy, which refers to the perception that the evidence generation and use has been unbiased and fair in its treatment of divergent stakeholder views and interests. These factors, when viewed more broadly, aren't mutually exclusive, and no one factor could be considered more important than the other, even though the public health literature appears to implicitly place greater weight on measures of evidence credibility or forms of 'good evidence'.

The multiple concepts of credibility, salience, and legitimacy, reflecting 'good evidence' and 'good use of evidence' are captured in the adapted framework presented in Table 1 (see next page), which show the possible factors that may shape evidence use in IPTi and SMC policy development at WHO-GMP, based on some of the relevant literature summarised in this and the preceding introductory chapter. The concepts shown both emerged from my data, as well as helped structure my literature review and the analysis of my findings, and the subsequent order in which they are presented in my results chapters, although they aren't an exact mapping, given that some of the terms have multiple definitions and are open to interpretation. For example, some elements of salience could be interpreted as features of both appropriate evidence, as well as legitimate processes, both of which may have a role to play in making the outcomes of evidence use within policy development acceptable to participant actors.

Select factors that may influence the use of evidence in public health policy development, based on a targeted review of the literature (Chapters 1 and 2)	Factors affecting evidence use (Cash et al., 2003)	Factors affecting IPT evidence use, based on thematic analysis of data	Location of IPT ‘evidence use for policy development’ analysis within this thesis	
RCTs when applicable (e.g. Cartwright and Hardie, 2012, Petticrew and Roberts, 2003)	Credibility	Hierarchy of evidence	Features of evidence (Chapter 5)	Process of policy development (Chapter 6)
Evidence that is high quality, technically valid, following principles of good scientific practice (e.g. Nutley et al., 2007, Parkhurst, 2017)		Efficacy, repeatability, resistance, safety, rebound		
Technical rationality (Lin and Gibson, 2003) that evidence should be taken up (e.g. Court and Young, 2003, Smith, 2013)		Strength and quality		
Politically relevant and locally applicable evidence (e.g. Parkhurst, 2017)	Saliency	Local applicability		
Context-based evidence (Dobrow et al., 2004) provided and presented in useable ways (e.g. Contandriopoulos et al., 2010, Court and Young, 2003, Mitton et al., 2007, Nutley et al., 2007)		Contextual relevance		
External validity/generalisability (e.g. Contandriopoulos et al., 2010)		Generalisability		
Policy windows/opportune timing (e.g. Cairney and Kwiatkowski, 2017, Court and Young, 2003, Jones, 2009)		Timing		
Framing policy relevance via active advocacy (e.g. Cairney, 2015)		Framing		
Contestation of evidence (e.g. Contandriopoulos et al., 2010)	Legitimacy	Consensus, or lack thereof	Process of policy development (Chapter 6)	
Politicisation of issue (e.g. Contandriopoulos et al., 2010)		Membership/representation		
Democratic debate that is seen as fair and inclusive (e.g. Parkhurst, 2017)		Expectation and framing		
Advocacy/ boundary transgression (e.g. Cruz and Walt, 2013, Smith, 2013)		Conflicting agendas		
Political rationality (Lin and Gibson, 2003) where power is exercised and decisions made in transparent and accountable ways (e.g. Parkhurst, 2017)		Transparency and good, trustful relations		
Credible, trusted individuals and organisations (e.g. Nutley et al., 2007) not influenced by funding sources (e.g. Smith, 2013)				
Slowly-built trust over time (e.g. Cairney and Kwiatkowski, 2017) based on transparency (e.g. Oliver and Pearce, 2017)				

Table 1. Analytical framework – factors that may shape evidence use in IPT policy development at the WHO-GMP (adapted from Cash et al., 2003)

In this study I explore whether these possible factors relating to ‘credibility’, ‘salience’, and ‘legitimacy’, outlined in the framework above – and the various ways these might be perceived by the relevant actors within the context of my case study – also apply within WHO evidence advisory bodies for global malaria policy. These broad concepts allowed exploration of my study findings to consider how similarities and differences might be seen between the two policy processes studied, IPTi and SMC, in terms of features of the evidence base, its relevance to needs, and the process by which the evidence was used in the policy development for IPTi and SMC policy recommendations by WHO-GMP.

Differences between the two policy development processes affecting ‘credibility’ and ‘salience’ are explored in Chapter 5, titled “The features of the evidence used to form global malaria intermittent preventive treatment policy”. Differences between the two policy development processes affecting ‘legitimacy’ are explored in Chapter 6, titled “The process of forming global malaria intermittent preventive treatment policy”. First, I discuss my methods (Chapter 3), and the global malaria context and the case of intermittent preventive treatment (Chapter 4), which as this chapter has identified, provides the necessary contextual foundation for better understanding evidence use in policy development in this particular case.

Chapter 3. Methods

3.1 Introduction

This chapter outlines my thesis research methods – specifically, my approach, the case selection, method of data collection, and analysis – and reflects on the implications of my chosen approaches for the findings that follow in my research results chapters.

As noted earlier, this study explores the use of evidence in global malaria policy development, with a focus on the WHO-GMP and its evidence advisory bodies. In particular, I aim to:

1. Explore the factors that influenced the consideration of particular evidence at WHO-GMP in the case of IPTi and SMC.
2. Examine how factors associated with the policy process influenced eventual policy outcomes at WHO-GMP in the case of IPTi and SMC.

Focusing on one global policy study setting allowed me to explore what was considered ‘good evidence’ and ‘good use of evidence’, and why, in this particular case, and from the perspective of the actors involved.

3.2 Approach to the DrPH and case study

A case study was judged to be the most appropriate design choice for my needs because this study was complex with multiple dimensions to explore that were

context-specific, and because of the particular interest in why and how certain factors influence evidence use in policy development (Yin, 2009, Green and Thorogood, 2014, Walt et al., 2008).

Using case studies as a research method is well established in policy and political science, including in health and social care policy research (Exworthy et al., 2011). It is considered to be particularly appropriate for researching processes, such as policy processes (George and Bennett, 2005), as long as it is clear what the case study is ‘a case of’, and how it fits within the wider body of knowledge (Ragin and Becker, 1992), in addition to its real-life context (Yin, 2009). This particular thesis is a case study of WHO-GMP evidence advisory processes, specifically intermittent preventive treatment global malaria policy development, over a certain period, primarily 2006 to 2012. Because there were two intermittent preventive treatment evidence advisory processes that took place within this time period, and case study context (WHO global malaria policy development), that could be compared and contrasted to develop a deeper understanding of the complexity of evidence use for policy development, a single case study was judged to be sufficient for the purpose of my research aims.

The use of case study research as a form of study design does also have its criticisms however, for example around its difficulty in establishing causality and/or generalisability. Yin (2009) suggests that the challenge of establishing causality is seen by some as relating to particular types of case studies, namely those that are explanatory, rather than exploratory, of a certain phenomenon (Yin, 2009). Similarly, Ragin (1999) argues that exploratory case-oriented research compared to

more explanatory variable-oriented research have different objectives, with case study research being geared towards analysing the complexity of causal relationships, whereas variable-oriented research is more suitable for testing hypotheses about causal relationships. Instead of measuring effects and generating insights independent from context, case studies help us to understand the mechanisms that cause these effects and are often highly dependent on context (Gerring, 2004, Flyvbjerg, 2006). In addition, ‘cases’ are usually not randomly sampled, but are chosen for their significance and relevance to the theory or topic they aim to explore (Ragin, 1999). In fact, Ragin (1999) argues that cases should always be chosen based on their relevance to the study, and that it is the researcher’s task to make sense of these cases by identifying and interpreting their commonalities. Therefore, case study research can be viewed as usually being interpretative, as it relies on the researcher’s ability to make sense of the case.

In my case, my role as a malaria research manager at LSHTM, as well as a policy professional at WHO-GMP, informed both my approach and study design. At the time of developing my research question, and throughout the data collection and analyses, I was employed as a consultant by WHO-GMP to provide management support for the Malaria Policy Advisory Committee (MPAC), the principal evidence advisory body that developed one of the WHO policies I selected as part of my case study. My own position in the policy process and the subsequent insights gained and experienced, led me to undertake an interpretive and partially ethnographic ‘observer-participant’ approach that would be considered appropriate for this study based on previous studies that have also sought to understand policy development ‘from the inside’ of a policy-informing institution or government department.

For example, most recently, in Maybin's (2016) study on the production of health policy within the UK Department of Health, she describes her ethnographic approach as being especially well-placed to capture 'practice' in all its tacit complexity, as she was present, in context, and in real-time, to observe, engage, reflect, and interpret what was happening around her. In a separate study by Antrobus and Kitson (1999), they too undertook an ethnographic approach, as leaders within the Royal College of Nursing, to explore the influence of nursing leadership on health policy and nursing practice, and the socio-political factors that impact it, within a particular cultural (UK) context. An ethnographic approach enabled them to explore the underlying social construction of nurse leadership by their peers, and the multiple meanings attached to that construction. This 'immersive' aspect of gathering insights into beliefs and practices otherwise normally 'hidden' from public gaze is one of the key features of ethnography, which has been acknowledged as being a critically useful, although sometimes underutilised, methodology in health research (Savage, 2000, Reeves et al., 2008).

Interpretive research is by definition context-specific, stressing the situatedness of the subject or case of interest at a particular place and time, involving a particular set of actors, interactions, and relationships (Schwartz-Shea and Yanow, 2012), in this case in order to study the practice of evidence use to inform policy development within WHO-GMP and its evidence advisory bodies. As one of the actors within the context of my study, taking this approach meant constantly interpreting and reflecting between my own background knowledge, my position, the data I was collecting, and how they related to the concepts found in the literature I reviewed.

My initial worry was that I would identify too closely with the interviewees and/or context, and not apply enough of a critical lens to the data. However, I came to realise over the course of my study, as my understanding and appreciation of qualitative research and the case developed, was that in actuality, what I was really hoping to accomplish and contribute to the literature was explanations of evidence use according to the accounts of those individuals involved in the process, which is the essence of interpretive research (Yanow, 2015).

Typically in studies that critically examine the inner workings of an organisation, there is necessary concern about how freely individuals can or will speak about their work (Delaney, 1960). Whilst access to, and openness of, key informants can be an issue in organisational studies (Delaney, 1960), being an 'insider' helped identify participants whose participation in the policy process wasn't necessarily visible to 'outsiders', and facilitated a more open discussion during the interviews.

Many of my key informants, both researchers and policy makers, expressed their eagerness to reflect about their experience of evidence use, because as someone who straddled roles at both LSHTM and WHO, I was seen to at least appreciate, if not empathise, with their point of view. In my experience, the rapport built around the shared 'inside' experience of malaria research (or malaria policy work, depending on whom I was speaking to) helped mitigate some of the barriers some key informants might have otherwise felt in talking about their work. In short, my insider role helped overcome some of the main challenges often prescribed to interviewing 'elites', namely gaining access, acquiring trust, and establishing rapport (Harvey, 2011, Mikecz, 2012, Welch et al., 2002). In addition to facilitating access to both key

informants and otherwise hard-to-observe events such as closed session policy discussion meetings, being an ‘insider’ also helped aid my analysis, because I could contextualise my findings, which, as later chapters will hopefully illustrate, helped in my understanding of the nuanced ways in which evidence and policy development processes interacted in this case.

Being an insider did also have its challenges; I soon became more aware of the differences in disciplinary background, power, gender, and culture between myself and some of the key informants/elites I was interviewing (Lancaster, 2017, Welch et al., 2002), which I worried might influence my style of interviewing and interacting with my colleagues, and/or bias my analysis. For example, I sometimes sensed that certain responses to certain questions may have been presented in a particular way because I was perceived to be aligned with certain researchers at LSHTM, or staff at WHO (depending on whom I was speaking to), or because I was seen to be relatively ‘new’ to malaria (compared to some of my colleagues), or because I was undertaking a qualitative study (perceived by my clinically-oriented colleagues as being ‘soft’ and perhaps too open-ended, and therefore in need of some form of steering). I attempted to counteract this by trying to maintain my reflexivity during the course of my study. Which is to say, I made a conscious effort both during my interviews and when reflecting and analysing the data afterwards, to be self aware of my own position as an ‘observer-participant’ and the position of the person(s) I was observing or interviewing, and what we may and may not have had in common, taking care to ‘listen’ to what was being said and done, and not project what I may have been hoping to see, which is an acknowledged risk of ‘insider’ research in case

studies (Dwyer and Buckle, 2009, Unluer, 2012), but also viewed as being a manageable one (Brannick and Coghlan, 2007).

In addition, I also became aware that some of the specific anecdotes and insights offered by these key informants/elites made them identifiable in what is a small community working on intermittent preventive treatment evidence and policy, which raised issues related to maintaining anonymity that are common in elite interviewing (Lancaster, 2017). It is the reason I strove to preserve at least the confidentiality of key informants, by presenting data in summary (see Data Collection and Ethics sections of this chapter).

3.3 Case selection

Case selection is considered crucial for case studies (Gerring, 2004) and was partially influenced by the goals of the DrPH programme at LSHTM, which is to equip its graduates with the experience to deal with the particular challenges of understanding and adapting scientific knowledge in order to achieve public health gains.

Although there are many institutions where one could examine the challenges of evidence use in policy development, I focused on the influences on evidence use in policy making at the WHO for my case study for both pragmatic and strategic reasons. As mentioned previously, at the time of developing my study, I happened to be partly based at WHO, and I know that understanding and improving evidence use within WHO is of interest to many – both scholars, which include supporters as well

as critics of the WHO, as well as the WHO itself (D'Souza and Newman, 2012, Horton, 2006, Oxman et al., 2007, WHO, 2007b).

Contemporary assessments of WHO, for example its handling of the 2014 Ebola crisis (Gates, 2015, Moon et al., 2015, Piot, 2014), have not always been kind. However, there are reasons to believe that the WHO can and should be influential given its long-standing mandated and valuable role to form evidence-based health policy in order to improve international public health (Lee, 2008, Murray and Lopez, 1996, WHO, 2007b, Lee and Walt, 1992). Indeed, the few studies that have specifically examined evidence use for guideline development within the WHO in its normal work (versus in a global health emergency scenario) have urged the institution to improve its evidence use for policy development via more transparent, inclusive, systematic, and explicit processes for policy recommendation formulation (c.f. Burda et al., 2014, Oxman et al., 2007). However, by this they typically refer to better implementing the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach to rating the certainty of evidence. Evidence use, and the factors that may influence it, as discussed in Chapters 1 and 2 of this thesis, is more complex than implementing a standardised rating system for evidence suggests it might be.

Although there were many disease and policy topic areas within the WHO to choose from, the influences on evidence use in malaria policy making at WHO-GMP presented a useful area for case study because of the dynamic state of global malaria control at the moment (Bradley, 1999, Hay et al., 2004, WHO, 2016). On one hand malaria continues to remain a major public health problem in many low and middle-

income countries (LMICs), while at the same time many of these countries are witnessing impressive progress in the uptake of malaria control interventions, such as insecticide-treated mosquito nets, resulting in significant reductions of malaria-related morbidity and mortality (WHO, 2016).

As a result, there was and is a view among representatives of the global malaria community that malaria control, and in some cases elimination, has a critical window of opportunity for success before the tools at their disposal are no longer effective, or there is less funding interest either by governments or by donors to support them (RBM, 2015, WHO, 2015, Malaria Summit, 2018). This has led to increasing pressure on the global malaria policy setting process to keep pace with the volume of research and surveillance data being generated both through research efforts, and the massive implementation of malaria control interventions (D'Souza and Newman, 2012).

How the global malaria policy setting process/evidence advisory bodies within WHO-GMP, the WHO department that is the setting for this case, subsequently responded to, and interacted with, the evidence bases for two forms of intermittent preventive treatment (IPTi and SMC), amidst pressure to develop a policy recommendation, is the focus of this thesis. The reasons for why I focus on IPTi and SMC specifically were outlined in Chapter 1, and I provide more of the case background in the next chapter (Chapter 4).

3.4 Data collection

My main method of data collection was interviews, although this was supplemented by the identification and review of documents from the IPTi Consortium, WHO-GMP, and the BMGF, as well as my own observation and field notes from my work providing behind-the-scenes management support to MPAC, in order to help fill gaps, cross-check data, and establish the contextual timeline outlined in Chapter 4. That is to say, documents were used primarily to help construct and verify elements of the case study, but interviews were my main source of data for analysis.

Interviews were grounded in the value of the key informant's perspective. This form of interpretative data collection method offers understanding from the point of view of the participants in it (Green and Thorogood, 2014). In an interpretive study the idea of theory-free observation is sometimes problematised given that researchers, such as myself in this case, can never capture 'reality' exactly as it is, given they cannot eliminate the influence of particular interests, influences, and purposes (Smith, 2008). It is suggested that this is partially because interviews are products of social interaction and cannot be expected to establish 'the truth' (Silverman, 2006). In contrast to other types of data, such as survey data, interviews are likely to produce multiple narratives, which sometimes may complement or contradict each other, but together provide insights into evidence use and the policy process (Rapley, 2004).

My final sample included 29 key informants whom I interviewed in person during the span of a year between October 2014 and October 2015, primarily in London or

in Geneva. I selected key informants based on their specialist knowledge of the issues and processes being analysed. I began by identifying key individuals that would ensure a wide range of perspectives from those involved in the IPTi and/or SMC policy processes. They included: (a) staff from the Bill and Melinda Gates Foundation (BMGF), who funded the IPTi and SMC studies, as well as the policy strengthening process that led to the creation of MPAC; (b) staff from the research institutions who conducted the IPTi and SMC studies, many of whom had ties to LSHTM, even if they no longer worked or studied there; (c) members of two of WHO-GMP's evidence advisory bodies – the Chemotherapy Technical Expert Group (TEG) and the MPAC – who advised WHO-GMP on the IPTi and SMC policies; and (d) staff from WHO-GMP who were responsible for issuing the IPTi and SMC policies to relevant member states.

A table summarising the roles of each key informant in either or both policy processes has been provided for reference (see Table 2). In several cases, there was sometimes a shift of roles over time; for example, some IPTi Consortium members later went on to work at WHO-GMP or on its evidence advisory bodies such as the Chemotherapy TEG or MPAC. However, I have not specified job titles or the timings of particular posts at particular institutions in order to protect anonymity, as the global malaria community is quite small. The main purpose of the following table is to demonstrate that the key informants were well placed to provide a range of perspectives on the evidence advisory processes for SMC compared to IPTi, and to provide the reader with some background about the roles of key informants for when they are quoted anonymously in the results chapters that follow.

Interview number	Interview date	KI Code	Role(s)				Policy process	
			Research	WHO-GMP	Evidence Advisory Body	BMGF	IPTi	SMC
1	14.10.14	22		x		x	x	x
2	23.10.14	23				x	x	x
3	27.10.14	24	x	x			x	x
4	05.11.14	25	x					x
5	06.11.14	26	x					x
6	06.11.14	27	x					x
7	26.11.14	28	x					x
8	26.11.14	29	x		x		x	x
9	27.11.14	30	x					x
10	28.11.14	32	x				x	x
11	09.12.14	33	x					x
12	09.12.14	34	x		x			x
13	11.12.14	35		x			x	x
14	11.12.14	36	x	x	x		x	x
15	12.12.14	39	x	x	x		x	x
16	16.01.15	40	x				x	
17	11.02.15	41	x	x	x		x	x
18	23.02.15	42		x			x	x
19	25.02.15	44	x		x		x	
20	26.02.15	45	x					x
21	04.03.15	46		x	x		x	x
22	05.03.15	48	x	x	x		x	x
23	16.03.15	49	x		x		x	x
24	19.03.15	50		x			x	x
25	29.04.15	51	x		x		x	x
26	02.05.15	53	x		x		x	x
27	05.05.15	54	x					x
28	10.06.15	55	x		x		x	x
29	26.10.15	58				x	x	x

Table 2. General summary of Key Informant roles and their involvement in the IPTi and/or SMC policy processes

All of the informants I contacted were receptive to being interviewed and expressed interest and support for the processes I was trying to analyse and understand. As explained previously, it helped that I knew many of them personally, and where I didn't, I was easily introduced. I made clear that I was not specifically evaluating the WHO, BMGF, or their own institutions, or IPTi and SMC as malaria control

interventions, but rather exploring the policy development process itself, and hopefully contributing towards ways to improve it.

Because many of my key informants were quite senior, and all were very busy, I had to be diligent in reconfirming their availability since many of my interviews were scheduled several months in advance. Because of how I had split my time between Geneva and London during the year of my data collection, in cases where I had to be rescheduled, I was able to respond to alternative interview openings at short notice. In addition, there were some opportunistic chances to meet and interview key informants at major malaria-related conferences and meetings in New Orleans, Oxford, and Philadelphia where we both happened to be in attendance.

The interviews, which lasted on average for an hour, were all recorded using a digital sound recorder and transcribed shortly after, typically within two days. I took notes during interviews primarily to remind myself about questions or issues I would need to follow up on. I achieved saturation of data on the range of concepts explored with key informants using the topic guide (see Appendix 1). By saturation of data in this case I mean that in addition to my pre-identified themes and the themes that emerged over the course of my interviews (see Analytical Framework), no new themes and/or additional observations and reflections were shared by those I interviewed that hadn't already been raised and discussed at length by my pool of key informants.

The topic guide allowed me to structure the conversation to elicit data exploring the factors that influenced evidence use in the IPTi and SMC policy processes. The sequence of questions was broadly chronological, starting with the origins of the

policies, their experience of the evidence base and evidence review process, internal and external influencing factors, and the roles of the various actors involved. This sequencing of questions felt intuitive, providing a narrative with a beginning and an ending that all interviewees were likely to be familiar with. It also allowed for reflection on the use of the evidence and the role of policy setting processes towards the end of the interview. I did not find reason to significantly revise the topic guide after applying it in the first several interviews, but did adapt the follow-up questions and probes based on my key informant, and their responses to my questions, along with exploring any relevant case aspects that emerged from previous interviews with other informants.

However, as with any qualitative research process, it could be argued that all accounts were partial in the sense that they reflected the insights of a particular individual, involved in a particular role, at a particular point in time. These point to the subjective nature of interview data, and the reality that interviewees had genuinely different views on aspects of evidence use for policy development, depending on their own role in the process.

Given that several years had passed since the IPTi policy process in particular, there was potential for recall problems. For this reason, I focused mainly on SMC, the more recent policy process, mainly delving into IPTi policy process issues as a comparator. In either policy process, I asked for concrete examples and drilled down into issues during my follow-up questions. At times, it seemed that in using what they perceived as negative aspects of the IPTi policy process, interviewees were

better able to reflect and express what they viewed as more positive aspects of the SMC process in comparison.

A number of interviewees noted that they could not remember some details, for example, the dates of certain evidence review meetings, or the exact wording of meeting conclusions, but these were details I was able to follow up on and cross-check due to my access to the supplementary data mentioned previously. These data included published and unpublished documentary sources, including IPTi Consortium documents, official WHO policy documents for IPTi and SMC, evidence advisory body meeting reports for IPTi and SMC, and internal BMGF and WHO-GMP documents on IPTi and SMC. Observational notes documented during meetings and conferences I was present for between March 2011 and October 2015 were also used for cross-checking and referencing against data arising from key informant interviews.

3.5 Coding and analysis

Using two policy processes for comparison within the case study setting of WHO-GMP allowed for exploring the complexity of evidence use beyond a single policy process. I used NVivo 10 to help manage my data, and a combination of inductive (data-driven) and deductive (theory-driven) approaches during the coding process.

For example, based on my initial literature review for my DrPH Review (upgrading document), I had broad categories from the literature that I used to help structure my analysis of the data. These included examining the actors involved (the perceived

values and implicit and explicit behaviour/processes of the individuals and institutions involved in IPT evidence generation and use); the context (the internal and external environments in which IPT actors operate); and evidence characteristics (features of the IPT evidence that were under consideration, and explanations of why they were important). However, reading and re-reading the data to generate initial codes led to the realisation that there were different issues and patterns emerging, which then led to an iterative process of going back to the literature to finalise the framework that most applied to my findings, which in turn helped shape and coalesce my eventual thesis literature review chapter, and the structure/sub-categories of my two results chapters on features of evidence, and processes of use, in this case.

The results were analysed thematically, relating to the emerging concepts of various forms of credibility, salience, and legitimacy, adapted from work by Cash and colleagues (2003) and my interpretation of the evidence use literature, but also influenced by repeated regular discussions over many years with Parkhurst (2017), one of my DrPH supervisors, whose own research interests also lie in both features of evidence, and processes of evidence use.

There were no strict boundaries between data collection and analysis, and some themes began to emerge during the course of data collection. Likewise, it was possible to go back to the original data to contextualise the information by re-reading the reference document e.g. a meeting report, or transcript of a previous interview. As a result, it was possible to ask interviewees about case aspects that had emerged from previous interviews with other informants. This in turn helped with further

refining and reflecting on emerging themes following subsequent interviews with other informants.

3.6 Ethics

I received approval to conduct my thesis research from the Ethics Committee of LSHTM in October 2014, following my DrPH Review in September 2014 and prior to the start of my data collection. My research was also approved by the WHO-GMP Director. Legal approval by the WHO-GMP Director's Office was enquired about but ultimately it was determined that it was not required as I was interviewing key informants in their personal capacity and not seeking formal statements of or about the WHO.

Prior to being interviewed, all key informants received an information sheet and signed a consent form (see Appendix 2). As the sample is small and the context in which the key informants work is insular, many if not all of the key informants are known to one another, and so in writing the results chapters that follow, I have endeavoured to at least preserve confidentiality so that no data can be linked to a specific individual. Names are never mentioned in association with quotes and the data is presented in summary.

Chapter 4: The global malaria context and the case of intermittent preventive treatment

4.1 Introduction

The purpose of this descriptive chapter, which expands on the brief summary first presented in section 1.4, and builds on the work initially done by Cruz and Walt (2013) on the IPTi policy process also mentioned in that section, is to synthesise and present the contextual background of my case study as an introduction to, and the narrative thread across, the two analytical results chapters that follow. The story of the policy processes for IPTi and SMC have primarily been pieced together from a combination of journal articles and key documents from the IPTi Consortium, the BMGF, LSHTM, and WHO, as well as interviewee accounts, news articles, and my own background knowledge gained during my DrPH Organisational and Policy Analysis (OPA) project at WHO-GMP.

Because the SMC studies were never part of a formal consortium, and the policy process was shorter and less contested, there is not the same depth of documented history as with IPTi, which can be considered a disadvantage when reconstructing the timeline of events within a case study. However, I did also have an advantage when it came to the SMC process; I was an observer during the WHO Technical Expert Group (TEG) meeting for SMC (it took place during my OPA) and I was the rapporteur for the first MPAC meeting where SMC was discussed and endorsed as a malaria control intervention for countries with seasonal malaria transmission.

In the following sections, I will outline the changing fortunes of malaria as a global health issue, and the policy journeys of IPTi and SMC within the context of its policy setting body, and the setting of this case study, WHO-GMP.

4.2 The fall and rise of malaria as a global health issue

Understanding the story of IPTi and SMC begins with appreciating the modern day story of malaria within the global health context.

According to many in the global malaria community (Greenwood and Mutabingwa, 2002, Bruno et al., 1997), and to those who study malaria as a global health issue (Brown, 2017, Chandler and Beisel, 2017, Litsios, 2002, Packard, 2007), the late 1990s marked a turning point in global interest in malaria. There was a resurgence of international attention for the disease, which had decreased after what was perceived to be the relative failure of the malaria eradication campaign of the 1960s (Litsios, 1997, Packard, 2007, Greenwood et al., 2008, Packard, 1998). Over the next 40 years, the malaria agenda had gone from the grand aspiration of eradication to a period of global neglect to a recovered vision (Bradley, 1999, Breman et al., 2004, Greenwood and Mutabingwa, 2002, Greenwood et al., 2005, Packard, 2007, White et al., 1999, Whitty et al., 2002). By 2007 there was another call for eradication, and a plan to eliminate malaria in some endemic countries (Feachem and Phillips, 2009, Chandler and Beisel, 2017). In fact, ‘accelerating towards elimination’ is once again a goal of the WHO Global Technical Strategy for Malaria 2016–2030, which was adopted by the World Health Assembly in May 2015 (WHO, 2015). Translating that vision into a reality once again appears to be a common goal of the global malaria

community (Tanner et al., 2015), although the political and cyclical nature of that aspiration has not gone unnoticed by some observers (Eckl, 2017, Chandler and Beisel, 2017).

After the initial and failed eradication campaign of the 1960s, the malaria policy environment was at a low point. The numbers of researchers working in malaria were relatively few and their networks were limited (Packard, 2007). In the 1970s and 1980s, biomedical scientists, public health specialists, and social scientists were attracted into other policy communities as the global health agenda focused on health systems and primary health care, health reforms, and financing (Zwi and Mills, 1995). Litsios (1998) suggests that over this period, malaria researchers isolated themselves by remaining loyal to the global malaria eradication agenda, and lost much of their influence on the development of other WHO public health policies and approaches.

However, by the 1990s, global attention began shifting back to malaria. This is reflected in the history and evolution of the Multilateral Initiative on Malaria (MIM), an African-led international initiative established in 1997 with a mission to strengthen and sustain, through collaborative research and training, the capacity of malaria-endemic countries in Africa to carry out malaria research (Heddini et al., 2004, Greenwood and Mutabingwa, 2002). In 1997, only 150 scientists (from Europe, the USA, and Africa) participated in their first malaria conference in Dakar because there were so few researchers involved in malaria. A decade later, the MIM conference in Nairobi in 2008 (still the only malaria-specific international conference in the world) drew over 3000 participants (MIM, 2017).

The resurgence in attention was accompanied by a huge rise in the funds available for malaria research, control, as well as advocacy. This is reflected not only in the creation of MIM in 1997, but also in the formation of the Roll Back Malaria Partnership in 1998, the Bill and Melinda Gates Foundation (BMGF) in 1999, and the Global Fund against HIV/AIDS, Tuberculosis and Malaria (GFATM) in 2001 (Chandler and Beisel, 2017). From approximate expenditure of US \$ 20 million in the 1980s, funding for malaria research grew to over US \$ 300 million in 2004 (Malaria R&D Alliance, 2005). In 2014, US \$ 610 million was invested on malaria research and development alone, a large proportion of which (23% or over US \$ 140 million) came from the BMGF, second only to the US National Institutes of Health which contributed 24% (Policy Cures, 2014). The BMGF has tripled funding on malaria (McCoy et al., 2009a) with Bill and Melinda Gates often repeating that they would like to see malaria eradicated within their lifetime (Liu et al., 2013, Roberts and Enserink, 2007, Tanner and de Savigny, 2008, Gates and Chambers, 2015), an assertion that has inevitably influenced the global health agenda around global malaria control, elimination, and eradication (Chandler and Beisel, 2017, Eckl, 2017, McCoy and McGoey, 2011).

The large increase in malaria research funding led to more and better opportunities for malaria research, and also led to greater discussion among malaria researchers around how few interventions against malaria existed (Breman et al., 2004, White et al., 1999, Whitty et al., 2002). At the end of the 1990s there were relatively limited tools for malaria treatment and control (Packard, 2007). For example, the anti-malarial drug *Chloroquine* was still widely used across Africa, despite large-scale

resistance and the wide availability of a similarly inexpensive, but more efficacious, alternative drug, *Sulfadoxine-pyrimethamine*, also known as SP (Shretta et al., 2000, White et al., 1999).

In this context of limited interventions to control malaria, evidence showing protective efficacy of Intermittent Preventive Treatment of pregnant women (IPTp) (Parise et al., 1998, Shulman et al., 1999), led to a policy recommendation of the intervention by WHO-GMP in 2000. Many interviewees felt this decision was rushed and based on limited evidence, which contributed to a slow uptake of IPTp by African ministries of health. The rapidity of the WHO IPTp decision was contrasted with the sluggish decade-long WHO policy development process for another intervention, insecticide-treated mosquito nets, which preceded it. Other interventions to tackle malaria from during this time period included the use of artemisinin-based combination therapies (ACTs), a form of anti-malarial treatment recommended by WHO-GMP in 2003 (WHO, 2003), and new studies on indoor residual spraying in particular areas (Roberts et al., 2000) which were encouraging, but limited to a few settings.

By this time, WHO had already “began to refashion itself as the coordinator, strategic planner, and leader of global health initiatives as a strategy of survival in response to [a] transformed international political context” (Brown et al., 2006, p. 62) that had seen its role and authority diminished. Part of this transition was to reinforce its role in normative guidance and policy setting, in this case for malaria. WHO-GMP reoriented its global malaria policy recommendations to focus on

malaria case control, focusing on artemisinin-based combination therapies, long-lasting insecticide-treated mosquito nets, indoor residual spraying, and IPTp.

In tandem, WHO-GMP's then director, Dr. Arata Kochi, a famously undiplomatic and controversial figure within the global public health community (Bohannon, 2006, Boseley, 2006, McNeil Jr., 2006), put forward a new three-level policy review process that had been successfully used in his previous WHO department, the Stop TB Initiative. It involved a number of Technical Expert Groups (TEGs), a Technical and Research Advisory Committee (TRAC), and a Strategic and Technical Advisory Group (STAG) (D'Souza, 2014) (See Appendix 3 for more details). Unfortunately, concerns about the transparency of the membership at each of these three policy-setting levels, combined with the delays inherent in a three-layered system – the prime example of which we will shortly dive in to – limited the utility of this approach (D'Souza, 2014).

As a result, and further aggravated by its lack of adequate funding, WHO-GMP's policy-setting activities were largely occurring as singly convened technical expert ad-hoc consultations, rather than through the regular meeting of standing technical expert groups (D'Souza, 2014). This led to the perception among important stakeholders that the leadership role of WHO-GMP in shaping the global malaria policy agenda was weakening (D'Souza, 2014). In that vacuum, a variety of other well-funded groups and entities began slowly encroaching on WHO-GMP's policy-setting functions (D'Souza, 2014). It was during this 'Kochi era' of WHO-GMP (described as such by WHO-GMP interviewees) that the story of the IPTi policy journey largely took place.

4.3 Twists and turns in the policy journey of the IPTi Consortium

In the context of the increasing interest in malaria, and greater availability of research funding, but few effective interventions (Bradley, 1999, Breman et al., 2004), the results of the first IPTi study, introduced in Chapter 1 – a RCT, published in the *Lancet*, showing 59% protective efficacy (Schellenberg et al., 2001) – generated much enthusiasm among the core group of scientists involved in the trial, and subsequently in the medical profession (The Lancet, 2008), because the results were considered potentially game-changing compared to the 35% pooled protective efficacy of malaria prevention interventions in pregnancy i.e. IPTp and insecticide-treated mosquito nets (Eisele et al., 2010).

The researchers from the first IPTi study, along with researchers from other academic institutions, and staff at WHO and UNICEF, subsequently formed a cross-institutional US \$28 million BMGF-funded global research partnership in 2003 – the IPTi Consortium. They stated in their funding proposal that they had “developed a research and implementation agenda that will rapidly resolve the outstanding scientific questions about this innovative form of malaria control, and move the intervention into policy and practice” within five years, by the end of 2008 (IPTi Consortium, 2003, p. 2). They also added, somewhat ambitiously, that they had “prepared a strategic plan showing how, by the end of 2005, sufficient information will exist on which to base a policy recommendation” (IPTi Consortium, 2003, p. 3). This date was also known within the IPTi Consortium as ‘the green line’, and was included in their proposal to the BMGF (see Figure 1, next page). Although shown

in black and white within the proposal, and therefore as black and white in Figure 1 below, the arrow indicating that a policy recommendation would be made in December 2005 was frequently shown in meeting presentations as green (later described within this thesis by a quoted interviewee to mean “green for go”). Although it appears to indicate that the IPTi Consortium considered multiple technical measures and outcomes of their RCTs to be of value for policy consideration, the figure also suggests that protective efficacy, delivered through the pre-existing Expanded Programme on Immunisation (EPI), were the sole primary considerations the IPTi Consortium presumed a WHO policy recommendation would be based on.

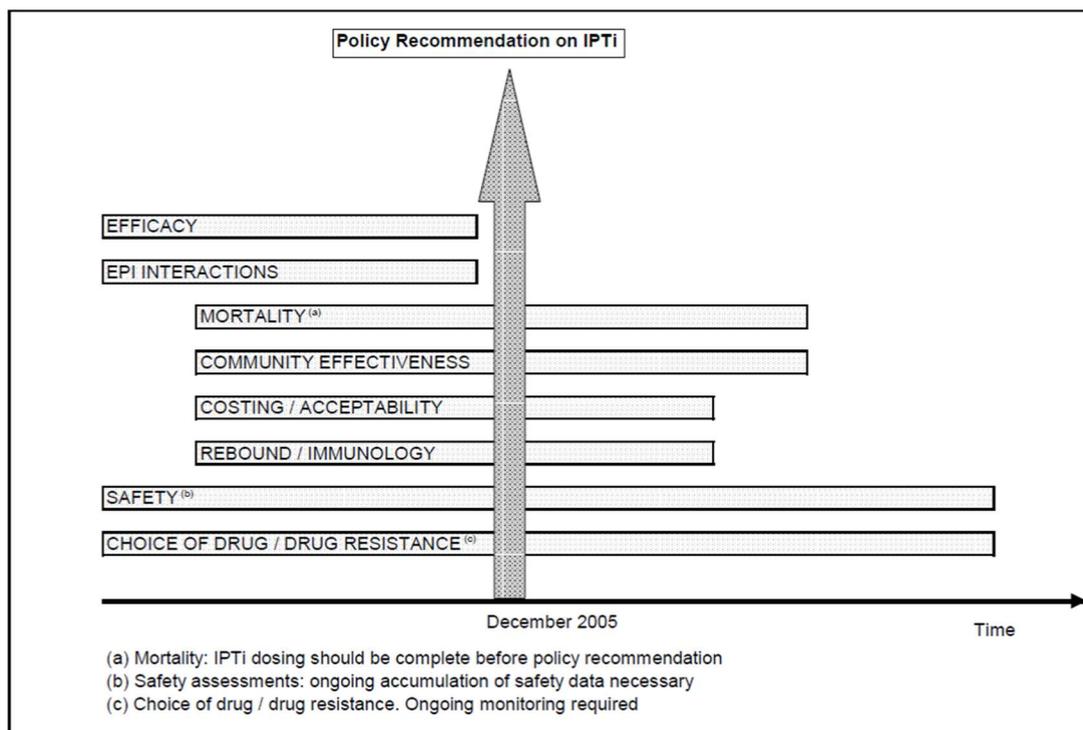


Figure 1. Target date for a WHO policy recommendation on IPTi, as projected by the IPTi Consortium to the BMGF (IPTi Consortium, 2003)

As part of the strategic plan and policy goals of the IPTi Consortium, a concurrent Policy Platform was established in WHO-GMP to review the evidence gathered through the Consortium's research groups (WHO, 2006b). This Policy Platform was both a part of the IPTi Consortium (see Figure 2 below) as well as part of WHO-GMP.

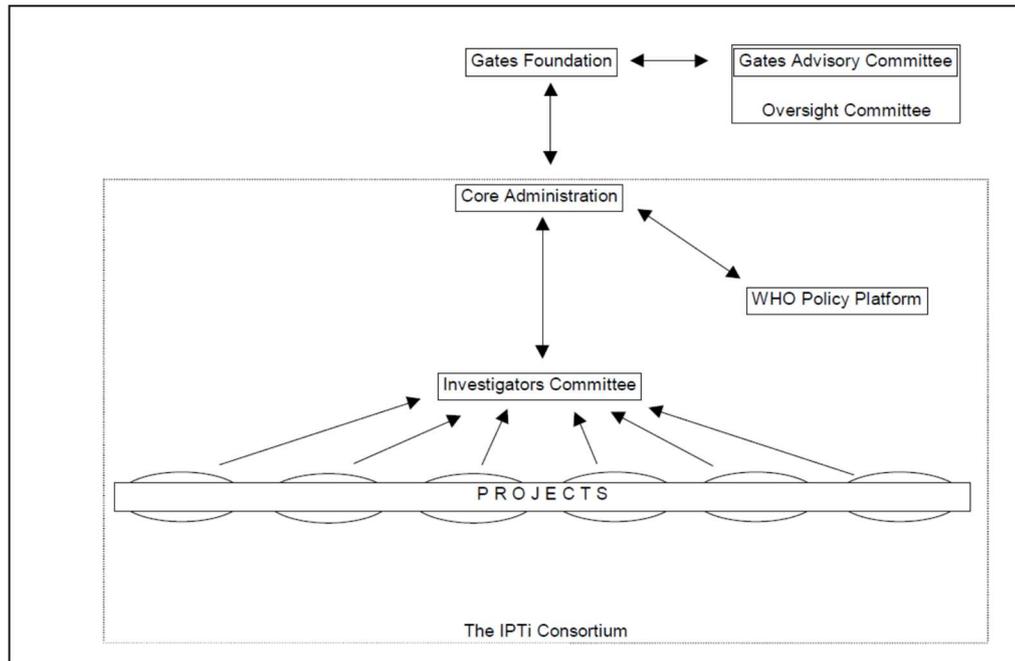


Figure 2. Schematic view of the interactions between the different institutional elements of the IPTi Consortium (IPTi Consortium, 2003)

The role of the Policy Platform was to facilitate the evidence review process of IPTi evidence, as it became available, so WHO-GMP could reach a policy recommendation on IPTi. This review process involved passing a series of WHO-GMP committees described in the previous section that had been set up by then-director Dr. Kochi – the TEG, the TRAC (that reviewed TEG recommendations), and the STAG (that reviewed TRAC recommendations).

The first TEG meeting for IPTi was held in October 2006, already past the ‘green line’ projection internally set by the IPTi Consortium, to assess the results of 11 studies on the efficacy and safety of IPTi in infants and children (WHO, 2006a), even though three of the studies were not yet published. Nevertheless, the recommendation of the 2006 TEG to WHO-GMP was that IPTi should become a WHO-recommended malaria intervention, provided that implementation would take place alongside rigorous drug safety and drug resistance monitoring, and that as additional data on IPTi emerged, there would be further assessments of the intervention. The TEG recommended:

In settings where *sulfadoxine-pyrimethamine* (SP) remains effective, the benefits of IPTi using SP appear to outweigh the risks ... IPTi is a promising new intervention to consider adding to the package of available interventions for malaria control where there is malaria burden in infants (WHO, 2006a, p. 11).

This TEG recommendation then went to the Technical and Research Advisory Committee (TRAC) where it was reviewed and recommended in December 2006. It was next due to be reviewed by the Strategic and Technical Advisory Group (STAG) but this meeting was then cancelled in favour of an additional TEG review, to take into account newly available trial data that was signalling the occurrence of severe adverse reactions. It was only in October 2007 that the second TEG meeting took place. Although this second TEG also recognised IPTi was a ‘promising intervention’ it recommended another review be held in 2008 when new data became available (WHO, 2007a). The TEG concluded:

Taking into account these safety concerns ... the uncertainty over the magnitude of the protective effect against anaemia and severe malaria, the uncertainty concerning the efficacy against highly SP resistant parasites and the optimal dose and timing of administration,

the committee cannot recommend general deployment of SP-IPTi (WHO, 2007a, p. 7).

The deliberations of the TEG were negatively perceived by some IPTi researchers as unnecessary delays in the evidence advisory process, and led to increasing frustration within the IPTi Consortium (Cruz and Walt, 2013). This led to increasing tensions both amongst the researchers, and with WHO-GMP and its TEG, over differences in perceptions of time urgency, the meaning of rigorous evidence review, and the role of scientists (Cruz and Walt, 2013).

In an attempt to drive what was perceived to be a circular and slow moving process forward, the BMGF decided in mid-2007 to commission an independent study, not from another U.N. agency or academic institution, but from a U.S. non-governmental organisation, the U.S. Institute of Medicine (IoM), to evaluate the IPTi results. This process, however, was viewed by multiple individuals interviewed as being at best irritating, and at worse undermining, to WHO-GMP.

A year later, in July 2008, the IoM review was finalised and, perhaps unsurprisingly according to some interviewees, concluded that there was “substantial evidence indicating that IPTi-SP significantly diminished the incidence of clinical malaria in infants living in areas of high and moderate intensity transmission” and “that an intervention with results of this magnitude is worthy of further investment.” (Institute of Medicine, 2008, p. 2 and 61). The IoM review also concluded that IPTi was “ready to move to a new level”, implying programme implementation in countries where IPTi would be effective (Institute of Medicine, 2008, p. 3).

So unusual was this series of events, that the angry reaction by then WHO-GMP director Dr. Kochi even ended up being covered by the newspaper *The New York Times* (see McNeil Jr., 2008). In the article, stemming from a leaked memo from Dr. Kochi to his boss, the then WHO Director General Dr. Margaret Chan, Dr. Kochi complained about the BMGF's "growing dominance" which was "stifling a diversity of views" and "wiping out the health agency's policy making function" (McNeil Jr., 2008). He accused "leading malaria researchers" (presumably members of the IPTi Consortium because he later explicitly used IPTi as his example) of being "locked up in a cartel", with "vested interest" from BMGF to have its funded research used in WHO policy recommendations as potentially having "implicitly dangerous consequences on the policy-making process in world health" (McNeil Jr., 2008). The news article goes on to quote Dr. Kochi with reference to IPTi:

Kochi wrote, although it was "less and less straightforward" that the health agency should recommend [IPTi], the agency's objections were met with "intense and aggressive opposition" from Gates-backed scientists and the foundation. The WHO, he wrote, needs to "stand up to such pressures and ensure that the review of evidence is rigorously independent of vested interests" (McNeil Jr., 2008).

It is difficult to say whether the 2008 IoM conclusion, or indeed any form of pressure from the BMGF, had any bearing on WHO-GMP (interviewees from both WHO and BMGF suggested it did not) but in April 2009, eight years after the first IPTi study was published, and following the early retirement of Dr. Kochi, a final meeting of the TEG judged the IPTi evidence base to finally be sufficiently acceptable, and advised a global policy recommendation on IPTi by WHO to member states (WHO, 2009).

4.4 Strengthening the policy process for global malaria control and elimination, and the emergence of SMC as a policy success

The story of the policy journey for IPTi is recognised within the global malaria community, and as outlined in Chapter 1 particularly by researchers at LSHTM and other institutions involved with the IPTi Consortium, as an example of a process where the inherent tension between researchers, their funders, and policy makers could have been better managed (Cruz and Walt, 2013, LSHTM, 2014b). The political fall-out from the perceived delays and tensions in the IPTi policy process was among the factors that precipitated WHO-GMP to review its many existing policy setting mechanisms in what, by that point, following the perceived to be bridge-burning ‘Kochi era’, was an even more increasingly competitive global health policy environment for WHO-GMP (D’Souza, 2014).

WHO-GMP recognised by 2010, under the leadership of a new director, and it should also be noted, former member of the IPTi Consortium, Dr. Robert Newman, that it needed to adapt to this new environment, while trying to maintain and strengthen its global leadership role in policy-setting (D’Souza, 2014). By that time, WHO-GMP’s normative role in setting policies and standards for malaria control had not been updated for several years, and WHO-GMP was perceived by many members of the global malaria community as being insufficiently able to respond to a rapidly changing political, funding, and epidemiological landscape (D’Souza, 2014).

In 2011, WHO-GMP embarked on a policy-setting strengthening exercise – funded by the BMGF – to increase the timeliness, transparency, independence, and

relevance of its recommendations to WHO member states in relation to malaria control and elimination (see Appendix 4 - D'Souza and Newman, 2012 - for more details).

In summary, in order to help re-design and implement a new policy-setting process, a small group of independent malaria experts was convened by WHO-GMP in March 2011 in Geneva to review previous and existing malaria policy processes and successful policy-setting models from other WHO departments (D'Souza and Newman, 2012). They proposed a framework for a new malaria policy committee to address the shortcomings of previous policy processes. During April and May 2011, feedback on the draft terms of reference was sought, received, and incorporated, from 50 external stakeholders (D'Souza, 2014). The result was the evidence advisory body, MPAC, first convened in 2012, which meets twice a year, as outlined in Chapter 1, to provide “independent strategic advice and technical input for ... the development of WHO policy recommendations ... as part of a transparent, responsive and credible policy setting process.” (D'Souza and Newman, 2012, p.2).

The first body of evidence to come under MPAC review was for SMC. Research on SMC had been going on for several years before the MPAC was formed. As in the case of IPTi, enthusiasm for SMC was based on positive findings from a RCT, but in Senegal instead of Tanzania, also published in the *Lancet*, but in 2006 instead of 2001, in this case showing an even higher 86% protective efficacy, compared to the 59% protective efficacy of the first IPTi RCT (Cisse et al., 2006, Schellenberg et al., 2001). More notably however, unlike with IPTi, an official consortium with an overt agenda to achieve policy goals was never formed, and there appeared to be little

tension between actors involved in the evidence advisory process. Instead, a series of informal collaborative meetings between SMC researchers and WHO-GMP with relevant national policy makers and programme managers, to identify outstanding priorities for research relevant to a SMC policy decision, took place in 2008 (Bhasin et al., 2014). These were followed by several large-scale evaluation studies in 2009 to address these outstanding questions (see Cairns et al., 2012, Dicko et al., 2011, Konaté et al., 2011). Meanwhile, there were periodic informal reviews of the evidence dossier by experts to ensure that the necessary information was being collated for an informed decision by policy makers for when the time came (Bhasin et al., 2014). This culminated in a formal (and single) meeting of the TEG to review the evidence for SMC in May 2011, which resulted in a unanimous positive recommendation for the intervention despite the lack of an implementation mechanism (WHO, 2011c). The TEG concluded:

Although there is evidence to support the initiation of SMC, there are still practical questions concerning the roll out of this additional malaria intervention. The committee did not feel that these questions should limit the imminent roll out and deployment of SMC, but can be incorporated into the implementation of the programme (WHO, 2011c, p. 6).

The recommendation was then reviewed by the newly formed MPAC in February 2012, and by March, less than a month later, WHO-GMP issued the policy recommendation for SMC (WHO, 2012c). The MPAC meeting report, which took longer to appear in the *Malaria Journal* (2012) than it did for WHO-GMP to issue the SMC policy, summarised the MPAC discussions:

The general conclusion was that there is a window of opportunity related to the current effectiveness of AQ-SP and that SMC should

be adopted soon, while operational experience and new evidence will be regularly reviewed by the MPAC. The MPAC recommended the adoption of SMC as a new malaria control strategy pending minor changes to the policy recommendation. There was strong consensus on the need to rapidly finalise and disseminate the SMC policy recommendation, ideally within two months of the MPAC meeting (MPAC meeting report, 2012, p. 5).

The story of SMC, viewed and framed, as mentioned previously in Chapter 1, as a policy ‘success’ according to stakeholders involved due to its speedy policy development and lack of conflict, is now often used as an example of the strength, impact, and influence, of LSHTM malaria research (LSHTM, 2014a) as well as that of a ‘good’ WHO policy making process outcome (Snow, 2016, Greenwood, 2018), particularly in comparison to IPTi.

For example, with reference to the 2012 meta-analysis of the results from the 2006-2011 SMC trials, which were used to help inform the WHO SMC policy decision, Professor Bob Snow, a pre-eminent Kenya-based Oxford University malaria epidemiologist, who was not involved with the SMC studies himself, although he was clearly familiar with the timeline of events, summarised the value of SMC, as well as what was unusual about its policy development, in a 2016 article in PLOS Medicine:

This [SMC meta-analysis] evidence led to policy statements by WHO the same year, and development of regional and national plans for implementation of SMC. Within a year, 3.2 million children aged less than five years were protected by SMC in seven countries. This history provides an exemplary illustration of how field research evidence can lead to early policy adoption and immediate donor assistance. Importantly, previous reservations on the use of drugs for malaria control seemed less of a concern for SMC than, say, for IPTi or MDA (Snow, 2016, p. 2).

The relative policy development success of SMC in comparison to IPTi, as part of the broader story of how all forms of intermittent malaria preventive treatment help in the fight against malaria, is a narrative that continues to be shared repeatedly within the global malaria community, most recently during the plenary talk, “Progress with Malaria Chemoprevention in Malaria Endemic Countries since 1997”, at the Multilateral Initiative on Malaria (MIM) conference in Senegal in April 2018 by Professor Sir Brian Greenwood (see Greenwood, 2018). Greenwood is an LSHTM professor of clinical tropical medicine and a malaria preventive treatment pioneer, who was involved with both IPTi and SMC sets of studies, and is one of the most-recognised and well-regarded UK contributors to the field of global malaria research (see The Royal Society, 1998).

During his MIM plenary presentation, Greenwood covered the clinical and epidemiological evidence for, as well the chronological policy development of, intermittent preventive treatment (IPT) in pregnant women (IPTp), infants (IPTi), children (IPTc/SMC), and schoolchildren (IPTsc) – which are all forms of IPT – as public health interventions of great potential, although, as previously mentioned in Chapter 1, barely implemented in the case of IPTi, compared to SMC, which was lamentable given its benefits, according to him (Greenwood, 2018). On a slide titled “Why has IPTi not been adopted more widely?” Greenwood suggested that it was due to four factors, in his opinion: a combination of IPTi having a relatively modest impact on the overall incidence of malaria; a relatively restrictive WHO policy recommendation; a lack of local champions, such as national malaria control programmes and researchers; and the changing age distribution of malaria in children (Greenwood, 2018). While this thesis does not go into a lot of detail on the

changing epidemiology of malaria, which would cover factors such as incidence and changing age distributions (although these and other epidemiological factors are of course part of the broader and dynamic context in which global malaria policy development occurs), it does explore why the WHO IPTi policy recommendation might have ended up being ‘relatively restrictive’ (covered in Chapter 5, and related to aspects of the credibility and salience of the IPTi evidence base, which might have made developing and recommending a more expansive policy difficult for WHO-GMP), and what might have led to ‘a lack of local champions’ (covered in both Chapters 5 and 6, and related to the salience of the IPTi evidence base, as well as the perceived legitimacy of its policy development process, which might have dampened enthusiasm for IPTi in some sub-Saharan African countries that might have otherwise benefitted from IPTi), among other perceptions and outcomes, in the case of IPTi, compared to SMC.

4.5 Reflective summary

A simplified timeline of steps involved in the development of the eventual WHO global policy recommendations for IPTi and SMC, which are outlined in more detail in previous sections of this chapter, is summarised in Figure 3 (see next page).

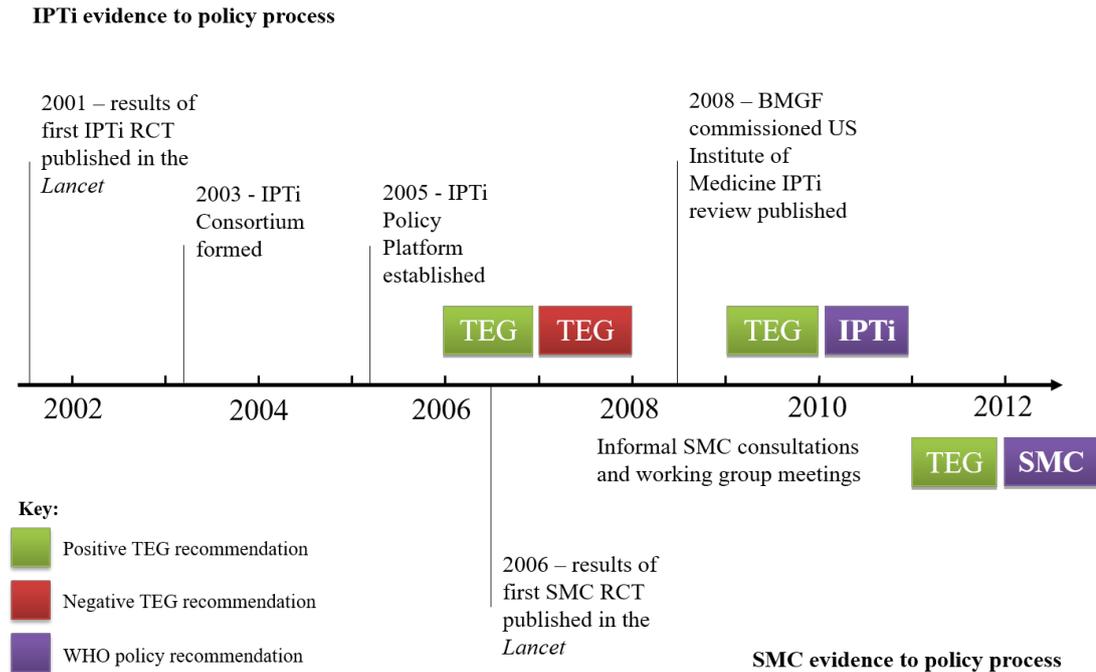


Figure 3. Simplified timeline of the IPTi and SMC policy development processes (D'Souza and Parkhurst, 2018).

Although the timeline is presented in a simplified format, in reality, the two ‘evidence to policy’ processes for IPTi and SMC took place within a continuously changing and dynamic internal and external environment for WHO-GMP. As Eckl (2017) points out, malaria policy is in reality often more conflictual than official accounts suggest, and those policies have narratives of their own (‘social lives’ as he puts it) that are often suppressed within the global malaria community’s desire for consensus around policy making.

However, as outlined in Chapters 2 and 3, these narratives provide necessary background and context for understanding the environments in which evidence advisory processes and policy development occurs, which in turn might affect the outcomes of those processes. The reality of global malaria policy setting for

intermittent preventive treatment, as we shall soon explore in the next two chapters, might be more complex than the global malaria community itself likely realises or acknowledges.

It is in the spirit of trying to at least better appreciate, if not better understand, the complexities of the policy development process, that the next two chapters explore how the features of the evidence (Chapter 5) and the perceptions of the policy processes (Chapter 6) of IPTi and SMC compared with each other, according to those actors directly involved, and what the learning opportunities might be for researchers, policy-makers, and funders alike.

Chapter 5: The features of the evidence used to form global malaria intermittent preventive treatment policy

5.1 Introduction

This chapter, the first of two main results chapters, explores the features of the evidence used to form policy in both the IPTi and SMC policy processes. In particular, and as outlined in my analytical framework in Chapter 2 based on the work of Cash and colleagues (2003), I explore the question of what is perceived to have constituted as ‘good evidence’ in this case, including interviewee interpretations and explanations of the ‘credibility’ and ‘salience’ of that evidence.

Based on their role in the IPTi or SMC policy process (or in some cases, their role in both processes), informants were asked how, in their experience, would they describe the evidence base for either policy. Based on their responses, and in some cases following probes for examples of what they meant by descriptors such as ‘strong’ or ‘good’, I asked about their experience of the evidence review process and what features of the evidence base(s) appeared to them to matter most, and why, when it came to forming the WHO policy recommendation for IPTi and SMC.

Responses by interviewees, comprising primarily of clinical researchers, or policy makers with medical backgrounds, often reflected traditional thinking about the hierarchy of evidence and the role of RCTs in informing policy. They provide an inside perspective on how do features of the hierarchy of evidence, and known technical concerns affecting ‘credibility’, influence policy development processes

within WHO-GMP and its evidence advisory bodies. The chapter also explores non-technical concerns, such as ‘salience’ and more nuanced facets affecting ‘credibility’, and the extent to which these factors also matter in policy development in this case.

5.2 Findings

First I present the themes that emerged from my analysis of interviewee accounts of differences between the features of the evidence bases for IPTi and SMC, before summarising the findings with some reflections on this subset of my thesis results.

5.2.1 Differences affecting credibility

Cash and colleagues (2003) define credibility (according to them, one of three core determinants of effective evidence advice, in addition to salience and legitimacy) as involving “the scientific adequacy of the technical evidence and arguments” (p. 8086). But as highlighted from the evidence use literature within public health (see Chapter 2), scientific adequacy has multiple dimensions when applied within the hierarchy of evidence common within public health policy development. For example, as described in section 1.4, for IPT RCTs, there isn’t one absolute concern, such as protective efficacy (the percentage reduction in the number of clinical malaria episodes in infants or children, typically in comparison to the control arm of the RCT), as critical as the protective effect may be, that is considered superior to other technical concerns. Policy makers have to balance other factors when considering the technical merits of an evidence base for policy consideration, such as

the consistency/repeatability of results (a reflection of the heterogeneity within pooled results from a collective body of RCTs, and how reliable an indicator they might be), possible drug side effects (which is a measure of drug safety) or other possible negative effects (increased drug resistance, and rebound effect, for example, both of which follow from only temporarily suppressing the numbers of malaria cases, before they might return at a higher rate than before, due to a lack of effective drugs, or loss of naturally acquired immunity). I will explore these known technical and measurable features of evidence (protective efficacy, repeatability/reliability, drug resistance and safety, and rebound) in the subsections that follow. In addition, I will explore how collectively these features of the evidence, along with some other more subjective elements, also appear to affect the perceived ‘strength and quality’ and credibility of the evidence, which will lead to the next chapter section (5.2.2) on differences affecting the salience of evidence.

(i) Protective efficacy

The IPTi Consortium conducted RCTs spanning different parts of East, South and West Africa and gathered data on a range of technical measures and outcomes, including efficacy, safety, drug resistance and drug choice, and interactions with the Expanded Programme on Immunisation (EPI), through which the intervention (IPTi drug doses) would be administered when the infant was taken to an immunisation clinic at 2, 3, and 9 months of age as part of its routine vaccination schedule (IPTi Consortium, 2010 - see also Figure 1).

The size of the studied population for IPTi was large: for example, approximately 8,000 children participated in the IPTi RCTs; over 300,000 infants per year participated in the operational studies led by UNICEF in six countries; and more than 80,000 *Sulfadoxine–Pyrimethamine* (SP) doses were given in the Tanzanian community-level effectiveness study (IPTi Consortium, 2010). In comparison for SMC, the RCTs were similarly multi-faceted, large, and thorough, except more geographically focused to West Africa (WHO, 2011a).

All of this seemed to bode well in terms of building a solid evidence base for both interventions, according to those involved in the research. However, at the end of all that work, the pooled protective efficacy— as described previously, the collective and averaged measure used to determine how many malaria cases were prevented, i.e. whether the intervention ‘worked’ based on the percentage reduction in the number of clinical malaria episodes between the RCT(s) intervention and control arms – was 30% for IPTi (WHO, 2010). In comparison, for SMC it was 75% (WHO, 2012c).

This difference in itself was not surprising to interviewees in retrospect, since unlike with IPTi, the SMC studies all took place within a narrow geographic band of West Africa with similar and highly seasonal transmission (60% of cases occurring within four months of the year). In contrast, IPTi trials took place all over sub-Saharan Africa in a variety of transmission and epidemiological settings (which is common for many malaria interventions). Therefore, it would have been expected that any given trial would show higher protective efficacy when tested in more narrow trial regions (although the absolute level would depend of course on features of the intervention, including the drugs used).

In addition, the pooled protective efficacy of IPTi is not dissimilar to other preventative malaria interventions widely recommended; for example, a systematic review of RCTs of the best known, and most studied, preventive intervention against malaria, insecticide-treated mosquito nets, showed that it has a pooled protective efficacy of 55% in children (Eisele et al., 2010), although there is statistical variation of this percentage figure depending on the study design and the unit of measurement (Kesteman et al., 2017). In any case, the complexity of preventing a complicated disease in a wide variety of (and ever-changing) epidemiological settings is the reason no ‘magic bullet’ exists in malaria control and why high coverage of a mix of interventions that is most suited to local transmission patterns is recommended by WHO (2015).

It should also be highlighted that many respondents, including those involved with SMC, noted that the amount of data collected to support IPTi far outweighed the evidence for a previous preventative global malaria policy on IPTp (Intermittent Preventive Treatment in pregnant women versus IPTi which targets malaria prevention in infants). As mentioned in Chapter 4, WHO issued a policy recommendation on IPTp in 2000 – since removed and replaced on the WHO website by an updated IPTp policy issued in 2012 (WHO, 2012a) – on the basis of just one study by Shulman and colleagues (1999) in Kenya showing an overall protective efficacy of 39%. The hasty initial recommendation by WHO of IPTp, based on seemingly little evidence, was argued by several interviewees to be nevertheless justified in 2000 because the burden of disease was great and there were few alternative interventions at that time. In comparison with IPTp, however, the more evidence that was generated by the IPTi Consortium, the more it seemed to be

subjected to contestation within the scientific community, according to interviewees, and echoing previous findings by Cruz and Walt (2013). The difference in pooled protective efficacy alone cannot sufficiently explain why this happened.

(ii) Repeatability, and reliability, of results

Another main criticism of several interviewees regarding the features of the evidence, and closely linked to pooled protective efficacy, was that the positive results from the first IPTi trial were not reproduced to the same high levels in later trials – the pooled protective efficacy of IPTi was 30% (WHO, 2010), compared to the 59% protective efficacy from the first trial (Schellenberg et al., 2001), which is to say that IPTi trials subsequent to the first one showed much lower protective efficacy on average. For some, this raised questions about the benefits of IPTi:

One of the big issues with IPTi was that the evidence didn't all point in the same direction. So the decisions were, you know, I think it was harder for people to have the level of confidence in them that they might have had with SMC where there's not much evidence going in the other directions. – KI41

Heterogeneity was not an issue for the SMC set of studies, where the pooled protective efficacy of the intervention was 75% (WHO, 2011b), compared to the 86% protective efficacy from the first trial (Cisse et al., 2006), which is to say that SMC trial results subsequent to the first one showed similarity with consistently high protective efficacy (WHO, 2011b, WHO, 2011c). Many interviewees seemed to assume this consistency between SMC trial results reflected positively on the strength of the results, which in turn might have helped the evidence base for SMC appear better, or less concerning, compared to IPTi. As one interviewee explained:

There was more heterogeneity in the IPTi results than the SMC results... And that's another thing that worries you – heterogeneity – particularly if the index study... and this has happened quite a few times in malaria, the first study by the protagonists: big effect, and then the follow-up studies: not such big effects. That's worrying. It didn't seem to be happening with SMC. The effects were pretty good everywhere. – KI51

However, the inconsistency between IPTi trial results can be explained (similar to the difference in protective efficacy between IPTi and SMC), as the difference can be due to features of the trial environments described in the previous section, i.e. there was more homogeneity between the highly targeted SMC study sites than between the heterogeneous IPTi study sites, which would have likely contributed to more consistent RCT results for SMC.

There is an additional explanation for the differences in consistency and overall protective efficacy between IPTi and SMC, suggested by a few interviewees as a possible confounding factor, and the source of some methodological contestation, which was the reliability of pooling data from six different trials for IPTi, which varied in terms of methods, dosing intervals, delivery schedules, and evaluation points. Even the IoM assessment (which had not reviewed the trials' raw data, but reviewed the same data as WHO) suggested that the IPTi Consortium “obtain an independent technical audit of the accuracy of the study-level data and analyses included in the pooled analysis” (Institute of Medicine, 2008, p. 3). In comparison for SMC, there was no contestation around pooled data, perhaps because the results were more homogeneous due to the homogeneous transmission setting across study sites (see WHO, 2011b).

(iii) Drug resistance and safety issues

Another key debate was around the usefulness of SP as the drug of choice for IPTi, first because of its growing resistance in some areas and second for its potential adverse effects. With regard to resistance, one interviewee observed:

We had increasing SP resistance [with IPTi] and, here, resistance really bites. Now, in pregnant women, you have a lot of background immunity. Not a huge amount, but they have...they will [still] benefit from a failing drug. But an infant has no immunity, so an infant infected with a resistant parasite's not going to benefit [from SP]. – KI55

When the IPTi Consortium studies were designed in the early 2000s, SP was efficacious in many settings and, as still is the case, there were limited alternative drugs. The researchers were aware however of the drawbacks of growing SP resistance, and some studies were designed with alternative drugs (see Gosling et al., 2009, Odhiambo et al., 2010). Later the IoM assessment of IPTi concluded that implementation should not be delayed or limited on the grounds of apprehension about an increase in SP resistance (Institute of Medicine, 2008). The issue of resistance was also raised as an issue for SMC, but instead of being viewed as a barrier, it worked as a facilitator; the argument being to use SP to reduce the malaria burden in West Africa while it still worked there (Ringwald et al., 2012).

Another debate for IPTi that arose was around SP's potential adverse effects. The first TEG review in 2006 found that: "Severe dermatological reactions tended to be reported more frequently in the SP group (5/3967) than in the placebo group

(1/3988)...[but] the observed risk of Serious Adverse Events was not statistically different in the SP and placebo groups....” (WHO, 2006a, p. 10).

However, the subsequent reporting of four cases of adverse events created delays in the policy process, as these were subjected to further TEG review. Some respondents felt WHO was correct to be cautious especially when prescribing drugs to healthy infants. But, some in the IPTi Consortium also expressed frustration at these delays. Indeed, additional investigations concluded that the reported severe side effects were unlikely to be what was initially feared to be Stevens-Johnson syndrome, a severe and untreatable skin reaction. Further, the review by the IoM which assessed the same data that the TEG had examined concluded that IPTi was a safe intervention (Institute of Medicine, 2008). By 2009, when the third TEG met (see Figure 3), safety concerns about SP had been minimised by evidence provided through a large operational study by UNICEF, an implementation study in Tanzania, and the detailed assessment by the Safety Panel of the IPTi Consortium, with regard to the reported serious skin reactions (WHO, 2009).

In comparison, no serious adverse events were reported for the SMC studies. However, as is the case for any form of mass drug administration, monitoring for side effects upon scaled-up programme implementation of SMC was a critical component of the WHO SMC policy recommendation (WHO, 2012c).

(iv) Rebound effect

Concern about rebound – that is, the possibility that treating largely asymptomatic, and otherwise healthy, individuals will ultimately lead to increased malaria morbidity and mortality once the intervention is stopped, due to decreased naturally acquired immunity (Breman and O’Meara, 2005, Aponte et al., 2009) – was, and still is, the subject of controversy for all forms of IPT as a type of mass drug administration. However, rebound is also hard to predict, partially because the biological mechanisms that might enable it (selection pressure for drug resistance mutations in malaria parasites, for example) are multi-faceted and not fully understood by scientists (Breman and O’Meara, 2005).

For the IPTi policy development process, the third TEG in 2009 deemed that the issue of a rebound effect deserved further monitoring in light of the three studies that reported a rise in either malaria infections, anaemia, or severe malarial anaemia after the intervention (WHO, 2009). On the other hand, the IoM review had considered that “in no case was the rebound sufficiently large to negate the overall benefit of IPTi-SP” (Institute of Medicine, 2008, p. 60). The balancing of harm versus benefit weighed heavily on those involved with the IPTi policy decision. One TEG member said:

[Long-term follow-up data] was one of the big problems [with IPTi] with the committee when we reviewed it. We wanted to know things like rebound, what was the overall benefit over a longer period of time. It’s pretty obvious ... that if you give anti-malarials to somebody in a malaria endemic area, you’re going to reduce malaria for a period of time. The question is, what’s the overall benefits of doing that and what is the harm? – K151

In the case of SMC, which did not have long-term follow-up data either, the protective benefit of administering SMC was considered so large, and the window of SP effectiveness in West Africa perceived as narrowing so quickly, they seemed to outweigh the hypothetical risk of a potential rebound further down the line.

(v) Strength and quality

The difference in measures of, in particular, protective efficacy and repeatability, were often described as proxy measures for the relative higher quality and strength of the SMC evidence base. As described earlier, in comparison to IPTi, which only demonstrated itself as ‘working’, i.e. having a large effect on morbidity, in one of its study sites, the SMC set of RCTs consistently demonstrated high protective efficacy in all its study sites (WHO, 2011b).

Some interviewees found the quality of both evidence bases to be comparable, with some suggesting that the evidence, and evidence use, for IPTi was marginally ‘better’ because of the volume and breadth of data collected, reflecting the popular notion (within public health) that Smith (2013) critiques, that more use of the ‘best’ evidence equals ‘better’ use of evidence. Nevertheless, features of the evidence traditionally associated with technical quality, such as the volume of RCT data, and the standards by which that data is collected, seemed to be less of a concern to interviewees, or more of a secondary consideration, when the size of the intervention effect was large. One MPAC member reflected:

I think that the evidence probably is comparable in terms of quality and the study design carried out. The IPTi studies were all done according to [Good Clinical Practice] standards. Every effort was

made to have those be comparable to what would be required for studies done for drug approval. Quite frankly, I think the SMC studies were not done, necessarily, to that standard but here the difference between the sort of controls and the impact was sufficiently large that people didn't question the validity of the evidence. – KI23

Ultimately though, many of those involved with the IPTi policy decision, felt that unlike with SMC, IPTi didn't do what it was supposed to do, which was sufficiently demonstrate that it protected the lives of infants. As one MPAC member explained:

There are two things about evidence. One is the quality of the evidence itself and the other is the result. I think the quality of the evidence for both IPTi and SMC were pretty good...The thing about SMC that impressed me as an outsider was that the studies were done in a large scale; they were done apparently well; and the effect was large. The more uncertain the effect, the more areas there are for arguments and concerns, and so on. So [SMC] had the advantage of having a bigger [protective] effect than IPTi. – KI51

When it comes to the perceived strength of an evidence base, it could be argued that SMC is more of an outlier for preventive malaria interventions, given its consistency, but also relatedly, the narrow geographic focus of studies. As mentioned earlier, one explanation for the difference in intervention results is that the SMC portfolio was in fact designed for one (highly seasonal) transmission setting, versus IPTi, which covered a range of transmission settings to, in theory, help with policy uptake. For the SMC studies, they appeared to be designed with consistency in mind, in order to deliver a complete package of results that might aid policy deliberation. One interviewee reflected:

Well I think the evidence base on SMC was more robust [compared to IPTi]. More coordinated, and what I mean by coordinated is that they used similar protocols in several sites. So I think the SMC

group, or the IPTc group then, they set out from the outset to try and answer... they designed studies to answer the policy question. So in that way they were able to influence the kind of data they generated because they asked the right questions. – KI42

SMC researchers asking the ‘right’ questions is a theme that came up often in interviewee responses. It is possible that this helped lead to the level of SMC evidence being perceived as stronger or more robust, even though delivering a complete and robust package of results was also the explicit purpose of the IPTi Consortium. Several interviewees did point out this irony, while others pointed out that although SMC researchers’ efforts did not appear to be as explicit, the robustness of their evidence base is not something that happened by coincidence either, and that SMC researchers put considerable effort into making their research accessible but also acceptable, according to the norms and standards of the public health and global malaria community.

This isn’t to say that the evidence base for IPTi didn’t similarly meet the standards of good scientific practice, because on face value, given the volume and breadth of RCT data considered valuable by those interviewed, it did. However, the IPTi RCT data also surfaced a lot more uncertainty compared to SMC, which made the interconnected factor of local applicability and relevance (salience) much harder to reach consensus on as part of the policy development process, and led to contestation over the evidence on IPTi. This juxtaposition between the evidence bases for IPTi and SMC appears to resemble what Contandriopoulos and colleagues (2010) highlight in their work, that in technically focused decision making, there is generally a perceived low level of contestation of the evidence. In such cases, technically focused debate tends to be resolved through ‘rational’ dialogues and

arguments, based upon a similar worldview amongst actors. In contrast, they say, high contestation of the evidence tends to lead to political debates and a strategic approach towards knowledge use (Contandriopoulos et al., 2010). The links between the contestation of otherwise seemingly credible evidence, and its political uses in policy development in this case study, will be explored in more detail in the next chapter.

5.2.2 Differences affecting salience

Contandriopoulos and colleagues (2010) also found in their systematic review of knowledge exchange interventions at the organisational and policy making level, that the external validity of evidence, that is the generalisability or local applicability (salience), and perceived alignment with existing knowledge, was awarded far greater weight than internal validity and scientific rigour (credibility) when considering which information was likely to be used in policy making. Cash and colleagues' (2003) definition of salience is that it deals with "the relevance of the assessment [of scientific information] to the needs of decision makers" (p. 8086), which leaves the term 'relevance' (and 'needs') open to interpretation and application. Parkhurst (2017) is more specific, and prefers the use of the term 'appropriate evidence' to replace 'good evidence' for policy, to stress the importance of evidence that isn't just technically valid and scientifically credible, but politically relevant and locally applicable as well.

It appears that salience, like credibility, can be viewed as being multidimensional and capturing several different elements, such as local applicability, contextual

relevance, generalisability, and even timing, as outlined in my analytical framework in Chapter 2. It should also be noted however, that specifically increasing the ‘timeliness’ and ‘relevance’ of its policy recommendations are two of the reasons why WHO-GMP established MPAC as the primary mechanism for its policy development to benefit its member states (WHO, 2012b). This implies that elements of salience are of value to WHO-GMP. This subsection explores these concepts relating to differences in the salience of the evidence bases for IPTi and SMC, and what the implications were in the context of my case study.

(i) Local applicability

The perception of higher ‘strength’ for SMC might have been compounded by the fact that the SMC study sites in the intervention region of West Africa were also the proposed implementation sites for the SMC policy, which resulted in an unusual situation for the evidence advisory committees (TEG and MPAC) that systematically reviewed the evidence base on SMC, in order to advise WHO-GMP on a policy recommendation. It was unusual because, in many other cases, these bodies need to deliberate about the applicability of study findings from a wide range of settings to the target contexts, which are often not in the same locations, i.e. they have to gauge if what worked ‘there’ will also work ‘here’ (Cartwright and Hardie, 2012). Yet with SMC, because the study region was the implementation region, the RCT evidence base reviewed was considered to have both high internal and external validity, which as several interviewees pointed out, made making a positive policy recommendation an easy choice and a relatively straightforward process compared to IPTi. Whereas in comparison, the TEG for IPTi (MPAC did not exist at the time) had far more

nuances to consider in its systematic review of the evidence available at the time (WHO IPTi Technical Expert Group, 2008).

For example, IPTi was sometimes described as ‘the wrong drug...at the wrong time’, to the extent that responding to this pervasive belief was part of a Q&A briefing pack prepared for IPTi Consortium spokespeople following one of their *Lancet* publications (IPTi Consortium, 2009). In reality, the programmatic feasibility (implementation) of IPTi was recognised as being extremely important by the IPTi Consortium. For example, two of the IPTi Consortium projects (see Figure 2) were a large operational study in six African countries led by UNICEF, and a community effectiveness study in Tanzania, which explored operational issues about how IPTi would work within the existing health system. Their results showed that overall IPTi was safe, affordable, acceptable, and possible to deliver within the existing health system (Manzi et al., 2009, Maokola et al., 2011, Pool et al., 2008, Schellenberg et al., 2010). While these findings (those that were available at the time) were examined by the third WHO TEG in 2009, and probably contributed to the decision to recommend IPTi, various respondents expressed additional concerns about implementation. For example, at the country level, capacity for implementation was considered an issue, and not only for IPTi. By the late 2000s it was known that IPTp coverage was low (Crawley et al., 2007, Worrall et al., 2007), especially for the required second drug dose (Menéndez et al., 2007), and that delivery problems accounted for delays in the spread of insecticide-treated mosquito nets, with considerable debate about best practice between different funding schemes.

From WHO-GMP's perspective, the operational feasibility of an intervention was reported to be as important as its effectiveness and safety. For example, clear guidelines to national malaria control programme managers were and still are considered to be crucial. But there was concern about how IPTi could be implemented and monitored in view of the increasing drug resistance to SP in some parts of Africa, and the lack of capacity in some countries, particularly at district level, to monitor levels of drug resistance in order to know where best to target the drug (making the drug essentially ineffective in those areas, hence the view that it might be the 'wrong drug').

(ii) Contextual relevance

WHO-GMP staff and some other interviewees were also uncertain as to how IPTi could be implemented and monitored in view of the local heterogeneity of countries' epidemiological profiles and the need to disaggregate their policy to sub-national levels. This was less of an issue for the SMC policy consideration, as there was epidemiological homogeneity for the reasons described earlier, and because the policy would only apply to certain parts of certain countries where 60% of cases occurred within four months of the year, the policy in some ways was already disaggregated to sub-national levels.

WHO-GMP guidelines also had to take into account the limited capacity of many national malaria control programmes, particularly at the district level. Although such issues were not specific to IPTi (they also apply to IPTp, indoor residual spraying for mosquitoes, and SMC, among other interventions), the actual relevance of IPTi was

also questioned in countries where EPI coverage was low, or where malaria was seasonal (which is to say that the delivery of the drug would not, in some areas of countries, be coinciding with the expected peaks in the number of malaria cases, hence the view that it might be delivered at the ‘wrong time’), as IPTi would have a very small effect (Chandramohan et al., 2005).

Although the WHO IPTi-related TEGs (WHO, 2006a, WHO, 2007a, WHO, 2009) and some respondents, expressed concern about the risk that IPTi might displace other more effective malaria control measures – insecticide-treated mosquito nets, indoor residual spraying, artemisinin-based combination therapies, for example – this contrasted with the views of others, particularly within the IPTi Consortium, that IPTi could actually play a complementary role in malaria control. It seemed to be generally accepted by all interviewees that there will always be various constraints to hamper optimal effectiveness of any malaria control intervention, and therefore interventions should be seen as a package, that is, as additional to each other, and not as competitors.

(iii) Generalisability

SMC, in comparison to IPTi, was described as having higher ‘practicability’ and ‘generalisability’ beyond just a research setting. This also seemed to contribute to its evidence base’s perceived strength. As one member of MPAC described:

I think the evidence base for SMC is pretty strong. I mean there are a number of really quite convincing and sufficiently large studies that show major impact. I mean you’re always concerned with, I think, a number of things; one is the size of the studies, the consistency of

the results, and the scale of impact, and that's the first step. Obviously you're then concerned about the practicability, because there it's quite possible to have an intervention which is in a controlled setting, demonstrably effective, but it may simply not be practical. I think SMC has the advantage of firstly, it's got a good evidence base; the studies are sufficient numbers, sufficiently large, and showing really major impact and certainly some of the studies have been conducted under conditions which would allow you to already extend it to the idea that this could be applied in a control setting rather than a small-scale research study. – KI34

The reasons for the difference in generalisability are varied, and among the explanations that were offered by interviewees was the difference in age group and banding (infants less than nine months for IPTi versus from six to sixty months for SMC), and also study location (highly seasonal transmission versus a variety of transmission settings). The SMC studies were focused only in areas of highly seasonal transmission, whereas the goal of the IPTi studies was to be generalisable to all of Sub Saharan Africa, which has far more variability in malaria transmission (year-round versus seasonal transmission), sometimes within the same country. This, in hindsight to those involved with the IPTi studies, made generalisability difficult due to the variability in results, compared to the relative homogeneity of the SMC study results due to the homogeneous transmission settings.

In short, by conducting the SMC RCTs in the very countries where the intervention, if successfully tested, would be eventually implemented, the SMC researchers helped ensure that their studies had good internal as well as external validity, and that their portfolio of research as a whole, despite having some weaknesses such as no pre-existing delivery mechanism, answered a wide enough range of useful questions to policy makers that it would be considered more relevant compared with IPTi. As one SMC researcher explained:

[SMC] was not just a purely academic study, it was really looking into how this will be translated into practice and I think that was what was really the most exciting aspect of it – it [was] really making sure that something that can work 100% will eventually work 100% and understanding the gaps...so we could come up with a battery of tools and answers to the implementation point, which I think is eventually with WHO and the national programmes to say, “Well, yes, this is efficacious, but will it be properly implemented and how?” And despite the fact that SMC didn’t have a clear delivery mechanism, like IPTi with the EPI system, different systems were tested through community health workers or health facilities or other [mechanisms]...So there was a comparison of what might work or might not work. – KI45

IPTi delivery via the Expanded Program on Immunisation (EPI), WHO’s vaccination schedule for infants, was viewed by many as a potential strength, as it meant delivery would be through the existing health system, when most mothers were already visiting health clinics with their infants for their WHO-recommended vaccination schedule. Some interviewees, however, perceived the lack of a single pre-existing delivery mechanism as a potential strength for SMC, rather than a critical weakness, as to them it meant that national malaria control programmes could have more flexibility and control over how the intervention could best be delivered in their local context.

On a final but critical point, in terms of implementation, some interviewees suggested that IPTi might have been of middle to low priority in Ministries of Health. While they perceived that research on IPTi ‘in country’ was considered to be highly credible (based on robust evidence, and undertaken by respected individuals and institutions), and IPTi was perceived to be a relevant intervention to address the existing burden of malaria, some interviewees perceived, and speculated, that

Ministries of Health were not especially interested in IPTi. They suggested that the timing or circumstance for introducing IPTi was not seen as urgent. Some suggested that this was due to the Global Fund review, which was happening at the time, which therefore resulted in a lack of resources to implement IPTi just when it was needed most. In comparison, SMC was perceived to have benefitted from the momentum of a relatively quick endorsement by the new MPAC, and a surge in implementation funds made available by UNITAID (a global health initiative hosted by WHO, and established by the governments of Brazil, Chile, France, Norway, and the U.K. to tackle infectious diseases like malaria) just as the WHO policy recommendation on SMC was made public, which is evidenced by its high level of policy uptake in comparison to IPTi.

(iv) Timing

By more fully and thoughtfully presenting the case for SMC, and eventually perhaps also benefitting from external circumstances outside the evidence review process such as the surge in implementation funding availability, the SMC researchers seemed to shine a light on an obvious potential window of opportunity for an SMC policy. One MPAC member pointed out:

There's a simple rule about getting things into policy, and that is you need loads of data. So, really big studies; and [SMC researchers] did really big studies. So, beyond safety and efficacy, there are other things you consider before you make a policy decision. Okay, well we debate a lot about whether we should consider price. Because price is a relative thing. I mean it's not the actual cost of goods; it's how much it will draw away from other interventions. So, if you have a policy, if you have something that somebody's going to pay for – it can be very expensive, but somebody is going to pay for it. However, with SMC it was dirt cheap. And so there was a feeling,

“This is really doable. We’ve got the drugs, they work...” There’s a window of opportunity. And it’s not going to cost too much. So there’s a bit of a trifecta in a way. – KI51

WHO-GMP staff agreed that this window of opportunity (inexpensive drugs that work extremely well, although in a rapidly decreasing area, due to spreading drug resistance) accelerated policy uptake, even with lack of evidence around implementation. One WHO-GMP staff member admitted:

There was a very strong sense that we have a limited window of opportunity because the two drugs in consideration were *Amodiaquine* and *Sulfadoxine-Pyrimethamine*. Both drugs actually have some evidence of resistance, certainly no longer useful in all of the Eastern and Southern Africa. But still effective in parts of Central Africa and mainly West Africa. So if we were going to, let's say, postpone the recommendation asking for *more* evidence, *more* experience, *more* operational research, you really risk that the whole system would be delayed, and we didn't have any other efficacy and safety data with alternative medicine, so this was like, the *only* body of evidence was these two medicines, and the evidence of impact was extremely strong – a 70% reduction in incidence and in severe malaria admissions. Okay, there was not so much experience on how you can roll it out, what is potentially a highly cost-effective intervention, because the medicines are relatively inexpensive. If you have a delivery arm that is community workers, it's not so expensive, you know. So [SMC] was an area where we can say the recommendations were in a way accelerated, or came into policy, without having first all the evidence [on implementation mechanisms]. – KI35

Several interviewees referred to SMC as being an easy choice in terms of its low cost, high efficacy, and a large supply of drugs. One way to explain this phenomenon is that it was a rare ‘window of opportunity’ where, unlike for the case of IPTi, Kingdon’s (2003) three streams – a ‘problem’ that needs solving, a ‘policy’ solution

that is available, and the ‘political’ will to act on it – seemed to have come together at the same time.

Kingdon’s (2003) multiple streams that intersect to form policy windows of opportunity, is one of several theories often stressed in the evidence use literature (for example, see Cairney and Kwiatkowski, 2017, Court and Young, 2003), which highlight the importance of opportune timing. In other words, whether a policy solution is perceived to be ‘the right drug, at the right time’, and how such policy solutions are constructed and negotiated, which is inevitably nuanced, given viable solutions involving major policy change take time to develop. Here SMC stands in some contrast to IPTi, which was often described as ‘the wrong drug, at the wrong time’.

Kingdon (2003) also describes ‘policy stream’ solutions as evolving; they can be proposed by one actor and then reconsidered, modified, and ‘softened’, by a large number of actors, as some issues take time to become accepted within policy networks. IPTi and SMC appear to demonstrate some ‘softening’ over time within the global malaria community; many interviewees touched on what is common knowledge if you have worked for long enough in global malaria, that although IPTi and SMC might sound like relatively new interventions, the initial trials for their previous iterations, upon which a more solid evidence base was then built, are more than 30 years old (Greenwood, 2018). In addition, because the evidence to policy process for IPTi mostly took place before the evidence to policy process for SMC, with a little bit of overlap, it is possible that that the SMC researchers were influenced by the IPTi researchers about how to (or not to) engage with the policy

process. Alternatively, SMC policy makers (for the most part the same experts who also advised on the IPTi policy) might have subconsciously warmed to the concept of intermittent preventive treatment over time.

As both IPTi and SMC policy development processes demonstrate, the production of a perceived policy solution, no matter how ‘credible’ or ‘salient’, may take a long time to be considered sufficiently acceptable, for reasons that are hard to untangle, and suggest that they might have more to do with just the evidence itself.

5.3 Reflective summary

The particular features of malaria (for example, that it was a severe problem and a global priority) should have assured IPTi a place on the global malaria policy agenda. Although there were some problems in attaining and interpreting data, the indicators used by most IPTi researchers were credible and well-established, and the IPTi researchers appeared to be credible and well-established themselves. It was around the protective efficacy and safety of IPTi-SP, however, that uncertainties arose, and led to increasing contestation of the evidence and the politicisation of IPTi as a policy solution, which as discussed previously, is seen to drive ‘political’ uses of evidence.

Although the results from the first trial and others suggested that IPTi was cost-effective, easy to implement through EPI, and that it fulfilled many of the standard (to the public health community) criteria of an effective intervention, the studies following the first trial did not reach the same level of protective efficacy, raising

questions for more research. After additional studies reported their results in 2007, uncertainty only increased. While this contributed to scientific debate, and arguably more scrutiny on IPTi than many other malaria interventions, it also slowed down the IPTi Consortium's ability to achieve its goal of a quick policy solution, for reasons that were confusing and frustrating to Consortium members, but seemingly logical to WHO-GMP's evidence advisory bodies, even though no feature of the evidence alone stands out as being so problematic that it would justify policy inaction (IPTi pooled protective efficacy, though relatively low in comparison for SMC, being otherwise relatively normal, or even good, compared to other malaria control interventions). In other words, despite the IPTi researchers' best efforts, 'good evidence' (in the form of the IPTi RCTs) did not appear to be enough for IPTi to be perceived as an acceptable policy solution to WHO-GMP and its TEG.

In the case of SMC, the factors that appear to have edged its evidence base over the evidence base for IPTi was that it was ultimately perceived to be more relevant to the question being asked by the TEG, with the perception of its relative quality as an intervention being boosted by the size of its effect (the large drop in morbidity), and the high consistency of the results in the various study sites. In other words, SMC appeared to be exactly 'the right drug, at the right time', emerging as a perceived policy solution of superior strength and quality in comparison to IPTi.

Exploring the features of the evidence alone does not entirely account for why this was the case, and suggest that other less obvious factors besides the credibility and salience of the respective evidence bases mattered in how IPTi and SMC policy development was perceived by WHO-GMP, its TEG, and other actors in the process.

The findings from this and the previous contextual chapter suggest that the process of evidence use, and the political nature of evidence, may also have a nuanced role to play in policy development (Liverani et al., 2013, Oliver et al., 2014b, Parkhurst, 2017) and in how, why, and to what extent, IPTi and SMC were perceived to be acceptable policy solutions, or rather, not an acceptable policy solution in the case of IPTi. Here exploring the third strand of Cash and colleagues' (2003) model, regarding legitimacy, and the importance of process, might provide further insights and lessons within this case study, and are the findings I explore next.

Chapter 6: The process of forming global malaria intermittent preventive treatment policy

6.1 Introduction

This results chapter continues the exploration of the various influences on the uses of the IPTi and SMC evidence bases in global health policy development, focusing on the processes through which evidence ultimately informs global malaria policy decisions, in the cases of the WHO IPTi and SMC policies.

This chapter focuses on the third element of my analytical framework, which was drawn from Cash and colleagues' (2003) model regarding legitimacy, and the multiple component factors that may influence perceptions of it. Exploring the angles of legitimacy in the context of this case complements the previous chapter on the features of good evidence because, although the conceptualisation of 'good' or appropriate evidence notes that evidence should address multiple social concerns, the processes through which those concerns are made clear and addressed also matter (Parkhurst, 2017), and require further exploration in order to improve our understanding of the complexity of evidence use in policy making.

Definitions of legitimacy can differ by academic discipline, but here I broadly refer to it as the "generalised perception or assumption that the actions of an entity are desirable, proper, or appropriate within some socially constructed system of norms, values, beliefs, and definitions" (Suchman, 1995, p. 594). Cash and colleagues (2003) offer a similar though slightly more defined view that legitimacy reflects "the

perception that the production of information and technology has been respectful of stakeholders' divergent values and beliefs, unbiased in its conduct, and fair in its treatment of opposing views and interests" (p. 8086) which could be considered a reflection of what they view to be 'desirable, proper, or appropriate' within their cases from the field of sustainable development. I prefer the use of the broader definition of legitimacy in the context of my case study, because I don't just explore the production of information, I also explore the development of policy itself. In addition, the broader definition acknowledges that concepts such as 'bias' and 'fairness' and other elements of 'appropriateness', which I explore in this chapter, are essentially socially constructed, which is left unstated and perhaps taken for granted in Cash and colleagues' narrower definition of legitimacy.

Within the context of global malaria preventive treatment policy development, and the global malaria community's own socially constructed system of norms, values, and beliefs, the policy development process for SMC was perceived by stakeholders to be 'better' by being seemingly smoother and less contentious a journey compared to the process for IPTi. This chapter attempts to explore how and why the SMC policy development process was considered to be smoother and less contentious relative to IPTi, and how often seemingly implicit, though sometimes explicit, codes, behaviours, and structures within policy development processes influence how the policy development process is perceived, which may in turn contribute to perceptions of its legitimacy, where actor/stakeholder acceptance of the policy development process or outcome could be considered an early embodiment of perceived 'policy success', as was the case for SMC.

6.2 Findings

First I present the themes that emerged from my analysis of comparing differences between IPTp and SMC policy processes, before summarising the findings with some reflections on this subset of my thesis results.

6.2.1 Differences affecting legitimacy

As we can gather, based on the exploration of the concepts of ‘credibility’ and ‘salience’ in the previous chapter, legitimacy is a broad concept that is made up from, and can rely on, a wide range of possible factors. These are explored in the following subsections on structural differences, expectations and framing, conflicting agendas, transparency, and representation, which emerged from my data and subsequently helped inform my analytical framework. Many of the themes discussed in this section on the legitimacy of IPTi and SMC policy development processes can be seen to relate to what March and Olsen (2011) would call the ‘logic of appropriateness’, and how it influences institutional behaviour as well as the behaviour of individuals within those institutions. They offer that policy making is driven by the ‘rules’ of appropriate behaviour, and that these rules are followed by actors within institutions because they are seen as “natural, rightful, expected, and legitimate”, and help fulfil their perceived obligations of their role within a group. In other words, actors will “do what they see as appropriate for themselves in a specific type of [institutional] situation.” (March and Olsen, 2011, p. 1)

According to March and Olsen (2011), as well as other scholars of institutional theory and approaches (Deephouse and Suchman, 2008, Lowndes and Roberts, 2013, Peters, 2005, Suchman, 1995), institutions (such as the IPTi Consortium, the BMGF, or WHO-GMP, in this case) come in a variety of forms, and can be viewed as collections of procedures, which are enacted by actors within those institutions, who often use rules as part of a code of appropriate behaviour, which is socially and collectively learned, and internalised.

In the context of my case, the IPTi Consortium was technically a network of institutions, a time-limited global malaria research partnership to be specific, whose explicit goal was to see IPTi through to becoming a WHO global malaria policy recommendation. In comparison to the looser or more informally connected association of actors that worked on SMC, the IPTi Consortium was a formal coalition of different and overlapping communities of researchers and policy makers (see IPTi Consortium, 2003 and Figure 2). At its centre, and similar to SMC, was a community composed of professional researchers and scientists (primarily linked to LSHTM, but also involving other renowned academic institutions specialising in malaria such as the Barcelona Institute of Global Health, where the IPTi Consortium's 'core administration' was based – see Figure 2). These actors shared a common commitment to tackling malaria to prevent morbidity and mortality, especially in infants and children in Africa, but, as we shall explore in the subsequent subsections, there were also several differences when it came to their own logics of appropriateness, and the rules by which they conducted themselves.

(i) Structural differences

One of the reasons for process-related differences which may have impacted eventual policy outcomes, and the reason why the two policy development processes within this case are not directly comparable (as previously discussed in section 1.4) is something I came to realise over the course of my interviews and concurrent analysis, which was that there were structural differences in how the IPTi and SMC research groups were organised, as well as differences in the WHO evidence advisory processes that reviewed both the IPTi and SMC evidence bases in order to make a policy recommendation to WHO-GMP. These research-related and policy development process-related structural differences, discussed next, would likely have affected the implicit and explicit rules or codes of appropriate behaviour followed by the actors within the IPTi Consortium and WHO-GMP for example, and may in turn have influenced the various elements affecting the legitimacy of the IPTi and SMC policy development processes, such as actor expectations, and research or policy process framing, transparency, and membership and representation on committees (themes that emerged from my interview data, which are explored in the subsections that follow this one on structural differences).

Research-related structures

As described in previous chapters, the encouraging results of the first IPTi trial in Ifakara, Tanzania in 2001 (Schellenberg et al., 2001) led to excitement among the core group of scientists involved in this trial, because they had proof of an intervention that could potentially transform the landscape of global malaria control

efforts, particularly in Africa. This led to the creation soon after of the IPTi Consortium, a formal research consortium whose primary aim was to inform policy and practice for IPTi in Africa through their own scientifically robust and policy-oriented research (IPTi Consortium, 2003). In comparison, the various researchers that worked on SMC studies did not have a formal structure and had no such explicit policy aim.

In addition, and unlike with the SMC set of studies, the BMGF was considered to be a member of the IPTi Consortium (see Figure 2), liaising with a broad set of stakeholders in order to see knowledge executed as practice. Other consortium members viewed the BMGF as a highly valued funder and active member of the consortium. Several interviewees referred to the strong professional reputations of the BMGF representatives involved in the IPTi Consortium, describing the BMGF as having the advantage of being able to identify problems and solutions quickly, providing leverage to move issues forward, as well as to acting as brokers or facilitators in the policy process, although as we will soon discuss, this was not necessarily always well received. In comparison, for the SMC set of studies, the BMGF maintained, and was perceived as maintaining, far more distance as a funder.

The third institution or set of actors involved with the policy process for both sets of studies was WHO-GMP. Similar to the BMGF (and in contrast to the SMC set of studies later on), WHO-GMP was also involved with the IPTi Consortium as a member, via the BMGF-funded and WHO-hosted IPTi Policy Platform (see Figure 2). As described earlier, the objective of the Policy Platform was to bridge the perceived research-policy gap, by facilitating the evidence from the IPTi studies

through the WHO evidence review process, so that WHO-GMP could reach a global policy recommendation on IPTi (WHO, 2006b).

Policy development process-related structures

As mentioned previously, at the time of the IPTi Consortium, and prior to the existence of MPAC, the evidence review process at WHO-GMP involved multiple levels of evidence review (see Appendix 3). The first level was the TEG, which reported to the TRAC, which in turn reported to the STAG, before a policy could finally be signed off by the WHO (D'Souza, 2014). Interventions involving vaccines (programme delivery through WHO's EPI vaccine schedule in the case of IPTi) also needed to be endorsed by the Strategic Advisory Group of Experts (SAGE) which serves as the high-level evidence advisory body of the Department of Immunisation, Vaccines and Biologicals (IVB) at WHO (essentially, the SAGE is the IVB and vaccines equivalent of what is now the MPAC for WHO-GMP and malaria). Since IPTi was designed to be delivered through the EPI programme, it was due to be reviewed by all four of the committees mentioned above.

In contrast, by the time for evidence review of the SMC set of studies in 2011, and benefiting from a restructure that was specifically intended to make the policy process more transparent, responsive, and credible (see D'Souza and Newman, 2012), there were just two levels, the TEG and the MPAC, which the TEG reported to.

Beyond these research and policy development process-related structural differences however, there were a few other themes that emerged from comparing the differences in the policy development processes for IPTi and SMC.

(ii) Expectations and framing

One marked difference between the policy processes for SMC and IPTi was that the SMC researchers did not have the expectation (nor the pressure of an explicitly stated goal) of a linear policy process where their research would have immediate policy impact.

In the proposal sent to the BMGF in 2003, the researchers who would later form part of the IPTi Consortium stated “the evaluation of IPTi should proceed ... rapidly ... if results of the early morbidity studies are consistent” (IPTi Consortium, 2003, p. 11). It was clear that despite mention of the conditional “if”, that there were high expectations that IPTi knowledge transfer would be quick and that “...by the end of 2005 it may be possible to make a policy recommendation on IPTi.” (IPTi Consortium, 2003, p. 15). Further, there was consensus at the time among all members of the Consortium (researchers and policy makers) that the process from research to policy should be rapid: “UNICEF and WHO are prepared to provide the necessary technical and policy support to enable programme implementation as soon as the relevant information becomes available.” (IPTi Consortium, 2003, p. 2).

It was thus planned that policy engagement would take place alongside (and not at the end of) the process of generating the evidence on IPTi. A strategy was devised

(known within the IPTi Consortium as ‘the green line’), which set out a clear schedule that by the end of 2005, the Consortium would have generated a substantive body of evidence on IPTi-SP (efficacy, EPI interactions, safety and drug resistance) to inform a policy recommendation (see Figure 1); and that by 2008 it would produce further scientific evidence on IPTi as related to the above areas but using drugs other than SP to provide WHO with alternatives in the face of increasing drug resistance (WHO, 2006b).

By framing the value of their research, and their own success as a consortium, around a quick policy recommendation by WHO, the IPTi Consortium put themselves, and by extension, the WHO-GMP evidence advisory process, under significant pressure. One interviewee later recalled:

Now where the IPTi consortium went wrong was that there was this day which was called the “green line” where we all go to it with all our evidence, and then the policy decision to implement IPTi would be made, but of course the reality is that the evidence would be *considered* and then a decision for IPTi policy would be made. But it wasn’t really figured out like that. It was figured out that the “green line” meant green for go, and IPTi would be recommended, and IPTi would be implemented. And I think that that was really the biggest error, [the] supposition that the data would support a decision to go ahead. – KI44

Although similar policy engagement also took place alongside the process of generating evidence on SMC, that process was perceived to be more organic, for example, via informal (by WHO standards) meetings between SMC researchers, WHO, and national malaria control programmes, in 2008.

The SMC researchers, in comparison, were not part of a formal ‘SMC Consortium’ with an overt agenda to achieve policy goals. One reason for this is that they might have learned lessons from observing the experience of global malaria colleagues in the IPTi Consortium, who were in the midst of repeated TEG reviews and tensions with WHO-GMP at around the same time, although no SMC interviewees explicitly stated that they were influenced by the IPTi Consortium in this way. In any case, SMC researchers did not appear to have high expectations of quick knowledge transfer, nor the pressure of self-imposed ‘green lines’ to contend with, which might have contributed to a less fraught policy process with relatively tempered expectations, despite consistently highly efficacious trial results.

The advocacy-oriented optimistic framing of the IPTi Consortium was clear in their proposal to establish the Policy Platform which was sub-headed “Planning for Success” (WHO, 2006b). In the ‘expected outcomes’ section of the proposal, it stated: “This 4-year programme of work assumes that the research evidence on IPTi will be favourable” (WHO, 2006b, p. 5).

While none of the subsequent trials to the first Ifakara one in Tanzania achieved the same high level of protective efficacy (Aponte et al., 2009) – in contrast to the SMC set of studies which showed consistently highly levels of efficacy described in the previous chapter – the 2006 TEG nevertheless advised WHO that IPTi be conditionally introduced where appropriate. Had WHO accepted the policy advice and issued a recommendation on IPTi, the IPTi Consortium’s internal framing and vision of a linear policy process with definitive RCT results would have been realised.

However, in 2007, the TEG and WHO-GMP rescinded their policy decision. This decision was based on the final results from the IPTi trials in Ghana in 2007, which reported the occurrence of some severe side effects. A second TEG meeting took place in October 2007 (see Figure 3), which reviewed the existing data, in addition to further data and analysis (WHO, 2007a). The conclusions of the second TEG were more cautious than the first one, citing safety concerns and uncertainty around the level of protective efficacy for IPTi, saying that while IPTi-SP “remains a promising intervention... [and the] established benefits ... might override the safety concerns”, it recommended another TEG review take place in 2008 when new data became available (WHO, 2007a, p. 7).

(iii) Broken consensus

As the linear approach of the IPTi Consortium was challenged, many in the research and policy community felt conflicted, which was perceived by many interviewees as relating to the tension between scientific independence and advocacy (Cruz and Walt, 2013). Some interviewees talked of the enormous ‘psychological effect’ from the positive results produced by the first trial, although a few interviewees suggested that with hindsight these may have been overly optimistic, as pooled protective efficacy results from Aponte and colleagues (2009) within the IPTi Consortium, and the drawn out policy development process for IPTi, later demonstrated.

The confidence in the initial results, and the seemingly large amount of funding (for the time period) invested in the IPTi Consortium (USD \$28 million), were suggested

to have led to pressure for a quick IPTi policy recommendation. Other interviewees suggested that the IPTi Consortium may have been partially blinded by its overt advocacy-oriented approach, and therefore couldn't see perceived flaws in its research or behaviour. On the other hand, while conceding that the energy generated by the first IPTi trial played a strong part in setting the tone for the Consortium and its work, some Consortium members pointed out that in a time of limited policy alternatives, their enthusiastic (almost evangelical, according to some interviewees) approach was justified.

Other reflections by interviewees also illustrated the growing unease among and between IPTi Consortium members. There was a perception among some members of the IPTi Consortium that there was some form of 'a party line' or unspoken rule about how they ought to frame or position their research in the face of uncertainty. For example, a few IPTi Consortium members felt that inconclusive results, or concerns over adverse side effects whose causes were unknown, were met with some hostility from more senior members of the IPTi Consortium. Others resented that there was a peer review process within the IPTi Consortium before papers could be submitted to scientific journals. They, as researchers, felt discomfort at the seeming conflict of interest that lay between producing evidence, and then shaping or presenting it in a way that felt, to them, somewhat corporate. These insights are consistent with Cruz and Walt's (2013) previous findings about the IPTi policy process, and the tensions and challenges between actors that arise when brokering the boundary between science and advocacy (Smith and Stewart, 2017). Yet other interviewees felt "it doesn't matter if someone's perceived to be an [advocate], as long as the process is good" (KI36). According to some interviewees, the lack of

consensus within the IPTi Consortium on how best to manage evidence generation and facilitation appeared to further break down the longer the seemingly strained policy development process went on.

In the following subsections, I explore the growing tensions and possible sources of conflict arising from what appeared to be differences in expectations and framing, and a breakdown in consensus, among the three main groups of actors involved in the IPTi and SMC policy processes: researchers, the BMGF (funders), and WHO-GMP (the policy makers/ stewards of evidence-based policy and guidance for malaria-endemic countries).

(iv) Conflicting agendas

As highlighted in the chapter subsections so far on the differences in institutional structures, and expectations of, and framing by, the IPTi researchers, the IPTi Consortium was specifically designed to draw on its strengths as a group of researchers, funders, and policy makers to support, analyse, and synthesise the findings from a number of IPTi studies across various disciplines, and through the Policy Platform to inform the evidence review process to get to a global IPTi policy decision (IPTi Consortium, 2003). However, the breakdown in consensus and increasing tensions between actors that have been described so far were moving the Consortium down a path where the political nature of evidence, and the tensions it was causing between actors, would soon come to a head, or rather, in terms of the policy development process, a stall.

Part of the cause for conflict might have been that the IPTi Consortium, from its inception, framed its activities as part of a linear process to translate research into policy by setting up the Policy Platform in parallel to evidence generation, and in order to accelerate the policy process (WHO, 2006b). However, in reality, the IPTi Consortium was made up of actors from different institutions, with different institutional logics, ranging from a focus on science (e.g. LSHTM), to a concern with ‘saving lives’ (BMGF), and agreeing global malaria policy (WHO-GMP).

Researchers as policy advocates

When in 2007 the TEG overturned its 2006 policy advice to WHO-GMP (see Figure 3), reportedly due to safety concerns, the decision reflected a tension created by the contestation over evidence which some IPTi researchers took seeming personal issue with. Some IPTi researchers suggested the change was due to how they were being perceived as advocates, rather than the evidence base itself. In these IPTi researchers’ view, WHO policy decisions should be based on evidence alone. One IPTi Consortium member explained the reason for their indignation:

The tool should be judged on the merit of the evidence, not on how the investigators are perceived...whether they’re more vocal or less vocal or activists or not activists. I mean it’s nonsense. The problem is the moment one accepts the world of perceptions to influence a policy making process then we have a big, big problem...In a policy making process [perception] is irrelevant as long as the data, and the quality [of the evidence] is good. All our [IPTi] data [was] published in very highly respected journals....We produced 60, 70 papers and it’s not that we hid the evidence; all the evidence was immediately put in the public domain. What else [could] we do? They can say, “We don’t like [IPTi researcher] because he’s a loud mouth.” Fine, I can perfectly understand that, but that should not impact the way the evidence is viewed. – KI36

However, researchers being perceived as advocates did appear to impact the way the (IPTi) evidence was viewed, and how it was subsequently dealt with by WHO-GMP's evidence advisory bodies, which speaks to what Smith and others (Smith, 2013, Smith et al., 2016) describe as some of the risks and unintended consequences of researchers engaging with public health advocacy, such as perceptions of bias, the loss of credibility due to perceptions of undue funder influence (discussed in the next subsection), and actually constraining, versus enabling, policy action. Related to this last point, one TEG member reflected:

[Because of] the safety, lack of efficacy, uncertainties...it was a political hot potato. That's how it was introduced to me. There're a lot of pressures. The investigators are pushing. BMGF are pushing. At the highest levels within WHO. This is a real political hot potato. So we decided that we weren't going to reject it, but we weren't going to accept it. We decided we needed more information. – KI51

This form of stalling appears to have contributed to a perception of the commonly-held view within public health of 'two sides' pitted against the other (Lin and Gibson, 2003). As one IPTi Consortium member summarised:

It was bad. Aggressive from some of the researchers, aggressive from some members of the BMGF, an aggressive push back from WHO, I've never seen anything like it before. Everyone seemed to rally on the two sides. – KI49

There was the earlier-described tension within the research community as well, where some IPTi Consortium members expressed their commitment to contributing to public health (reducing malaria morbidity and mortality) by wanting to directly impact the policy process via proactive advocacy-oriented engagement, which is

what Cairney (2015) suggests more researchers *should* be doing. Others felt, however, that scientists had to stay neutral and focused on the research, and that directly engaging with the policy process was outside their area of authority and comfort zone i.e. that it somehow felt inappropriate. Still others in the IPTi Consortium were torn between both science and advocacy, feeling compelled to generate robust evidence, but also responsible for actively influencing the policy process (see also Cruz and Walt, 2013).

Although these tensions were less of an issue within the SMC policy process, many SMC researchers also echoed these mixed views about the role of researchers, and where exactly they should step into the part of the policy development process that involves some level of advocacy, sometimes at the necessary expense of objectivity according to Cairney and Kwiatkowski (2017). One SMC researcher explained their own views on the matter:

You try to make sure that the key people know about it and that's by having a meeting or a symposium. Taking that any further, I've always been on the side that investigators shouldn't become lobbyists, and that somebody else should do that. You may need a lobbyist, but those are different people, it shouldn't be the investigators who did the trials...they may be asked to help, but you shouldn't have one of the key investigators initiating that process. –
KI29

It would appear that the perceived overt advocacy by some IPTi Consortium members, a role not congruent with how good scientists should be seen to behave according to the expectations of many of their peers, caused this set of actors to appear less neutral and therefore less credible, and so undermined their perceived legitimacy within the IPTi policy development process. This was a consistent

reflection across the various groups of interviewees – funder, researcher, TEG members and WHO staff. For example, one member of BMGF reflected:

I think clearly a problem [was] that WHO perceived the IPTi Consortium as being a mixture of investigators and advocates, and without a clear separation of those. So they saw this group as putting evidence forward and advocating strongly for implementation, for adoption of policy and implementation of IPTi. In fact, I think, in some ways the Consortium was perceived more as advocates than as sort of independent, unbiased investigators and so that colours the way things are looked at. If you think these people are flogging something and they've got lots of biases, then surely their data is biased and they're not revealing ... For example, they may not have done the studies well enough to be sure that there aren't adverse reactions. That was a big issue. You could ask "Really? Did you really set things up so you picked up the signals?" –KI23

Many within the IPTi Consortium also expressed unease at the fine line between science and advocacy, the pressure it created, and ultimately the breakdown, instead of building, in trust it brought about between various actor groups, another critical component of a 'good' policy development process (Cairney and Kwiatkowski, 2017). One Consortium member recalled an incident during a conference call to discuss the pooled analysis of IPTi results:

All these people are on a pooled analysis phone call and the end point of the pooled analysis would be manipulated to get the best figure. And one day they got manipulated and suddenly the death rate was higher in the [research] arm. So it's "Oh, no we can't do that." You don't manipulate the data to make it look good. And I think that kind of behaviour undermined the consortium so massively that people just thought these people they're, you know, they have their own agendas, they're pushing this because, so I mean right from the start you know when you look at it from that kind of tainted lens you're just paranoid about the consortium. –KI44

The claim of data manipulation is not a point that was commonly repeated, although it was generally acknowledged that pooling data for IPTi was difficult due to the variation in results across sites, and that changing figures, and aggressively pushing for them, drew suspicion, particularly from WHO-GMP. As one WHO-GMP staff member explained:

I got irritated by what I saw of...the internal communication in the IPTi Consortium...the way they were planning how to work with WHO, how to get through to which levels and deciding what kind of decision making approval and what WHO policy is and so on, instead of leaving that to us...that pushiness definitely made things worse; it made me extremely irritated. –KI46

In comparison, the researchers who were part of the SMC studies were perceived to have played their expected neutral role, which might have helped maintain their credibility, through appearing to be more fair and unbiased. One WHO-GMP staff member reflected:

I think a lot of people like I perceive the [SMC researchers] to be behaving the way that you expect scientists should behave...really seeing various sides and carefully looking at various angles. –KI35

This perceived caution and neutrality, perhaps meant to be symbolic of their scientific impartiality and rigour, was also reflected by many SMC researchers as something they were proud of, as it was a value that set them apart from IPTi researchers. One SMC researcher elaborated:

I would say that the [Principal Investigators] involved in IPTi were very emotional, very much driven by, kind of *ideology* driven. They had strong belief that this is the best policy. And then, secondly, that spilled into promising this funder that this is a fantastic policy, it *will* become a policy by X number of years, we are creating data to make that policy, we are *sure* to make it a policy. [SMC researchers] didn't

have an expectation. There was no [ideology]...even though we saw 80 plus per cent protective efficacy, still there were doubters. –KI32

It seems that the behaviour and actions of the SMC researchers may have helped maintain the perceived legitimacy of the SMC policy-development process relative to IPTi. In addition, the SMC researchers' relatively neutral behaviour did not go unnoticed by observers of WHO's evidence advisory processes, who could also be considered sources of legitimacy for WHO policy decisions, since they form part of the audience or jury that judges whether the policy development process has been credible and acceptable, which in turn affects how policies themselves are perceived.

One IPTi and SMC stakeholder explained:

SMC [researchers], whilst being obviously also funded by the BMGF did not have the same aggressive push. I've never heard anybody say anything bad about how SMC was introduced [for policy consideration]. – KI49

Funders as consortium members

One of the IPTi Consortium's most influential members was the BMGF, credited with, amongst other things, inaugurating a new era of scientific commitment to global health problems through its energetic advocacy (The Lancet, 2009) and research (Black et al., 2009). The BMGF's participation in key meetings of the Consortium was largely seen as positive and helpful, particularly in the instance of what felt like the 'lost year' of 2008 when frustrations among Consortium members had reached a peak because they perceived the WHO evidence review process to have stalled.

In the IPTi Consortium members' view, the WHO-GMP evidence review and policy development process for IPTi lacked transparency and was too influenced by WHO-GMP staff, such as then WHO-GMP director Dr. Kochi, who were believed to have had personal reservations about IPTi as a malaria prevention intervention. One member of BMGF explained their perspective of what happened during the IPTi process:

There was a certain degree of slowness, if not reluctance, within WHO, the [Global] Malaria Programme, to actually review the IPTi data...I think there was not a lot of enthusiasm amongst people responsible for this, to get this done. So it really required a lot of pushing. And as you know, we eventually said, "Well, it's not happening in WHO. We're gonna go to the Institute of Medicine" and we asked the Institute of Medicine...So it's interesting to see how they handled that and how IOM came out with their report, which stands as some contrast to how the WHO handled the process. It really required pushing to get things done. You've got to have a policy making process which is ... a transparent, predictable, credible process that's accepted by the community... [For IPTi] it became a matter of individuals and the position and influence of individuals who were in the [WHO Global Malaria] Programme. – KI23

This period, thus, exposed tensions as to whose mandate it was to translate evidence into policy and practice. WHO-GMP felt pressurised by the BMGF to move faster than it deemed reasonable. The BMGF responded to other IPTi Consortium members' perceptions of a stagnant process, by, for example, commissioning the IoM review. From the BMGF's perspective, their behaviour was justified by the Consortium's frustration and lack of trust in the WHO-GMP policy development process. They explained:

I think the difficulty was, we actually had to push on WHO just to get this done, which is why we went to the Institute of Medicine. I

mean, it's like saying, "Can we can get some other group to look at this and kinda push WHO into doing *something?!?*" [WHO] sort of said, "Well, you know, you don't have enough evidence yet" and began to insist on peer review publications of all evidence, which is bogus. I mean, that's totally bogus and that's what we felt. "Well, we really can't consider this because these are not published yet in peer review journals." That's a bunch of nonsense. Sorry. – KI23

The BMGF's behaviour was then criticised by some stakeholders as challenging WHO's – albeit perceived to be weak at the time – policy development process without taking into consideration either the responsibilities WHO had towards its members states when providing a global policy recommendation, not to mention its formal mandate to be the provider of that particular type of policy advice. Several interviewees expressed their discomfort with the seeming power struggle between two influential institutions (WHO and BMGF), with one IPTi consortium member admitting:

WHO at that time didn't have a totally transparent and accepted approach to [set policy] which led the BMGF to go to the Institute of Medicine to do another review because they weren't happy with the process... that's not ideal, the Institute of Medicine in Washington shouldn't be deciding policy for African countries; they don't have any mandate to do that. – KI54

One possible reason for these perceived missteps was that the BMGF was both a funder (in their case, wanting to see positive outcomes, in this case a WHO recommendation, as promised to them as a near certainty in the IPTi Consortium's proposal to them in 2003, which they subsequently approved and funded) and an IPTi Consortium member. Although the Consortium was coordinated via a 'core administration' secretariat based in Barcelona, the BMGF essentially still managed

sub-project finances and results reporting (IPTi Consortium, 2003), including the Policy Platform established within WHO-GMP (WHO, 2006b) – see Figure 2.

By seeming to have attempted to undermine WHO-GMP through its efforts to speed up the policy development process, the BMGF might have inadvertently undermined its own credibility as an actor within the IPTi policy process, thus affecting the perceptions of the various actors involved, and the perceived legitimacy of the process itself. One staff member at the Foundation reflected on their lessons learned:

Quite clearly, the Gates Foundation was not regarded as independent. In fact, I think there was a concern that because we were funding WHO, we contaminated the process. It was perceived that we were funding WHO not to do an independent assessment, but to develop a policy recommendation for IPTi. That our goal was not an independent review, but a policy recommendation, almost like it didn't matter what the evidence was... You know, it wasn't just making the grants and the whole process of shepherding this effort... we were also trying to get this process to work. With that investment of money and effort, if you were to ask me now, "Was it worth it?" I would say, "No, we got it wrong." –KI23

This is in contrast to the SMC policy process where the BMGF was perceived at least to be very much 'hands off' and less aggressive, which might have made the process appear more acceptable as a result. A SMC researcher reflected on their experience compared to that of IPTi colleagues:

[SMC] was also funded by the Gates Foundation, interestingly, but there was no pressure from the Gates Foundation at all. It was completely the academics who did the study, [and] went to WHO. [There was] less pressure. – KI32

Other stakeholders and observers of both the IPTi and SMC processes echoed this perception, of a more tempered approach by BMGF when it came to SMC, which

perhaps benefitted from their experience from the IPTi policy development process.

For example, one stakeholder remarked:

SMC came through a similar process but somehow, and I think it's because the Gates Foundation, and others, probably learnt key lessons, and it was more clearly through a [process] and a different way of funding that didn't look like it was the Gates Foundation versus the WHO. – KI49

Reflections on policy development process learnings like these were common; the lack of pressure and, as a result, conflict during the SMC policy development process was considered by many key informants to be its positive defining feature, in contrast with what was viewed by many as almost 'par for the course' for IPTi and its seemingly constant legitimacy undermining missteps.

WHO as consortium members

One such perceived misstep was WHO-GMP's own role as both participant and reviewer of the IPTi Consortium's work. From the start, the IPTi Policy Platform was in an ambiguous and precarious relationship within the WHO – it was part of the Consortium, but also part of WHO-GMP (WHO, 2006b). One of the Platform's first actions was to support the independent TEG meeting held in 2006, but when the reports of potential serious side effects were made, the WHO staff who were part of the Policy Platform felt caught between strongly convinced IPTi Consortium members, and uncertainty about safety from researchers and programme managers within and outside the Consortium.

It appears that two key assumptions in the original concept of the Policy Platform, that the partnership and cohesion between institutions would remain high, and that the Policy Platform would help direct the WHO policy development process rapidly towards an IPTi policy decision (WHO, 2006b), turned out to be mistaken. In reality, the Policy Platform was unable to negotiate the tensions over the distinctly different expectations of the various actors involved. One of the SMC researchers who had also been involved in the IPTi process reflected:

I think having the IPTi Consortium funding a position within GMP created a bit of a tension. Because [it's like] you're having a plant in the policy-making department, that we are producing this information, and that person is paid by the IPTi Consortium. So, some of the people who were not part of the IPTi Consortium within GMP, they were probably seeing the pressure coming from [the Consortium]. So there's a bit of a division within the GMP staff themselves - those pro-IPTi, and those cautious towards IPTi. But SMC did not have such a position within GMP. There may have been divisions, there may have been differences of opinion, but that's not because of the SMC people funding somebody. That's the difference. – KI32

In retrospect, many key informants felt that the Policy Platform was a strategic mistake, and that WHO-GMP should never have been part of the IPTi Consortium, let alone home to its policy facilitating platform; that this was a conflict of interest and detracted from the legitimacy of the process and the 'balancing act' that is a WHO policy recommendation. One IPTi Consortium member who later went on to work at WHO explained the reason for their now changed point of view:

There was one WHO staff member who was put on the IPTi proposal as part of the Consortium. Later on, this wound up raising questions about whether one should have someone as part of a consortium who is part of the institution that will be judge and jury of the evidence being generated. Does that blur those lines too

much? I have to say that I have probably changed my view of that over time. I remember at the time being indignant that how could WHO have agreed to be part of the consortium, and then later reversing its position and claiming that it was not right for WHO to play that role. Now that I have spent time at WHO, and understand the importance of the independence of that evidence making process, I now understand those concerns. And I think that it probably is not a good idea to have someone as part of a consortium who is part of the agency that is convening the evidence review process; some separation is necessary. It doesn't need to be a firewall. There can be a dialogue, but you can't have that person be part of the group. They need to be having regular exchanges with the group and helping to steer the sort of evidence base that's required, but not be implicated as part of that group. I think that is an important balancing act. – KI39

This was not a mistake that appeared to be repeated for the SMC set of studies. Not only was there no irate consortium to deal with, and it would appear, no overt policy agenda, WHO-GMP was the one positively perceived as a 'hands on' partner, meeting for informal consultations between 2009 and 2010 when SMC researchers were collectively preparing their dossier for evidence review by the TEG. This was not perceived to be a conflict of interest by WHO-GMP, but rather that it was in everyone's interest to make the process smooth while still maintaining institutional integrity via independence, mutual respect, and transparency. One WHO-GMP staff member recalled their experience with SMC:

I think [the SMC researchers] were much more systematic. A very good indication was the convening of early meetings with WHO to discuss how the evidence should be presented, and who should be attending the evidence review meeting. This preparatory work was essential and very productive for both sides. – KI42

Thoughtful preparation, and a clear WHO process for evidence review, that was transparent to all involved, appeared to be quite an important feature of the SMC

policy development process according to many interviewees, both within and outside of WHO. As a result, it would appear that during the SMC policy development process, WHO-GMP was able to fulfil its own ideal expectations of itself and its mandate without having to defend itself against other actors as it felt forced to do during the IPTi policy development process. By maintaining its credibility during the SMC process, WHO-GMP appears to have maintained its legitimacy as a global health policy actor, which might have helped maintain the legitimacy of the policy development process itself.

(v) Consensus versus transparency

The data suggest that the breakdown in consensus and lack of trust in the policy process, due to the diverging expectations, perceived biases, and conflicting agendas of the various groups of actors involved (researchers, funder, WHO), led to a slower policy development process for IPTi, in comparison to SMC.

One MPAC member explained what they viewed to be the link between consensus within the policy development process, and the quality of the evidence base, and subsequent policy outcomes:

I was aware of the very strong and divergent views of some of the people involved in [IPTi] and the fact that that was the case, that it was over a long period of time, that it had engendered really quite divergent views, implied ... usually when there's very divergent views and the [policy process] is stretched out it normally implies that the evidence base isn't clear. Because if the evidence base is clear then it won't be difficult to come to a decision. IPTI – in my understanding – didn't achieve good consensus very quickly, and I'm not sure that it ever achieved consensus, and I think that's

reflected in the degree to which it's not been taken up by countries. –
KI34

Although several interviewees also highlighted the lack of consensus around IPTi as being problematic – either cause for concern from the point of view of WHO-GMP staff, or cause for frustration from the point of view of IPTi Consortium members – others, however, suggested that they didn't view a lack of consensus to be a defining issue for IPTi (given policy decisions in malaria are rarely as clear cut as they seemed to be in the case for SMC), but rather it was the lack of transparency around the policy process for IPTi, which really lead to problems and deepening mistrust between all the actors involved. These key informants suggested that in many ways they viewed lack of consensus, or contestation, to be relatively normal, and that it was not unusual to respectfully agree to disagree with colleagues in scientific debates (although in the case of IPTi, disagreements were not always viewed as being respectful), as long as it was clear how policy conclusions were drawn. Many informants suggested that there was an implicit understanding that policy makers often have multiple considerations beyond evidence when making policy decisions, however that made process transparency all the more key. One researcher who was involved with both IPTi and SMC policy processes elaborated:

For IPTI, it did not seem like a clear process; it seemed a bit cloak and dagger, or that events were taking place in a smoky dark room. There was no transparency as to how the process was supposed to be conducted. For the review of SMC, the fact that the Malaria Policy Advisory Committee had been convened in a transparent way, that everyone was aware who was on it, that there was clear terms of reference for the committee, that the Director General had signed off on the process, I think gave a lot of credibility in advance to the process, which is really important. If people coming into an evidence review have no idea what to expect, no idea what the steps are going

to be, no idea who ultimately is making those decisions, then I think the process is on the rocks before it even gets going. – KI44

This was a view that was echoed by many interviewees, and would appear to imply that transparency of the evidence consideration and policy making steps might have been equally critical, and potentially even more important, than achieving consensus, at least in this case.

(vi) Membership and representation

The data also suggest that there was an additional form of transparency that was important to respondents, other than the evidence review process itself (that is, the various steps involved and the criteria for evidence review and policy consideration). This had to do with transparency about who was represented on the WHO evidence advisory bodies, and why.

For example, during the policy development process for IPTi, there was a perceived lack of transparency about representation on the TEG. Although according to those interviewed, TEG members were appointed by the director of WHO-GMP following consultation with other members of the WHO-GMP secretariat, it was not clear what the criteria for TEG membership was. Some interviewees were of the view that the TEG membership was not always appropriate. Since the TEG was the critical decision node for IPTi, interviewees had very strong views on its membership, how the meetings were conducted, and the dominance of some members over others. Some interviewees expressed concern about a perceived lack of balance in the TEG because one of the co-chairs was an expert on Asia rather than Africa, and appeared

to be strongly against the use of SP for IPTi because of their own career-defining work on malaria drug resistance. However, although several interviewee accounts seemed to echo this concern, in reality the same co-chair later (in April 2009) supported the recommendation of IPTi, and later also supported the recommendation of SMC (which also uses SP), which suggests that perhaps some of these concerns might have just been perceived conflicts of interest, or internal explanations of slow processes.

In comparison for the SMC process, although the TEG meeting in May 2011 was held in closed session (it was before WHO-GMP's policy strengthening exercise was completed and MPAC was first convened), the MPAC membership process was (and still is) open to application (versus director appointments), against clear membership criteria, and a mixed (internal and external stakeholder) nomination review panel. In addition, its deliberation proceedings are held in open session, which are all criteria that appear to matter to WHO-GMP stakeholders when it comes to policy development (D'Souza, 2014).

Another element to membership and representation mentioned by some interviewees, and echoed by SMC researchers, was that the IPTi policy development process might have benefitted had there been more developing country researchers and policy makers involved, given the links and ultimate benefit to the policy's end users in sub-Saharan Africa. One interviewee reflected:

The thing that I think made SMC very powerful is that it was very powerfully rooted in country research institutions, so that the countries that might potentially benefit from SMC were very strongly involved in setting up the research agenda, and executing

that research agenda, so that there was traction in seeing this through to the end, in a sense. That if it were recommended, it wouldn't run up against a brick wall because it really came from an understanding on the ground of the value of the research. – KI39

These interviewee reflections suggest that improved representation (in both evidence advisory bodies and within research groups), in addition to improved transparency around evidence advisory body membership, might have had a role to play in improving the perceived legitimacy of policy development processes for SMC compared to IPTi.

6.3 Reflective summary

The study findings suggests that in a time where it has become the norm, at least within the field of major infectious diseases such as malaria, for diverse groups of actors (researchers, funders, policy makers) to collaborate on large research projects, that further investigating actors' perceived roles and expectations is a potentially useful way of better understanding how evidence and policy interact in sometimes complex and not immediately obvious ways. These actors' subsequent actions within the policy development process, and how this in turn influenced their perceived neutrality and credibility, might be a potentially useful way of better understanding legitimacy within policy processes, and the various factors that influence perceptions of legitimacy.

The case of IPTi demonstrates that when research, funding, and policy making institutions have common goals but conflicting agendas, how they are viewed by other actors in the process gets affected, which in turn can negatively impact the

perceived legitimacy of the policy development process itself. Conversely, the case of SMC demonstrates that clearly defined roles and more transparent, inclusive, and clear processes, can in turn positively influence whether policy development processes are perceived in various ways as being credible and acceptable, or as Cash and colleagues (2003) would suggest, respectful of stakeholders' values and beliefs, and fair in its treatment of opposing views and interests.

If the previous chapter concluded that in comparison to IPTi, the SMC policy development process benefitted from what Parkhurst (2017) would define as more 'appropriate' evidence (that is, high quality evidence, relevant to the policy concerns, constructed in useful ways, and applicable to the local context), the exploration in this chapter indicates that SMC policy development also benefitted from better processes of evidence use, such as clearer and more transparent evidence advisory structures and operational procedures than IPTi, which was clearly an influencing factor, among others, in how the SMC policy development process was, and still is, positively perceived.

Although this chapter focused primarily on stakeholder experiences and perceptions of the policy process, the necessary steps taken by WHO-GMP to improve their policy development processes in the period between the IPTi and SMC policy recommendations – such as open consultation and participation in meetings, and more transparency during the evidence advisory process – can each be seen as perhaps contributing to WHO-GMP and its evidence advisory bodies' ability, and credibility, in providing timely and relevant policy advice that is accepted as

legitimate by policy actors and researchers within WHO's evidence advisory systems, and by members of the global malaria community more broadly.

Chapter 7: Discussion, conclusions, and lessons learned

7.1 Introduction

We know from the evidence use literature that evidence, in its multiple forms, is often perceived as playing key roles in public health policy development, although how and why evidence is used and when, despite the wide range of research on the subject, is less clear. This study was born of the notion that a more holistic understanding of what influences the use of evidence in policy making may help shed more light on the complexity of evidence use. This understanding may help, in multidimensional ways, to increase and improve evidence use, which is the goal of many public health organisations, including the WHO, so that they may ultimately improve public health outcomes. Critically appreciating the particular challenges of understanding and adapting scientific knowledge in order to achieve gains in public health outcomes is also one of the aims of LSHTM's DrPH programme.

In the context of the aims of the DrPH programme, and as a public health practitioner with a research interest in ways to improve the good governance of evidence, the aim of my thesis was to better understand the influences on the use of evidence within global health policy making organisations such as the WHO, using two intermittent preventive treatment policy development processes (IPTi and SMC) within the case study setting of the WHO's malaria department – the Global Malaria Programme. Specifically, my thesis objectives were to: (a) explore the factors that influenced the consideration of particular evidence; and (b) examine how factors associated with the policy process influenced eventual policy outcomes. I did this by

exploring the features of the evidence used (Chapter 5) and the process of forming global intermittent preventive treatment policy within WHO-GMP (Chapter 6) during what was, and in some ways continues to be, a dynamic time period in the field of global malaria control and elimination (see Chapter 4).

This last chapter discusses the key findings from the analysis of IPTi and SMC policy development differences affecting ‘credibility’, ‘salience’ and ‘legitimacy’ that was presented in the preceding two results chapters, beginning with some concluding reflections, followed by the limitations of the study, implications for public health researchers and practitioners, and finally ending with some overarching conclusions on what the study contributes to improving public health policy and practice worldwide, which is the overarching goal of the DrPH programme, as well as the mission of LSHTM, my employer, more generally.

7.2 Discussion and concluding reflections

Explaining the differences in the policy development processes between IPTi and SMC requires understanding a set of interacting factors related to features of the evidence base as well as features of the process by which it was brought to bear on policy making.

IPTi was introduced as an innovation that was pursued by a group of committed public health practitioners and researchers, and internally framed along the lines of a quick and linear process. The IPTi Consortium’s proposal to BMGF included a clear schedule of, and a Policy Platform to facilitate, its idealised policy development

process. IPTi Consortium members believed that more evidence delivered in a timely way would persuade policy makers to recommend IPTi. However, over time, this internal expectation and pressure to meet the deadlines they had set for themselves in their proposal to BMGF, led to a breakdown in consensus and trust between actors, followed by delays in IPTi's policy development.

In comparison, the SMC policy process was never viewed as a battle between the actors involved. Here the policy process was viewed as open, inclusive, and transparent, which was WHO-GMP's intention of what a good policy process should look like when it formed MPAC (D'Souza and Newman, 2012). By learning from its experience with IPTi, and optimising the design and function of its principal evidence advisory committee (MPAC) to better serve its institutional needs, WHO-GMP was perceived as having strengthened its malaria policy development process.

When it comes to the features of the evidence used to inform policy, what appears to have edged the SMC evidence base over the one for IPTi was that, ultimately, it was more relevant to the question being asked by WHO-GMP's evidence advisory committees, with its perceived value as an intervention being boosted by the size and potential impact of its protective efficacy, and the high consistency of the results across RCT sites. Although the reasons for this difference (the highly focused and similar transmission settings for SMC studies) can be explained, a pooled protective efficacy of 75% for SMC compared to 30% for IPTi made the potential public health impact of SMC a difficult policy option to ignore. In other words, while the results of the RCTs for IPTi would be considered credible by standard evidence hierarchy measures, and comparable to other preventive malaria interventions, the evidence

base for SMC compared to IPTi was perceived to be both credible and salient, which contributed to making it appear better, or more appropriate, for policy consideration.

The study findings also suggest that the breakdown in consensus and trust in the policy process, due to the different expectations, conflicting agendas, and in some instances, the overt advocacy of the actors involved, might have contributed to the perception of problems that undermined the legitimacy of the policy development process for IPTi, in comparison to SMC. The contestation around the IPTi policy process might have contributed to negative perceptions of its policy value. Contestation, as a form of deliberation and consensus building, is not necessarily a 'bad' thing, particularly when built into institutional arrangements that aim to improve the legitimacy of governing processes through deliberation and inclusion of multiple views (Scharpf, 2006). Some scholars have seen the need for deliberation as particularly important when public policy often relies on delegation to scientific experts that serve to provide scientific advice (van Eeten, 2001). Institutional approaches in the policy sciences recognise that institutions can be thought of in terms of formal structures, and also as rules that shape how decisions are made (Lowndes and Roberts, 2013, Peters, 2005, March and Olsen, 2011). In the case of SMC, although there was not necessarily as much deliberation over the evidence as there was for IPTi, it appears that having clear expectations from all sides of the evidence advisory process, with a clear structure and terms of reference for MPAC members, as well as transparency of the evidence consideration, might have led to the process for SMC appearing more legitimate to those involved in it evidence advice and policy development.

In summary, Cash and colleagues' (2003) findings from the field of sustainable development, that evidence must be credible, salient, and legitimate to be accepted by the public, appears to equally apply within evidence advisory committees in this particular case. It should be noted however, that these findings are not meant to imply that one evidence base was stronger or weaker than the other was, or that the process of evidence use is necessarily more important than features of the evidence itself. Indeed, both feature in important but differing ways. As such, these findings help to reinforce how the factors of credibility, salience, and legitimacy all appear to influence evidence use, with particular insights into an agency (WHO) with a particular technical remit and expert bodies of stakeholders informing global health policy making for malaria control and elimination.

While these findings emerge from a pair of specific malaria policy developments, there may be reasons to believe similar issues could be relevant elsewhere. Indeed, the issues of credibility, salience, and legitimacy were drawn from a very different study conducted on sustainable development related to concerns of the lay public as well as of scientists. Thus seeing similar issues arise in a technical body made up of individuals with broadly similar scientific training helps to illustrate that even in these groups, features outside scientific quality can matter when it comes to evidence use for policy development.

Although context is not specifically a factor in Cash and colleagues' (2003) framework, it is clear that it too had an influencing role to play in how evidence use for policy development was perceived in the case of IPTi and SMC, and helps highlight how the concepts of credibility, salience, and legitimacy are themselves

perhaps more complex, multidimensional, and inter-related than the simplicity of the framework implies. For example, the high salience of the SMC evidence base appeared to increase both its credibility and its legitimacy, but the context-specific uniqueness of the time and place of the development of the SMC evidence base (that it was targeted only for areas with highly seasonal malaria transmission, using drugs that were still highly effective in countries where drug resistance was rapidly encroaching) suggests that had the trials taken place a decade before, or a decade later, perhaps the credibility, salience, and legitimacy of the SMC evidence base and the processes for its use for policy development may have been perceived differently.

Similarly, context could also have played a role in how the advocacy planning of the IPTi Consortium was positively framed at its inception but negatively perceived during its execution. For example, forms of advocacy would have likely played a role in the resurrection of malaria as a global health issue, and the decision by the BMGF to make it a core programme area for funding global research partnerships such as the IPTi Consortium. But the perceived ‘sanctity’ of global policy development at WHO, and the importance it places on its institutional values, such as neutrality and independence, meant that the IPTi Consortium’s overt advocacy and the BMGF’s subsequent interference, which could be argued was open and obvious and therefore not necessarily underhanded even though it was perceived that way, was not acceptable to WHO-GMP and other stakeholders during the IPTi policy development process. This suggests that the legitimacy/acceptability of advocacy as a public health tool, and the credibility of those actors involved with advocacy efforts, may change depending on the stage of evidence use for policy development

it is being deployed for. For example, it is possible that the credibility and legitimacy of the IPTi evidence base and the actors involved may have stayed intact had they delayed their advocacy efforts until after a global policy was developed, and national policy makers were considering how best to adopt it to their local settings (salience being an issue for the IPTi evidence base, and one of the reasons developing a sub-Saharan Africa wide policy was challenging). So instead of viewing academic advocacy in public health as being somewhat of a dichotomy between ‘selling’ and being ‘facilitational’, which is what a recent review of the public health advocacy literature suggests (Smith and Stewart, 2017), perhaps it is possible to be both (or neither) depending on the stage of the evidence use for policy development process, and of course, the context.

What the case of SMC policy development compared to IPTi highlights is not just the role of context in shaping the multidimensional ways in which credibility, salience, legitimacy, and even advocacy, can be perceived, but also the role and importance of appropriate institutional processes for maintaining evidence, policy, and actor legitimacy. Although this study focused on the internal evidence advisory processes within WHO-GMP, it is possible that having better internal processes for maintaining certain ‘checks and balances’ might have also benefited the IPTi Consortium and the BMGF before they continued down the decision pathway of applying seemingly increasing pressure on WHO-GMP global policy development processes.

Regarding global policy development, what might be an important additional factor for WHO however, as it continues to improve its internal policy and guideline

development processes (WHO, 2007b), is to consider more specifically the processes followed by its evidence advisory bodies, in addition to concern over how to judge or rank evidence, and how to institutionalise these processes, for example via the terms of reference and operating procedures for its evidence advisory bodies. Specifically considering how to build evidence advisory structures that are perceived to be open, inclusive, and transparent – manifestations of a fair process where it is clear that multiple considerations and values have been taken into account (Parkhurst, 2017, Cash et al., 2003) – might serve to promote the legitimacy of WHO's policy decisions and decrease potential conflicts of interests in a global health-funding environment where private funders, in particular the BMGF (Black et al., 2009, Cohen, 2002, McCoy et al., 2009b), are viewed as, and often criticised for, having increasing influence on the global health agenda, in ways that might not be free of conflicts of interest, or accountable in the same ways as traditional forms of international development and aid funding from governments (Cohen, 2006, Okie 2006, Stuckler et al., 2011, Harman, 2016, McCoy and McGoey, 2011, McGoey, 2015, McGoey, 2012).

For example, the BMGF are already one of the largest donors to the WHO (Brown et al., 2006), and within the field of global malaria, they funded both the IPTi Consortium and many of the SMC studies, in addition to the policy-strengthening grant that led to the creation of MPAC (Bhasin et al., 2014, D'Souza and Newman, 2012, IPTi Consortium, 2003). Rightly or wrongly, there is very little in the world of global malaria control and elimination that is not funded or at least influenced by BMGF (Eckl, 2014). While many in the global health and malaria communities are quick to point out the positive outcomes of what funding coming from the BMGF

can achieve (Targett et al., 2009, The Lancet, 2009), the study findings illustrate the importance of process legitimacy in addition to concern over outputs and outcomes, and ways in which those processes might be embedded, or institutionalised, in evidence consideration for WHO policy development.

The thesis findings help address a gap in the evidence use literature, and contributes to the public health advocacy literature, by providing a unique insider perspective and detailed account of what actually influences the use of evidence within an influential global health policy making institution, the WHO, and on an important global health issue, preventing malaria illness and death in infants and children. The congruence of the study's findings within the existing literature (that it isn't just evidence that matters in policy making, and that politics can and will have a role to play as well, but that the process can be successfully managed via better systems of evidence advice) also helps strengthen their validity, which in turn can help inform lessons for public health research and policy professionals, as well as future research, bearing in mind the limitations of the study and areas for future research, which are discussed next.

7.3 Limitations and areas for future research

This case study, being highly context-specific as case studies tend to be, has some limitations that might influence how the findings should be interpreted, and the broader lessons that can be drawn from them, as well as areas for future research.

This study compared two intermittent preventive treatment policy processes in depth (IPTi and SMC), using the accounts of actors involved in one or both processes as its main sources, in addition to supporting background documents, and my own observation notes from my time at WHO-GMP. The original intention was to do a comparative case study of the two policies, because the evidence-to-policy journeys appeared to be very similar at first glance. However, in reality, although there were indeed some similarities, there were also major differences, not least the change in evidence advisory systems within WHO-GMP between the IPTi and SMC policy decisions that were intended to improve evidence use, as well as the uniqueness of the evidence base for SMC (as mentioned previously, it is rare to have a WHO-GMP-recommended intervention with such high protective efficacy, targeted to such a specific sub-region) which made a direct comparison of IPTi with SMC difficult.

The unit of case study ended up being WHO-GMP itself, as an example of a global health institution seeking to improve its evidence advisory systems, with the analysis of the two policy processes still providing insight into the complexity of how evidence actually informs eventual policy decisions, and what factors influence its use. In retrospect, given the number of interviewees that also mentioned IPTp (the original IPT in pregnancy policy from 2002) as a comparator to both IPTi and SMC, it might have been interesting to more formally include it as part of my case study analysis of evidence use within WHO-GMP over time.

That said, there is no shortage of interesting policy decisions within malaria (or other major global health challenges) one theoretically could have focused on; my eventual choice, as mentioned in my methods chapter, was partially informed by my

work, and those actors I had access to. This might have influenced my findings, although every effort was made to provide a broad range of perspectives (junior and senior researchers, policy makers, and funders involved with both IPTi and SMC) about what took place at the time of evidence advice to WHO on IPTi and SMC.

The length of time that had lapsed since the IPTi policy decision might have affected recall, although given I was less concerned with establishing a single ‘truth’ and was more interested in capturing experiences and perspectives (which will vary depending on the point of view of the person being interviewed), I have no reason to believe that any key informant held back on their descriptions of their experiences. Indeed, I was surprised by how many interviewees (researchers, policy makers, and funders) who had been involved with IPTi still felt quite passionately about their experience. It is difficult to say whether this openness might have been influenced by the fact that many interviewees also considered me a colleague and ‘one of them’, and so we, to some extent, had a shared history and a common language; my own impression is that the researchers and policy makers wanted and were very willing to share their experiences of evidence use and policy making, regardless of who was interviewing them (perhaps it was refreshing to be on the other side of research given their daily work, or perhaps it is part of being human to want to share stories of previous experiences, especially negative ones).

This of course is to some extent speculation and a reflection of my own experience having spent a significant period of time at LSHTM (eight years) and WHO (five years) working on malaria, but based on my findings and interactions with my key informants to describe their experiences, I do sense this ‘shared history’ for lack of a

better term, also influenced evidence use over time, particularly given most all of the members of WHO-GMP's evidence advisory bodies are researchers themselves, and tend to switch back and forth between the two roles, in many cases over several decades. For example, as previously noted, some current members of MPAC, as well as some WHO-GMP staff, were former members of the IPTi Consortium, which would influence their perceptions of what good evidence use might mean. But because my case was singularly focused on two specific IPT policy development processes, there was a limit to how far back in time I analysed the relationships and links between actors, and reported them in my study findings. For example, at present, within the community of IPTi and SMC researchers, and their respective evidence advisory counterparts, exist friendly rivalries and alliances that in some cases go back to a time when some of the actors were doctoral students themselves, or mentors and mentees whose relationships were later fractured (though in some cases subsequently mended) and that history is carried through to subsequent generations of their own doctoral students, who in turn became independent researchers, evidence advisors, and doctoral supervisors, themselves. As I mentioned at the start of my thesis, the global malaria community is in reality quite small – a bit like an interconnected family tree – and as it turns out, the extended network of direct and indirect links to LSHTM is quite large.

Although these insights were not directly offered as reflections to my interview questions, they were sometimes alluded to during the course of my interviews and interactions, and might be an interesting area of study for other forms of social science research in future. In any case, what these realisations highlight to me is that there is an extraordinary depth of contextual information that, despite best efforts

(for example, see Chapter 4), probably doesn't get sufficiently captured in case studies such as this one. In fact, one could argue that had I not had such intimate knowledge of my interviewees through working so closely with them, I might not have realised the historical connections between actors, to then report them as a limitation of the study i.e. to not have better explored those connections in retrospect.

Another area of future research to supplement the findings from this study would be to include more in-country perspectives on evidence use i.e. views from local researchers and policy makers. Although I did include some in-country perspectives, I decided against focusing too heavily on this set of actors, because my study was more focused on what led to the global level policy decision for IPTi and SMC among global level policy actors, rather than how this then impacts local policy consideration and implementation. However, better understanding local policy consideration and implementation of global malaria policies, and how they may be interlinked (i.e. enthusiasm for implementation at country level as reflections of the evidence advisory process at the global level), may also shed light on the complexity of evidence use in policy making, and the relationship between global and national policy development processes. For example, it is possible that the relative credibility, salience, and legitimacy, of SMC policy development at the global level, is reflected in the stark differences in national level policy uptake and implementation between SMC (currently 12 countries) and IPTi (still one country).

In addition, I would consider broadening the time scale to include all forms of intermittent preventive treatment policy development within WHO-GMP, to see if each policy development process has had a subsequent effect on the evidence

consideration or acceptability of the next form of IPT. Circumstantial evidence would suggest that evidence advisors and policy makers appeared to ‘soften’ and become less stringent over time, but that could also be due to the addition of more drug safety and drug resistance information to the research literature as the IPT interventions are more widely implemented.

Despite these limitations, and the wide ranging possibilities for future research, the findings as presented within this thesis still provide unique insight and a wealth of lived experience of the complexity of evidence use within a WHO department. Case studies of this kind are not common within the field of evidence use, or within the global malaria community, and the interviewee accounts serve as a form of documented history in the evolving story of intermittent preventive treatment, and its role within global malaria control and elimination.

7.4 Key lessons for public health researchers and policy professionals

The findings from this thesis allow for a number of potentially useful lessons for public health researchers, as well as the policy professionals who often work closely in tandem with them.

1. Embedding good governance and systems of evidence use is important and necessary to ensure the outcomes of policy processes are accepted as legitimate

Policy development processes within technical evidence advisory bodies are subject to many different influencing forces, including – appropriately – political

ones, and weathering the exigencies of these forces, via better systems of evidence use, is part of managing the process, and maintaining its legitimacy, so that policy solutions are accepted by the actors within that process. For example, appreciating and acknowledging the differences in the institutional norms, values, and expectations, of individual members of research consortia prior to the evidence review and policy development process, might improve their future interactions when working together to reach a policy solution. However, norms, values, and expectations can vary across and within institutions, contexts, and over time, and therefore good governance should be viewed as an ongoing process in itself, in need of continuous quality improvement, rather than simply a checklist or an activity that is done at a particular time, and in a particular setting, or in a particular way. Indeed, although there are some elements of good governance and how they are implemented that might be viewed as transferable good practice (see below), some elements can also be unique and context-specific, as what is perceived to be appropriate evidence and processes for policy development may vary depending on the policy issue, its political importance, and the actors involved, among other factors.

That said, optimising the processes of evidence review and policy development to maximise quality, relevance, and legitimacy, by making them as explicit and transparent as possible, through clear evidence review criteria, public availability of background documentation, and open session evidence review meetings, for example, can and should be a governance aim for all evidence advisory-oriented organisations, including WHO (in fact, this is the subject of a recently published September 2018 special issue of *Global Challenges* that draws lessons from

across different evidence advisory committees across multiple institutions; a peer-reviewed paper based on this thesis contributes to that special issue and is included as Appendix 5). Other measures could include open calls and transparent selection processes for the membership of evidence advisory bodies, so that there is confidence that those involved in these processes are as fair, equitable, and representative of local populations as possible (Boaz et al., 2015, Parkhurst, 2017). This does not mean that conflict will not occur; scientific debate may take time to resolve, especially if more evidence is needed for resolution, but it may help manage potential conflict.

Finally, based on the findings from the case of IPTi and SMC, it must be recognised that rigorous evidence review processes are costly in terms of time, and sufficient staff and financial resources should be guaranteed for this task, that ideally are not funded by sponsors or producers of evidence, i.e. some degree of independence should be maintained, to help maintain the legitimacy of the policy development process.

2. Employing advocacy as a tool to facilitate evidence use in policy development should be handled with care, and be mindful of contextual appropriateness

While the idea of an advocacy-oriented Policy Platform to accompany the research process was well intentioned, a key lesson from the IPTi Consortium (one that SMC and subsequent malaria researchers appear to have absorbed) is that placing it within WHO did not sufficiently recognise potential conflict between the institutional norms and values of WHO and other partners in the

IPTi Consortium. So anticipating the process of translating research into policy, and being prepared to advocate for research when policy windows may allow it, might be worthwhile, but embedding a policy and evidence support team in an independent (non-WHO) organisation might be preferable.

For example, such a team might be positioned in a research or academic organisation (or possibly a non-governmental organisation) not itself involved in the subject of the research, but with access to those involved, and the skills to review and synthesise data produced. One example from within LSHTM is the Policy Innovation Research Unit (PIRU) that works at the request and on behalf of the UK Department of Health and Social Care and the National Health Service, while still being a separate entity (PIRU, 2018).

It would also be important for such a policy support team to have good links to, or members from, the countries most potentially affected by the research findings, so that national level policy makers and programme managers can help ensure that any evidence use and policy development are contextually relevant.

3. Including ways for potential beneficiaries in be involved in evidence review and policy development processess may also help policy and programme implementation in the long-term

While the normative power of a WHO endorsement is necessary to policy adoption and implementation in many countries, it is likely to be far from sufficient. A real challenge, and as discussed within the limitations section, a

potential area for future research, is within global policy development, what are the processes that influence improved country level policy uptake and implementation. This may involve ‘bottom-up’ processes, with strong national researchers and policy makers involved throughout, as happened with the case of SMC. But this depends on building capacity in countries and between northern and southern institutions over decades, as well as adequate and sustainable funding.

A possible lesson from the SMC policy process, though not explicitly explored in this thesis which was focused on what led to a global level policy decision, is that involving key regional and local policy makers and programme managers who contributed to decision making processes about highly locally relevant research, may have facilitated the way the issue was perceived at country level, and as a result, the processes of national policy adoption and implementation. This possible interconnection between global and local policy making would be an interesting area, among others (see previous section), for future research on evidence use in policy development, which may help to improve policy and programme implementation, and public health outcomes, in future.

7.5 Final thoughts

In the case of the policy development processes for IPTi and SMC, the study findings show that ‘good evidence’ from a purely technical (credibility) perspective was not sufficient to ensure universal agreement and uptake of recommendations, even within a highly technocratic body such as the WHO-GMP. The findings

suggest that evidence also needed to be relevant (salient) to the policy question being asked, and that technical actors retained a concern over the legitimacy of the process by which technical evidence was brought to bear in policy development. Cash and colleagues' (2003) findings from the field of sustainable development, that evidence must be credible, salient, and legitimate to be accepted by the public, appears to equally apply within evidence advisory committees, at least in this case, albeit nuanced by their specific contextual realities.

While the WHO has principally focused on technical criteria for evidence inclusion in its policy and guideline development processes, the study of the MPAC suggests that the design and functionality of its evidence advisory committees might also have a role to play within its overarching evidence advisory system. Other evidence advisory committees within WHO should also consider enabling transparent, responsive, and credible processes of evidence review, to ensure that they are effective in producing advice that ultimately leads to policy recommendations by WHO. This is already the subject of work recently undertaken by other scholars in this field (Global Challenges, 2018, Gopinathan et al., 2018, Gopinathan and Hoffman, unpublished), which will hopefully lead to stronger systems of evidence use within WHO, for the public health benefit of its member states, which is a stated goal of the organisation (WHO, 2018). Such legitimacy may also be important for implementation of WHO recommendations by WHO member states, particularly considering the current funding environment in which WHO is highly reliant on external sources of funding, both for programmatic work, as well as for funding research that aims to ultimately inform public health policy and practice.

Strengthened systems of evidence use may also be important for improving the strategic agility of public health institutions like WHO in responding to new global health threats, and the ever-changing political and epidemiological contextual dynamics of old threats, such as malaria. For example, at the time of submitting this thesis, there are indications that malaria may once again not be as high a global health priority it once was between 2000 and 2015, which is the time period my case study took place in, and that “after an unprecedented period of success in global malaria control, progress has stalled” (WHO, 2017b). This is evidenced by the 5 million case increase in malaria cases worldwide in 2016, following a plateau in global malaria funding investment (WHO, 2017b), which speaking as a member of the global malaria community, is challenging.

The lessons from this thesis on the implicit and explicit complex realities of evidence use in policy development might also apply to other types of evidence advisory bodies, such as NICE in the UK and other similar organisations, and are important considerations for both generators of evidence (public health researchers within academic research institutions, such as LSHTM) as well as the institutions, such as the BMGF, that fund them.

As a public health practitioner myself, I have found the process of conducting this study, and engaging with my findings and what they might mean, a valuable and motivating lesson in how I perceive evidence, and ways to improve its use, in policy and programme decision making in my current work and in the future; I hope my peers and colleagues will find these study findings and reflections useful to their own current and future practice as well.

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Appendix 1: Interview topic guide

Objectives	Question	Follow-up/Probe
	Tell me a little bit about what you do and what you see as your role in the SMC evidence to policy process?	(And/or depending on actor) How would you describe your role in the IPTi policy process?
Explore the factors that influence the consideration of particular evidence	<p>In your experience, how do policy topics make their way to the global malaria agenda?</p> <p>In your experience, how would you describe the evidence base for SMC? For IPTi?</p> <p>In your experience, how would you describe the evidence review process for SMC? For IPTi?</p> <p>In your experience, how do policy decisions get formulated within GMP?</p>	<p>In your view, how did SMC get on the policy agenda? What about IPTi? Why do you think that is?</p> <p>How does this compare to [the other policy]? Why do you think that is?</p> <p>Do you have an example of what you mean?</p>
Examine how factors associated with the policy process influence eventual policy outcomes	<p>What do you see as the role of the different people or groups involved in the SMC policy process? In the IPTi policy process?</p> <p>What do you see as the internal factors that might have affected the SMC policy process? And the IPTi policy process?</p> <p>What do you see as the external factors that might have affected the SMC policy process? And the IPTi policy process?</p>	<p>(Repeat for all three factor categories) Why do you think that is? Can you tell me a little bit more about that?</p> <p>(Lastly) Is there anything else you can think of that might have had a role to play in the SMC policy process? In the IPTi policy process? (repeat probes)</p> <p>Thanks. Looking back, what would you say were the biggest things that had an impact on the SMC policy? on the IPTi policy? (repeat probes)</p>
Describe current evidence review and policy setting processes, and how and why they came about	<p>Tell me your views or experiences about the MPAC?</p> <p>What do you see as the role of MPAC? What about within GMP?</p> <p>How does this compare to previous policy setting processes at GMP? If so, how would you describe them in comparison to how MPAC operates?</p>	<p>Tell me a bit more about that... From your experience, how would you describe how they arrive at policy recommendations? How would you describe their evidence review procedures? In your view, is there anything else that influences, or should influence, how they make recommendations?</p> <p>What do you see as the reasons WHO-GMP might have created this committee?</p> <p>What is similar? Different? Anything else?</p>

Thank you very much for your time. Is there anything you would like to add before this interview wraps up?

Appendix 2: Interview information sheet and consent form

London School of Hygiene & Tropical Medicine
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& TROPICAL
MEDICINE



INTERVIEW INFORMATION SHEET AND CONSENT FORM

Study title: Evidence use for policy recommendations: a comparative case study of Intermittent Preventive Treatment policy processes at the WHO Global Malaria Programme

Investigator Name: Bianca D'Souza

Contact Details: bianca.dsouza@lshtm.ac.uk or +44 (0)789 435 1117

This study forms the thesis component of a Doctorate in Public Health that is being undertaken by the investigator at the London School of Hygiene and Tropical Medicine, University of London.

The aim of this study is to better understand the factors that may influence the use of evidence in policy making using a comparative case study of two recent malaria treatment policy processes within WHO's malaria department. The study objectives are to: (a) describe current evidence review and policy setting processes, and how and why they came about; (b) explore the factors that influence the consideration of particular evidence; and (c) examine how factors associated with the policy process influence eventual policy outcomes.

Participation in this study is voluntary. You may choose not to answer any question or to withdraw from the interview at any time.

This study has been approved by the Director of the WHO Global Malaria Programme and by the London School of Hygiene and Tropical Medicine's Research Ethics Committee.

Participant name: _____ **Participants signature:** _____

Date: _____

My questions have been answered by Bianca D'Souza

I agree to be interviewed for this study	Y <input type="checkbox"/>	N <input type="checkbox"/>
I agree for this interview to be recorded	Y <input type="checkbox"/>	N <input type="checkbox"/>
I agree to be quoted anonymously	Y <input type="checkbox"/>	N <input type="checkbox"/>
I would like to be contacted to approve specific quotes	Y <input type="checkbox"/>	N <input type="checkbox"/>
I am happy to be contacted for any follow-up questions or clarifications	Y <input type="checkbox"/>	N <input type="checkbox"/>

Appendix 3: Previous (pre-MPAC) WHO-GMP policy setting processes for malaria (source: WHO-GMP, see D'Souza, 2014)

I) Pre-2005: WHO Expert Committee on Malaria

This Committee, made of members of the WHO Expert Panel on Malaria, is the formal body of experts mandated by the WHO constitution to advise the Director-General on technical policies and strategies for malaria control and elimination. It is a group convened by the Director-General for the purpose of reviewing and making technical recommendations on malaria. Expert committees are established by the Executive Board or the World Health Assembly, and it is the Director-General who convenes the meetings and decides on the participants, who are drawn from the expert advisory panels. The membership of an expert committee is not standing. In fact, a member of an expert committee is an expert appointed by the Director-General (from among the Expert Panel) to serve at any particular meeting of that committee. Reports of meetings of the WHO Expert Committee on Malaria after approval by WHO Director General are presented as a part of a series of formal publications titled the WHO "Technical Report Series".

The WHO Expert Panel met 20 times, at regular intervals from 1947 to 1968 (almost on an annual basis), and then progressively less frequently. The Expert Committee last met in 1998. As a policy-setting body, the Expert Committee suffered from cumbersome nomination and convening procedures that limited its nimbleness in reviewing evidence and setting policy. This limitation was highlighted by the ever-increasing pace with which evidence was being generated, the increasing degree of specialisation within malaria control, and a changing malaria landscape in countries, which led to increasing demands from global malaria actors for timely policy documents. While the committee has not met recently, the Expert Panel members themselves are still called upon to review documentation relating to Malaria Elimination Certification. It is the Chairperson of the Expert Committee who is tasked with gathering the opinions of other panellists regarding country petitions for elimination certification, and making a recommendation to the WHO Director-General.

II) Post-2005/ Pre-2012: Three-level policy review process

In the mid 2000's, owing to the expansion of malaria control options and the growing areas of knowledge and specialization pertaining to malaria control and elimination, WHO-GMP established a new 3-level policy review process

a) Level 1 -- Technical Expert Groups (TEG)

TEGs were convened by the WHO-GMP director, if and when necessary, to advise WHO-GMP on work relating to the following six key areas for malaria control;

- Economics, Finance and Impact (EFI);
- Scaling-up and Capacity Development (SCD);
- Case Management (CM);
- Insecticide-treated bed nets (ITN);
- Indoor residual spraying (IRS);
- Preventive Chemotherapy (PC).

The TEGs comprised of senior scientists and experts in the relevant specialised areas of work, and policy makers and implementers in endemic countries selected by the WHO-GMP secretariat, often in consultation with the WHO Regional Malaria Advisers. In each of the six areas of work identified above, they were tasked with: a) reviewing new evidence in the

relevant areas of work and their implications for strategy, policy, and plans; b) helping identify gaps in evidence and define specific priority areas of research; and c) monitoring and evaluating activities directed and managed by WHO-GMP within their specific area of work. While some of these TEGs were quite active, others only met once.

b) Level 2 --Technical and Research Advisory Committee (TRAC)

The TRAC was designed as a study group, convened by the WHO-GMP director, with the aim of advising and guiding WHO-GMP on the development of policies and guidelines, ensuring operational coordination at all levels. It also discussed the priority research agenda on malaria control. The Committee was composed of persons with experience and expertise on malaria, public health and programme management, ensuring comprehensive geographical representation.

The terms of reference of TRAC mandated that they: a) advised on malaria epidemiology and disease burden; b) oversaw the development and progress of operational policies and plans to assist in scaling up intervention coverage to achieve the malaria targets in countries; c) advised on strategies and opportunities to ensure that the malaria control interventions received predictable and sustainable resources; d) oversaw the franchising and commissioning of research by WHO-GMP; and e) reviewed the outputs from TEGs and transformed evidence and experiences from research into technically sound and feasible policy.

TRAC composition included leading experts, who were appointed as the Chairs of each of the TEGs, and other selected experts. WHO-GMP supported the TEG chairs to compile draft work plans of their respective TEGs to be shared with TRAC members. The TRAC aimed to serve as a steering group to ensure that WHO-GMP proposals and plans were technically sound and responsive to the needs of countries. It also provided a forum for discussion of the proposed research and funding opportunities among leading scientific experts, international agencies, donors, and national implementers.

c) Level 3 --Strategic and Technical Advisory Group (STAG)

The STAG was a steering group, which was designed to advise the Director-General on priorities for WHO strategy development, and how WHO should best organize its work to provide global leadership on malaria. It was constituted by high level officials, representatives of member states, and key stakeholders such as aid organizations, NGOs, academia and researchers. This high level group was also tasked with advocating and overseeing the global research agenda on malaria. Many departments at WHO headquarters currently have a STAG; these STAGs or their equivalents generally meet on an annual basis.

Organisational delays, funding limitations, and complexities inherent in a three-layered system, limited the utility of that approach, and, as a result, the TRAC and the STAG each met only once. In addition, not all TEGs were convened on a regular basis. WHO-GMP policy-setting activities post-2005 largely occurred as ad hoc technical consultations of convened experts – mainly of TEG members plus additional experts co-opted for the specific issue being addressed. Regular meetings of the TRAC and STAG, and the regular convening of the WHO Expert Committee on Malaria stopped taking place.

Appendix 4: Publication resulting from DrPH Organisational and Policy Analysis Project

D'Souza BJ, Newman RD. 2012. Strengthening the policy setting process for global malaria control and elimination. *Malaria Journal*, 11, 28.

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COMMENTARY

Open Access

Strengthening the policy setting process for global malaria control and elimination

Bianca J D'Souza^{1,2} and Robert D Newman^{1*}

Abstract

The scale-up of malaria control efforts in recent years, coupled with major investments in malaria research, has produced impressive public health impact in a number of countries and has led to the development of new tools and strategies aimed at further consolidating malaria control goals. As a result, there is a growing need for the malaria policy setting process to rapidly review increasing amounts of evidence.

The World Health Organization Global Malaria Programme, in keeping with its mandate to set evidence-informed policies for malaria control, has convened the Malaria Policy Advisory Committee as a mechanism to increase the timeliness, transparency, independence and relevance of its recommendations to World Health Organization member states in relation to malaria control and elimination.

The Malaria Policy Advisory Committee, composed of 15 world-renowned malaria experts, will meet in full twice a year, with the inaugural meeting scheduled for 31 January to 2 February 2012 in Geneva. Policy recommendations, and the evidence to support them, will be published within two months of every meeting as part of an open access *Malaria Journal* thematic series. This article is a prelude to that series and provides the global malaria community with the background and overview of the Committee and its terms of reference.

Keywords: global, malaria, policy recommendations, WHO

Background

The World Health Organization Global Malaria Programme (WHO-GMP) has four essential roles [1] (i) to set, communicate, and promote the adoption of evidence-based norms, standards, policies, and guidelines; (ii) to keep independent score of global progress; (iii) to develop approaches for capacity building, systems strengthening and surveillance; and (iv) to identify threats to malaria control and elimination, as well as new opportunities for action.

Last year, WHO-GMP embarked on a major review and re-design of its policy setting process in order to be more responsive to the rapidly evolving malaria landscape. As highlighted in the *World Malaria Report 2011* published last month, the world is witnessing impressive progress in the development and uptake of malaria control tools, resulting in significant reductions of malaria-related morbidity and mortality in many countries [2]. At the same time, there is increasing pressure on the malaria policy

setting process to keep pace with the evidence being generated both through research efforts and the massive implementation of malaria control tools. A stronger and more agile policy setting approach is increasingly important and necessary in the face of a projected shortfall in funding and growing resistance of *Plasmodium falciparum* to anti-malarial drugs and of anopheline mosquitoes to insecticides [2-4]. The global malaria community must make the most effective use of the tools it has in order to meet international targets for malaria control set for 2015 [2].

A small group of independent malaria experts was convened in March 2011 in Geneva to review previous and existing malaria policy processes and successful policy-setting models from other WHO departments. They proposed a framework for a new malaria policy committee - strongly modelled on the Strategic Advisory Group of Experts (SAGE), which sets global policy for immunizations - to address the shortcomings of previous policy processes. During April and May 2011, feedback on the draft terms of reference was sought, received, and incorporated from 50 external stakeholders.

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Following approval of the terms of reference by the WHO Director General in August, an open call for nominations was held in September 2011. From the 100 applications received, an independent nomination panel with representation from key partner organizations selected 15 members, who were appointed in November 2011 by the WHO Director General [5].

The inaugural meeting of the Malaria Policy Advisory Committee (MPAC) will take place in Geneva from 31 January to 2 February 2012 in open session [6]. The complete terms of reference for the Committee, outlined in this article, are publicly available online for reference [7].

Aims and functions of the Malaria Policy Advisory Committee

The mandate of MPAC is to provide independent strategic advice and technical input for the development of WHO policy recommendations on all aspects of malaria control and elimination as part of a transparent, responsive and credible policy setting process.

The MPAC advises the WHO Director-General specifically on:

1. appropriate malaria policies and standards based on programmatic experience by WHO member states and malaria control partners as well as reviews of the best available evidence;
2. engagement of WHO-GMP in malaria-related initiatives;
3. major issues and challenges to achieving global malaria goals;
4. the identification of priority research and control activities to address identified challenges.

Roles and responsibilities of MPAC members

The MPAC's 15 members serve in a personal capacity and represent a broad range of disciplines, expertise, and experience encompassing many aspects of malaria control and elimination. Members of MPAC, including the Chair, have been appointed to serve for an initial term of three years. Each term may only be renewed once, for a period of up to an additional three years.

The MPAC has no executive or regulatory function. Its role is solely normative; it provides advice and recommendations to the WHO Director General, including response to urgent issues as needed. Members of MPAC play a critical role in ensuring the reputation of WHO in providing high quality, well considered, evidence-informed advice and recommendations on malaria control and elimination. A register of members' declaration of interests is maintained by WHO and will be made available on the WHO-GMP website.

Meetings and operational procedures

The MPAC will meet bi-annually for three days, with dates generally set at least six months in advance. The

frequency and duration of meetings will be adjusted as necessary. MPAC recommendations will be taken by consensus. In the exceptional situation that consensus on a particular issue cannot be reached, the Chair shall report the majority and minority view.

Representatives of the Roll Back Malaria Partnership Secretariat, the Global Fund to fight AIDS, Tuberculosis and Malaria Secretariat, the United Nations Children's Fund and the Office of the United Nations Special Envoy for Malaria have been invited to participate as standing observers in MPAC meetings and deliberations. Relevant staff from WHO Headquarters and Regional Offices will attend as members of the Secretariat. In addition, three rotating National Malaria Control Programme managers from around the world will be invited as resource persons to observe and participate in the meeting.

The MPAC meetings are open to other observers, including representatives from WHO regional technical advisory groups, non-governmental organizations, technical agencies, academic institutions, and donor organizations. Additional experts and technical resource persons may also be invited to meetings to contribute to specific agenda items. Observers will not take the floor unless requested to do so by the Chair and will not participate in the formulation of MPAC recommendations.

The MPAC will work with WHO-GMP to develop its priorities of work and meeting agendas, with input from malaria endemic countries. In time, a wider group will be invited to contribute on agenda items in advance of each meeting via open consultation on the WHO-GMP website.

The MPAC will be kept informed by WHO-GMP and partner agencies of progress in the implementation of strategies and the attainment of objectives at both a country and regional level.

Evidence review mechanism

Time-limited and specific Evidence Review Groups (ERGs) will be established to review and provide evidence-based information and options for recommendations. These options will be discussed by the full MPAC in sessions open to representatives of stakeholders interested in malaria.

Selected current Technical Expert Groups (TEGs), e.g. the TEG on malaria chemotherapy, will continue to function but will fall under the umbrella of MPAC together with the shorter-term ERGs. The MPAC, together with the WHO-GMP Director, will review the need for existing TEGs, and the creation of new ones, on a regular basis.

A transparent and timely policy setting process

In order to seek broader input and allow for the exchange of information and views, and to ensure transparency and inclusivity, the majority of discussions will occur in open

session. However, the actual deliberations and development of recommendations by the MPAC will take place in a closed session in order to protect the integrity and independence of the committee from pressure and undue influence. Transparency is still ensured however as minutes will be made available on the WHO-GMP website following each meeting, together with the approved MPAC recommendations which will be published within two months of every meeting in the *Malaria Journal*. Approved meeting agendas, minutes, and recommendations will be archived and will continue to remain publicly available and easily accessible on the WHO-GMP website.

This article is the first in what will be a thematic series of policy recommendations to be published in the *Malaria Journal* following every MPAC meeting.

Conditional policy recommendations

In the absence of a robust evidence base, temporary conditional recommendations, clearly identified as such and based on a combination of the best available evidence and expert opinion, may be issued to provide guidance for regions and countries in the interim period. Conditional recommendations will be reviewed regularly at MPAC meetings in case adjustments need to be made based on newly available evidence.

Discussion

The call to strengthen the policy setting process for malaria control and elimination so that it is more responsive to the rapidly evolving malaria landscape has been heard. In critically reviewing its policy setting process and implementing changes to increase the timeliness and transparency of its policy recommendations, WHO-GMP is highlighting both its willingness to engage with key partners and its commitment to assist WHO member states in meeting their goals for malaria control and elimination.

WHO-GMP has reached this stage of strengthening the policy setting process for malaria control and elimination through the support of the global malaria community. Convening the MPAC is just the first step in making the policy setting process truly timely and transparent.

WHO-GMP and MPAC will need to continue to engage with the global malaria community in order to successfully fulfil their roles and functions. Further strengthening the policy setting process for malaria control and elimination will involve drawing on the strengths of the global malaria community and the tools in their arsenal. This will include requesting expertise and experience for ERGs and TEGs in order to inform malaria policy recommendations.

Conclusion

The malaria landscape will continue to evolve. However, change, if anticipated and effectively responded to, can

bring about positive transformation. WHO-GMP, MPAC, and the global malaria community as a whole, together have an unprecedented window of opportunity to set policies and programmes in place that will enable them to achieve the ambitious global goals that have been set for malaria.

List of abbreviations

ERGs: Evidence Review Groups; MPAC: Malaria Policy Advisory Committee; SAGE: Strategic Advisory Group of Experts on immunization; TEGs: Technical Expert Groups; WHO-GMP: World Health Organization Global Malaria Programme.

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Authors' contributions

BD and RN conceived the idea for the article. BD wrote a first draft of the article which was edited by RN. Both authors read and approved the final manuscript.

Competing interests

The authors declare that they have no competing interests. BD provides part-time secretariat support for the Malaria Policy Advisory Committee to the WHO and is also a part-time DrPH candidate and staff member at the London School of Hygiene and Tropical Medicine. RN is the director of the WHO Global Malaria Programme.

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Appendix 5: Publication resulting from DrPH Thesis

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When “Good Evidence” Is Not Enough: A Case of Global Malaria Policy Development

Bianca J. D’Souza* and Justin O. Parkhurst

This paper presents findings from a case study of two different policy development processes within the WHO’s malaria department. By comparing the policy processes for the interventions of intermittent preventive treatment in infants versus children, the findings suggest that “good evidence” from a technical perspective, though important, is not sufficient to ensure universal agreement and uptake of recommendations. An analysis of 29 key informant interviews finds that evidence also needs to be relevant to the policy question being asked, and that expert actors retain a concern over the legitimacy of the process by which technical evidence is brought to bear in the policy development process. Previous findings from the field of sustainable development, that evidence must be credible, salient, and legitimate to be accepted by the public, appears to apply equally within scientific advisory committees. While the WHO has principally focused on technical criteria for evidence inclusion in its policy development processes, this study suggests that the design and functionality of its advisory bodies must also enable transparent, responsive, and accepted processes of evidence review to ensure that these bodies are effective in producing advice that engenders change in policy and practice.

1. Introduction

This paper presents findings from a study investigating evidence use in global malaria policy development at the World Health Organization (WHO). Past work looking at decision making at WHO has engaged with topics such as its criteria for guideline development,^[1] or critical reflection on the organization’s response to global health crises.^[2] Here, however, the

focus is not so much on the outcomes of decisions, but rather on the internal processes involved—observing what is sometimes referred to as the “black box” of how evidence actually informs the policy process,^[3] within the primary global health institution responsible for the production of normative guidance to 193 member states.^[4]

The use of evidence has been a long established part of the policy process, and within public health, research evidence is widely considered as the necessary foundation for many health policy decisions.^[5] However, many have argued that the implied linear process between the knowledge produced by researchers and the policies developed by policy makers oversimplifies and does not adequately account for the complexities and political nature of policy making.^[6]

There is already a substantial body of work focused on the use of evidence in policy.^[5c,7] Many works concerned with “uptake” of research findings have attempted to identify ways to overcome “barriers” and increase “knowledge transfer”.^[8] Yet, numerous scholars have also drawn attention to the shortcoming of these approaches, including how they tend to exclude political considerations from policy decision making.^[6b,9] The public health community, it has been argued, has to consider how to move beyond simple notions of barriers and facilitators or a “more is better” approach.^[6b,9] Parkhurst,^[6b] for instance, argues that a shift is needed to engage with questions of what improved evidence use looks like by asking explicitly normative questions about how we might judge “good evidence” in terms of policy appropriateness, and the “good use of evidence” from a perspective of the decision making process. These considerations can then enable reflections on how to improve “evidence advisory systems” over time, rather than simply focusing on uptake of single pieces of research.^[6b]

Scientific advisory committees within technical agencies (such as WHO) could be seen in many ways as archetypal technocratic agencies within such evidence advisory systems—made up of experts that are explicitly tasked with review of scientific information. In the case of the WHO Global Malaria Program (WHO-GMP), the focus of this study, scientific advisory committee members are tasked with reviewing the evidence and advising WHO in their development of global policy recommendations to control and eliminate malaria.^[10]

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There is also a growing literature providing insights into the role and function of scientific advisory committees. Many of these are concerned with how to improve their inner workings in one way or another, for example by including patient experience information,^[11] or economic information,^[12] in order to promote the integration of evidence into health policy and practice. Other literature has been concerned with exploring how such bodies deal with constructing or facilitating a process less prone to bias, for example by applying clear, comprehensive, and consistent evidence inclusion criteria.^[13]

What many of these studies have in common is their focus on advisory bodies serving national governments. In health care, an exemplar often referenced is the National Institute for Health and Care Excellence (NICE) in England and Wales, which serves a mandated role to develop guidelines and make decisions that can have direct influence over policy and practice for the National Health Service. Yet, few studies examine the processes and perceptions of global health scientific advisory committees, which advise institutions such as the WHO. This may be an important distinction, however, because global health governance systems are decidedly different to national bodies, given the lack of a supreme authority and much more indirect systems of accountability to population groups.

This paper focuses on WHO-GMP, as an example of an international policy and guidance producer, and presents the findings from a case study of two different policy development processes for malaria control and prevention that took place within the department between 2006 and 2012. Both policies relate to what is known within the global malaria community as “intermittent preventive treatment”, or IPT, which is the delivery of a treatment dose of an antimalarial drug given at prespecified times for the prevention of malaria, regardless of the presence of symptoms or confirmed malaria infection. The two policy development processes that are compared are for the policies for IPT in infants (IPTi) versus in children (IPTc – now known as Seasonal Malaria Chemoprevention or SMC). Although there are commonalities between the two policies, the two policy development processes that led to them resulted in two very different perceptions by stakeholders about the success of those processes. For IPTi,^[14] the process through which evidence was used to inform policy was contentious and considered less than ideal to those who were involved.^[15] In comparison for SMC,^[16] the process was viewed by those involved as a model of efficiency.^[17]

By comparing the negative perception of one process in relation to the positive assessment of the other, however, this paper aims to explore some of the key features and influences shaping the use of evidence to inform policy decisions according to key stakeholders who serve within this technical body advising on global health guidelines.

2. Data Collection and Analysis

Data for this analysis came from 29 key informants interviewed between October 2014 and October 2015. The interviews were semi-structured and sampling was purposive to ensure a wide range of perspectives from those involved in the IPTi and/or SMC policy processes. They included: (a) staff from the Bill & Melinda Gates Foundation (BMGF), funders of the IPTi and

SMC studies; (b) staff from the research institutions who conducted the IPTi and SMC studies; (c) members of two of WHO-GMP’s scientific advisory committees—the Chemotherapy Technical Expert Group (TEG) and the Malaria Policy Advisory Committee (MPAC)—who advised WHO-GMP on the IPTi and SMC policies; and (d) staff from WHO-GMP responsible for issuing the IPTi and SMC policies to relevant member states.

Data also included published and unpublished documentary sources, including official policy documents for IPTi and SMC, scientific advisory committee meeting reports for IPTi and SMC, and internal BMGF and WHO-GMP documents on IPTi and SMC. Observational notes documented during meetings and conferences between March 2011 and October 2015 were also considered, as supplementary to the interview and document analysis. Data was organized and analyzed with the use of the Nvivo10 software package. Results were analyzed thematically, with no strict boundaries between data collection and analysis, as some themes began to emerge during the course of data collection. The interviews produced multiple narratives, which sometimes complemented or contradicted each other, but collectively provided insights into evidence use and the policy process from the point of view of the participants in it, which was the purpose of this interpretive case study.

The broad starting framework for analysis was derived from a study by Cash and colleagues,^[18] conducted in the field of environmental sustainability. The authors found that the effectiveness of science to inform policy rested on three key factors: credibility, which refers to the scientific adequacy of the evidence; salience, which refers to the relevance of the science to the needs of decision-makers; and legitimacy, which refers to the perception that the evidence generation and use has been unbiased and fair in its treatment of divergent stakeholder interests. Parkhurst,^[6b] similarly draws on this work to discuss the concepts of “good evidence” for policy or the “good use of evidence” within policy processes. “Good evidence” in this work is taken to capture evidence which is both appropriate to specific decisions being made (reflecting salience), but also of high quality according to principles of scientific good practice (often espoused by champions of so-called evidence based, or evidence informed, policymaking). “The good use of evidence” for policy, however, is presented by Parkhurst as capturing multiple concepts of legitimacy—including input legitimacy (decisions made by authorized representatives of the public); output legitimacy (decisions that achieve their intended goals to serve the public); and throughput legitimacy (decision processes themselves judged legitimate by beneficiaries). These broad concepts related to credibility, salience, and legitimacy, then allowed exploration of data to consider how similarities and differences might be seen between the two policy processes studied—in terms of features of the evidence base, its relevance to needs, and the process by which the evidence was used.

3. Findings

3.1. A Tale of Two Processes

Malaria is a complex, mosquito-borne, infectious disease, and a major global public health problem. In 2015 there were over

200 million new cases of malaria and nearly 500 000 deaths.^[19] An estimated 90% of malaria cases and 92% of malaria deaths occur in Africa, the majority among children below five years of age.^[19] This makes this particular age group in this particular geographical location an important target for global health policy makers and funders of public health research and programs who have a vested interest in reducing the global burden of malaria for moral, economic, and global health security reasons.^[20]

According to many in the global malaria community, the late 1990s marked a turning point in global interest in malaria.^[21] There was a resurgence of international attention for the disease after what was perceived to be the relative failure of the malaria eradication campaign of the 1960s.^[21b] Over the following decades, the malaria agenda went from the grand aspiration of eradication to a period of neglect to what is once again a recovered and enthusiastic vision of “accelerating toward elimination”, which is the goal of WHO’s 2016–2030 global strategy for malaria.^[20,21b]

The resurgence in attention was accompanied by a huge rise in the funds available for malaria research, control, as well as advocacy. This is reflected in the creation of Multilateral Initiative on Malaria in 1997, the Roll Back Malaria Partnership in 1998, BMGF in 1999, and the Global Fund against HIV/AIDS, Tuberculosis and Malaria in 2001.^[22] The increase in funding, particularly from the BMGF,^[23] provided new opportunities for research for increasing numbers of researchers, and it led to greater discussion among researchers around how few interventions against malaria existed.^[24] At the end of the 1990s there were limited tools for malaria treatment and control, but that would soon change.^[21b]

In 2001, the results of a randomized controlled trial (RCT) in Tanzania using Intermittent Preventive Treatment in infants (IPTi) employing the antimalarial drug Sulphadoxine–Pyrimethamine, delivered through the Expanded Program on Immunization, showed that this could be a useful intervention as it reduced clinical malaria episodes in infants by 59%.^[25] This generated much enthusiasm among the core group of scientists involved in the trial, and subsequently in the medical profession,^[26] because the results were considered potentially game-changing compared to the 35% pooled protective efficacy of malaria prevention interventions in pregnancy, i.e., Intermittent Preventive Treatment in pregnant women (IPTp) and insecticide-treated mosquito nets (ITNs).^[27] The researchers involved along with researchers from other institutions, and staff at WHO and UNICEF, subsequently formed a cross-institutional BMGF-funded global research partnership in 2003—the IPTi Consortium—that declared that they had “developed a research and implementation agenda that will rapidly resolve the outstanding scientific questions about this innovative form of malaria control, and move the intervention into policy and practice” within five years, by the end of 2008.^[28] They also added, somewhat ambitiously, that they had “prepared a strategic plan showing how, by the end of 2005, sufficient information will exist on which to base a policy recommendation.”^[28]

As part of the strategic plan and policy goals of the IPTi Consortium, a concurrent Policy Platform was established in WHO-GMP in 2005 to review the evidence gathered through the Consortium’s research groups.^[29] Its role was to prepare evidence as it became available from the IPTi studies for a

WHO technical review, so that WHO-GMP could reach a global recommendation on IPTi. This technical review involved the assessment of evidence by a series of WHO scientific advisory committees—a TEG, a Technical and Research Advisory Committee (TRAC) that reviewed TEG recommendations, and a Strategic and Technical Advisory Group (STAG) that reviewed TRAC recommendations.

For IPTi, the first TEG meeting was held in October 2006 and assessed the results of 11 studies on the efficacy and safety of IPTi in infants and children.^[30] At the time of the 2006 review, three of the trials on efficacy and safety were not published. The recommendation of the 2006 TEG to WHO was for countries to implement IPTi alongside rigorous monitoring, and if as additional data on IPTi emerged, there would be further assessments of the intervention. This TEG recommendation went to the TRAC in December 2006 where it was endorsed. The final level of review, before going to the WHO Director General, was at the STAG due to be held in May 2007. However, WHO cancelled this meeting and decided that a second TEG should be convened. This decision was triggered by newly available results of the outstanding trials released early in 2007, which reported the occurrence of severe adverse reactions that had not been reported in previous trials. In October 2007 a second meeting of the TEG took place, recognizing IPTi was a “promising intervention” but they recanted their previous recommendation and, to be cautious, suggested another review be held in 2008 when new data became available.^[31] The deliberations of the TEG were negatively perceived by some IPTi researchers as unnecessary delays in the evidence advisory process, and led to increasing frustration within the IPTi Consortium.^[15] This led to increasing tensions both amongst the researchers, and with WHO-GMP and its TEG, over differences in perceptions of time urgency, the meaning of rigorous evidence review, and the role of scientists.^[15] In an attempt to drive what was perceived to be a circular and slow moving process forward, the BMGF decided to commission an independent study from the U.S. Institute of Medicine (IoM) in mid-2007 to evaluate the IPTi results. This process, however, was viewed by multiple individuals interviewed as being at best irritating and at worse undermining to WHO-GMP. In July 2008, the IoM review concluded that IPTi was “worthy of further investment” and was potentially “ready to move to a new level,” implying program implementation in countries where IPTi would be effective.^[32] It is difficult to say whether the 2008 IoM conclusion had any bearing on WHO-GMP (interviewees suggested it did not) but in April 2009, eight years after the first IPTi study was published, a final meeting of the TEG judged the IPTi evidence base to finally be sufficiently acceptable, and endorsed a global policy recommendation on IPTi by WHO to member states.^[33]

The political fall-out from the perceived delays and tensions in the IPTi policy process was among the factors that precipitated WHO-GMP to review its many existing policy setting mechanisms in what by that point was an increasingly competitive global health policy environment for WHO-GMP.^[34] Specifically, in 2011, WHO-GMP embarked on a policy setting strengthening exercise to increase the timeliness, transparency, independence, and relevance of its recommendations to WHO member states in relation to malaria control and elimination.^[35]

The result was the scientific advisory committee, MPAC, first convened in 2012, to provide “independent strategic advice and technical input to the WHO for the development of policy recommendations covering all aspects of malaria control and elimination.”^[35]

The first body of evidence to come under this new system of MPAC review was for SMC. SMC is defined as the intermittent administration (once a month, up to four months) of full treatment courses of an antimalarial medicine (Amodiaquine + Sulphadoxine–Pyrimethamine) to children under the age of five during the malaria season to prevent malarial illness by maintaining therapeutic antimalarial drug concentrations in the blood throughout the period of greatest malarial risk.^[16]

Research on SMC had been going on for several years before the MPAC was formed. As in the case of IPTi, enthusiasm for SMC was based on positive findings from a RCT, but in Senegal instead of Tanzania, also published in the *Lancet*, but in 2006 instead of 2001, in this case showing an even higher 86% protective efficacy, compared to the 59% protective efficacy of the first IPTi RCT.^[25,36] More notably, however, unlike with the previous case, an official consortium with an overt agenda to achieve policy goals was never formed, and there appeared to be little tension between actors involved in the evidence advisory process. Instead, a series of informal collaborative meetings between SMC researchers and WHO with relevant national policy makers and program managers to identify outstanding priorities for research relevant to a SMC policy decision took place in 2008.^[37] These were followed by several large-scale evaluation studies in 2009.^[38] Meanwhile, there were

periodic informal reviews of the evidence dossier by experts to ensure that the necessary information was being collated for an informed decision by policy makers.^[37] This culminated in a single formal meeting of the TEG to review the evidence for SMC in May 2011, which resulted in a unanimous positive recommendation for the intervention despite the lack of an implementation mechanism.^[39] The recommendation was reviewed by the newly formed MPAC in February 2012, and by March, six years after the first SMC study was published, WHO-GMP issued the policy recommendation for SMC.^[16]

Although the overall timeline between initial results publication to an eventual policy recommendation by WHO-GMP had some similarities for both IPTi and SMC (**Figure 1**), as described earlier, many stakeholders viewed the policy development process for SMC as considerably better—a “model” process^[17]—to that for IPTi. The reasons for why appear to relate to both features of the evidence itself as well as perceptions of the policy process, explored next.

3.2. Strength and Quality of Evidence (Credibility)

Although there were several questions about the efficacy of IPTi (such as the extent to which IPTi merely delayed the onset of malaria and how much that mattered, or the impact of increasing drug resistance to Sulphadoxine–Pyrimethamine in parts of East Africa), the main criticism of several interviewees regarding the nature of the evidence was that the positive results from the first IPTi trial were not reproduced to the same

IPTi evidence to policy process

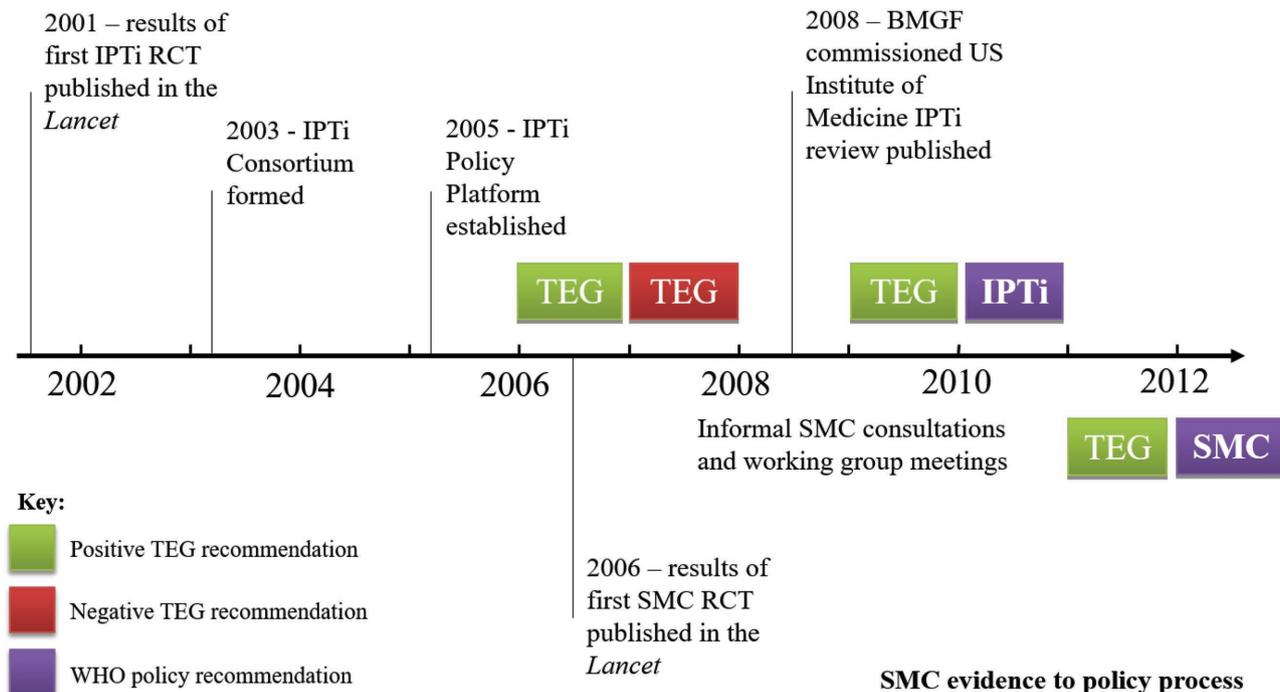


Figure 1. A simplified timeline of the evidence to policy process for two forms of intermittent preventive treatment (IPTi and SMC).

high levels in later trials—the pooled protective efficacy of IPTi was 30%,^[14] compared to the 59% protective efficacy from the first trial,^[25] which is to say that IPTi trials subsequent to the first one showed much lower protective efficacy on average. For some, this raised questions about the benefits of IPTi:

One of the big issues with IPTi was that the evidence didn't all point in the same direction. So the decisions were, you know, I think it was harder for people to have the level of confidence in them that they might have had with SMC where there's not much evidence going in the other directions. – KI41

Heterogeneity was not an issue for the SMC set of studies, where the pooled protective efficacy of the intervention was 75%,^[40] compared to the 86% protective efficacy from the first trial,^[36] which is to say that all SMC trial results showed similarity with consistently high protective efficacy.^[39,40]

Many interviewees seemed to assume this consistency between SMC trial results reflected strength of the results, which in turn might have helped the evidence base for SMC appear of higher quality compared to IPTi. However, the inconsistency in IPTi trial results is not necessarily a sign of weakness or lower quality, as the difference can be due to features of the study environments. The SMC studies all took place within a narrow geographic band of West Africa with similar and highly seasonal transmission (60% of cases occurring within four months of the year). In contrast, IPTi trials took place all over sub-Saharan Africa in a variety of transmission and epidemiological settings (which is common for many malaria interventions). Therefore, it would have been expected that any given trial would show higher protective efficacy, and greater consistency, when tested in more narrow trial regions (although the absolute level would depend of course on features of the intervention, including the drugs used).

In addition, the protective efficacy of IPTi is not dissimilar to other preventative malaria interventions widely recommended; for example, the best known preventive intervention against malaria, ITNs, has a protective efficacy of 55% in children.^[27] The complexity of preventing a complicated disease in a wide variety of (and ever-changing) epidemiological settings is the reason no “magic bullet” exists in malaria control and why high coverage of a mix of interventions that is most suited to local transmission patterns is recommended by WHO.^[20] So when it comes to protective efficacy as a proxy measure of the strength of an evidence base, it could be said that SMC is more of an outlier for preventive malaria interventions, given its consistency but also relatedly, the narrow geographic focus of studies. When thinking about the IPTi case in retrospect, many interviewees conceded this point, but opened up as to other reasons why they found the SMC evidence base to be relatively stronger and more credible.

3.3. Policy Relevance (Salience)

The perception of higher “strength” for SMC might have been compounded by the fact that the SMC study sites in the intervention region of Africa were also the proposed implementation sites for the SMC policy, which resulted in an unusual situation for the scientific advisory committees (TEG and MPAC) that

systematically reviewed the evidence base on SMC in order to advise WHO-GMP on a policy recommendation. In many other cases, these bodies need to deliberate about the applicability of study findings from a wide range of settings to the target contexts. Yet with SMC, because the study region was the implementation region, the evidence base reviewed had both high internal and external validity, which as several interviewees pointed out, made making a positive policy recommendation an easy choice and a relatively straightforward process compared to IPTi. Whereas in comparison the TEG for IPTi (MPAC did not exist at the time) had far more nuances to consider in its systematic review of the evidence available at the time.^[41]

For example, IPTi was sometimes described as “the wrong drug... at the wrong time,”^[42] even though in reality, the programmatic feasibility (implementation) of IPTi was recognized as being extremely important by the IPTi Consortium.^[43] Unfortunately, this did not appear to be enough. WHO-GMP and some other interviewees were uncertain as to how IPTi could be implemented and monitored in view of the increasing drug resistance to Sulphadoxine–Pyrimethamine in some parts of Africa and the lack of capacity in some countries, particularly at district level, to monitor levels of drug resistance in order to know where best to target the drug (making the drug essentially ineffective in those areas, hence the view that it might be the “wrong drug”). In addition, the actual relevance of IPTi was also questioned in countries where the coverage of its delivery mechanism, the Expanded Program on Immunization, was low, or where there was highly seasonal malaria transmission (which is to say the delivery of the drug would not in some areas of countries be coinciding with the expected peaks in the number of malaria cases, hence the view that it might be delivered at the “wrong time”), as IPTi would have a very small effect.^[44] Although these issues were not specific to IPTi, WHO guidelines had to take into account local heterogeneity of countries’ epidemiological profiles and the need to disaggregate their policy to sub-national levels. This was less of an issue for the SMC policy consideration, as there was epidemiological homogeneity for the reasons described earlier, and because the policy would only apply to certain parts of certain countries where 60% of cases occurred within four months of the year, the policy in some ways was already disaggregated to sub-national levels.

SMC, in comparison to IPTi, was also described as having higher “practicability” and “generalizability” beyond just a research setting. This also seemed to contribute to its evidence base’s perceived “strength” and salience. As one member of MPAC described:

I think the evidence base for SMC is pretty strong. I mean there are a number of really quite convincing and sufficiently large studies that show major impact. I mean you're always concerned with, I think, a number of things; one is the size of the studies, the consistency of the results, and the scale of impact, and that's the first step. Obviously you're then concerned about the practicability, because there it's quite possible to have an intervention, which is in a controlled setting, demonstrably effective, but it may simply not be practical. I think SMC has the advantage of firstly, it's got a good evidence base; the studies [have] sufficient numbers, are sufficiently large, and showing really major impact, and certainly some of the

studies have been conducted under conditions which would allow you to already extend it to the idea that this could be applied in a [real-life] setting rather than a small-scale research study. – KI34

The reasons for the difference in generalizability are varied, and among the explanations that were offered by interviewees was the difference in age group and banding (infants versus children), and the study location (highly seasonal transmission versus a variety of transmission settings). The SMC studies were focused only in areas of highly seasonal transmission whereas the goal of the IPTi studies was to be generalizable to all of Sub Saharan Africa, which has far more variability in malaria transmission, sometimes within the same country. This, in hindsight, made generalizability difficult due to the variability in results, compared to the relative homogeneity of the SMC study results due to the homogeneous transmission settings.

In short, by conducting the SMC RCTs in the countries where the intervention, if successful, would be eventually rolled out, SMC researchers helped ensure that their portfolio of research answered a wide enough range of useful questions to policy makers that it was considered more relevant compared with IPTi. This is despite SMC having some perceived implementation-related weaknesses such as no single pre-existing delivery mechanism. For example, IPTi delivery via the Expanded Program on Immunization was viewed by many as a potential strength, as it meant delivery would be through the existing health system, when most mothers were already visiting health clinics with their infants for their WHO-recommended vaccination schedule. Some interviewees, however, perceived the lack of a single pre-existing delivery mechanism as a potential strength for SMC, rather than a critical weakness, as to them it meant that national malaria control programs could have more flexibility and control over how the intervention could best be delivered in their local context.

3.4. Legitimacy of the Process

A final theme explored was features related to the perceived legitimacy of the two processes, and how this may help to explain why interviewees saw the SMC process as better than that for IPTi. At the time of the IPTi Consortium, the evidence review process at WHO-GMP involved the assessment of evidence by a series of scientific advisory committees—the TEG, TRAC, and STAG.^[34] By the time of evidence review for the SMC studies in 2011, however, a restructure intended to make the policy process more “transparent, responsive, and credible,”^[35] meant there were two levels, the TEG and the MPAC, which the TEG reported to. Beyond this, however, two further sub-themes emerged related to the legitimacy of the processes.

3.4.1. A Difference in Expectations and Framing

One difference between the policy processes for SMC and IPTi was in the researchers’ expectations of the policy process. As mentioned previously, in the IPTi Consortium funding proposal approved by the BMGF in 2003, the researchers had high

expectations that results would be consistent, and knowledge transfer would be quick. Policy engagement was planned to take place alongside the process of generating evidence on IPTi. A strategy was devised which set out a clear schedule that in 2006, that is to say at the time of the first TEG meeting, the Consortium would have generated a substantive body of evidence on IPTi to inform a WHO policy recommendation in that year. By framing the value of their research and their own success as a Consortium around a quick policy recommendation by WHO, the IPTi Consortium put themselves, and by extension, the WHO-GMP evidence advisory process, under significant pressure. One interviewee recalled:

Now where the IPTi consortium went wrong was that there was this day which was called the “green line” where we all go to it with all our evidence, and then the policy decision to implement IPTi would be made, but of course the reality is that the evidence would be considered and then a decision for IPTi policy would be made. But it wasn't really figured out like that. It was figured out that the “green line” meant green for go, and IPTi would be recommended, and IPTi would be implemented. And I think that that was really the biggest error, [the] supposition that the data would support a decision to go ahead. – KI44

Although similar policy engagement also took place alongside the process of generating evidence on SMC, that process was perceived to be more organic, for example, via informal (by WHO standards) meetings between SMC researchers, WHO, and national malaria programs in 2008. The SMC researchers were not part of a formal “SMC Consortium” with an overt agenda to achieve policy goals. One reason for this is that they might have learned lessons from observing the experience of global malaria colleagues in the IPTi Consortium, who were in the midst of repeated TEG reviews and tensions with WHO-GMP at around the same time. In any case, SMC researchers did not appear to have high expectations of quick knowledge transfer, nor the pressure of self-imposed “green lines” to contend with, which might have contributed to a less fraught policy process with relatively tempered expectations, despite consistently highly efficacious trial results.

3.4.2. Conflicting Agendas

The IPTi Consortium was made up of actors from different institutions with different primary objectives ranging from a focus on science to a concern with delivering programs. One thing they did have in common was high expectations that IPTi knowledge transfer would be quick and uncomplicated.^[28] Unfortunately, perceptions of the IPTi Consortium and views of it having an overt agenda, appeared to affect the functioning of the advisory bodies involved. This led to the perception of two sides pitted against the other. One interviewee summarized:

It was bad. Aggressive from some of the researchers, aggressive from some members of the BMGF, an aggressive push back from WHO, I've never seen anything like it before. Everyone seemed to rally on the two sides. –KI49

There was also a tension within the research community. Some IPTi Consortium members were strongly committed to

contributing to public health by clear engagement in the policy process. Others felt, however, that scientists had to stay neutral and research-focused. Although these tensions were less of an issue within the SMC policy process, many SMC researchers also expressed similar views about the role of researchers:

You try to make sure that the key people know about [your study results] and that's by having a meeting or a symposium. Taking that any further, I've always been on the side that investigators shouldn't become lobbyists, and that somebody else should do that. You may need a lobbyist, but those are different people, it shouldn't be the investigators who did the trials...they may be asked to help, but you shouldn't have one of the key investigators initiating that process. – KI29

The perceived overt advocacy by some IPTi Consortium members may have contributed to undermining their legitimacy within the IPTi policy development process. This was a consistent reflection across the various groups of interviewees—funder, researcher, and WHO staff. One interviewee shared their perception of the tension between WHO-GMP and the IPTi Consortium from that time:

I think clearly a problem [was] that WHO perceived the IPTi Consortium as being a mixture of investigators and advocates, and without a clear separation of those. So they saw this group as putting evidence forward and advocating strongly for implementation, for adoption of policy and implementation of IPTi. In fact, I think, in some ways the Consortium was perceived more as advocates than as sort of independent, unbiased investigators and so that colors the way things are looked at. If you think these people are flogging something and they've got lots of biases, then surely their data is biased and they're not revealing ... For example, they may not have done the studies well enough to be sure that there aren't adverse reactions. That was a big issue. You could ask "Really? Did you really set things up so you picked up the signals?" – KI23

In comparison, the researchers who were part of the SMC studies were perceived to have played a more neutral role, which was seen to help maintain their legitimacy. For example, one interviewee reflected:

Many people, including myself, perceived and liked that the [SMC researchers] behaved the way that you expect scientists should behave...they really saw the various sides and carefully looked at the various angles [of the research question]. –KI35

Reflections like these were common; the lack of pressure and, as a result, conflict during the SMC policy development process was considered by many interviewees to be its positive defining feature, in contrast with IPTi and its seeming legitimacy undermining missteps.

A big perceived misstep was the creation of the IPTi Policy Platform, which was part of both the Consortium and WHO-GMP.^[29] Many interviewees felt that WHO-GMP should never have been part of the IPTi Consortium or home to its Policy Platform, as it was a conflict of interest and detracted from the legitimacy of the process and the independent “balancing act” that is a WHO policy recommendation. One interviewee shared what they perceived to be a valuable lesson learned:

There was one WHO staff member who was put on the IPTi proposal as part of the Consortium. Later on, this wound up raising questions about whether one should have someone as part of a consortium who is part of the institution that will be judge and jury of the evidence being generated. Does that blur those lines too much? I have to say that I have probably changed my view of that over time. I remember at the time being indignant that how could WHO have agreed to be part of the consortium, and then later reversing its position and claiming that it was not right for WHO to play that role. Now that I have spent time at WHO, and understand the importance of the independence of that evidence making process, I now understand those concerns. And I think that it probably is not a good idea to have someone as part of a consortium who is part of the agency that is convening the evidence review process; some separation is necessary. It doesn't need to be a firewall. There can be a dialogue, but you can't have that person be part of the group. They need to be having regular exchanges with the group and helping to steer the sort of evidence base that's required, but not be implicated as part of that group. I think that is an important balancing act. –KI39

Having an overt policy agenda was not a mistake repeated by the researchers for the SMC set of studies. In addition, here WHO-GMP involvement was viewed positively; they were seen as a “hands on” partner, meeting again for informal consultations between 2009 and 2010 when SMC researchers were collectively preparing their dossier for evidence review by the TEG. This was not perceived to be a conflict of interest by WHO-GMP. It was seen to be in everyone's interest to make the process smooth while still maintaining institutional integrity via independence and transparency. Having a clear and transparent evidence review process for SMC appeared to be quite important to many interviewees. One interviewee recalled:

For IPTi, it did not seem like a clear process; it seemed a bit cloak and dagger, or that events were taking place in a smoky dark room. There was no transparency as to how the process was supposed to be conducted. For the review of SMC, the fact that the Malaria Policy Advisory Committee had been convened in a transparent way, that everyone was aware who was on it, that there was clear terms of reference for the committee, that the Director General had signed off on the process, I think gave a lot of credibility in advance to the process, which is really important. If people coming into an evidence review have no idea what to expect, no idea what the steps are going to be, no idea who ultimately is making those decisions, then I think the process is on the rocks before it even gets going. – KI44

During the SMC policy development process, WHO-GMP was able to fulfill its own ideal notion of structural and legitimate power, without having to defend itself against other actors as it felt pressured to do during the IPTi process. By maintaining its power during the SMC process, WHO-GMP maintained its legitimacy as a global health policy actor, which might have helped maintain the legitimacy of the policy development process itself.

4. Discussion

Explaining the differences in the policy development processes between IPTi and SMC requires understanding a set

of interacting factors related to features of the evidence base as well as features of the process by which it was brought to bear on policymaking. IPTi was introduced as an innovation that was pursued by a group of committed public health practitioners and researchers, and internally framed along the lines of a quick and linear process. The IPTi Consortium's proposal to BMGF included a clear schedule and a Policy Platform to facilitate the policy development process. Consortium members believed that more evidence delivered in a timely way would persuade policymakers to recommend IPTi. However, over time, this internal expectation and pressure to meet the deadlines they had set for themselves in their proposal to BMGF led to a breakdown in consensus and trust between actors, followed by delays in its policy development. In comparison, the SMC policy process was never viewed as a battle between the actors involved. Here the policy process was viewed as open, inclusive, and transparent, which was WHO-GMP's intention of what a good policy process should look like when it formed MPAC.^[35] By learning from its experience with IPTi, and optimizing the design and function of its principal scientific advisory committee to better serve its institutional needs, WHO-GMP was perceived as having strengthened its malaria policy development process.

What appears to have edged the SMC evidence base over the one for IPTi was that, ultimately, it was more relevant to the question being asked by the TEG, with its perceived value as an intervention being boosted by the size and potential impact of its protective efficacy, and the high consistency of the results across RCT sites. Although the reasons for this difference (the highly focused and similar transmission settings for SMC studies) can be explained, a pooled protective efficacy of 75% for SMC compared to 30% for IPTi made the potential impact of SMC a difficult policy option to ignore. In other words, while the results of the RCTs for IPTi would be considered "credible" by standard evidence hierarchy measures, and comparable to other preventive malaria interventions, the evidence base for SMC compared to IPTi was perceived to be both "credible" and "salient", which contributed to making it appear better, or more appropriate for policy consideration.

The study findings also suggest that the breakdown in consensus and trust in the policy process, due to the different expectations, conflicting agendas, and in some instances, the overt advocacy of the actors involved, might have contributed to the perception of problems that undermined the policy development process for IPTi, in comparison to SMC. The contestation around the IPTi policy process might have contributed to negative perceptions of its policy value. Contestation, as a form of deliberation and consensus building, is not necessarily a "bad" thing, particularly when built into institutional arrangements that aim to improve the legitimacy of governing processes through deliberation and inclusion of multiple views.^[45] Some scholars have seen the need for deliberation as particularly important when public policy relies on delegation to scientific experts that serve to provide scientific advice.^[46] Institutional approaches in the policy sciences recognize that institutions can be thought of in terms of formal structures, and also as rules that shape how decisions are made.^[47] In the case of SMC, although there was not necessarily as much deliberation over the evidence as there was for IPTi, it appears that having

clear expectations from all sides of the evidence advisory process, with a clear structure and terms of reference for MPAC members, as well as transparency of the evidence consideration, might have led to the process for SMC appearing more "legitimate" to those involved in its evidence advice and policy development.

These findings are not meant to imply that one evidence base was stronger or weaker than the other was, or that the process of evidence use is necessarily more important than features of the evidence itself. Indeed, both feature in important but differing ways. As such, these findings help to reinforce how the factors of credibility, salience, and legitimacy all appear to influence evidence use, with particular insights into an agency with a particular technical remit and expert body of stakeholders informing global health policy making.

While these findings emerge from a pair of specific malaria policy developments, there may be reasons to believe similar issues would be relevant elsewhere. Indeed, the issues of credibility, salience, and legitimacy derived from a very different study conducted on sustainable development related to concerns of the lay public as well as of scientists. Thus seeing similar issues arise in a technical body made up of individuals with broadly similar scientific training helps to illustrate that even in these groups, features outside scientific quality can matter when it comes to evidence use for policy and planning.

What might be an important additional factor for WHO however, as it continues to improve its internal guideline development processes,^[4] is to consider more specifically the processes followed by its advisory bodies, in addition to concern over how to judge or rank evidence. Specifically considering how to build evidence advisory structures that are open, inclusive, and transparent might serve to promote the legitimacy of its policy decisions and decrease potential conflicts of interests in a global health-funding environment where private funders are viewed as having increasing influence on the global health agenda.^[48] For example, the BMGF are already one of the largest donors to the WHO, and within the field of global malaria, they funded both the IPTi Consortium and many of the SMC studies, in addition to the policy-strengthening grant that led to the creation of MPAC.^[28,35,37,48f,49] There is very little in the world of global malaria control and elimination that is not funded or at least influenced by BMGF.^[50] While many in the global malaria community are quick to point out the positive outcomes of what funding coming from the BMGF can achieve,^[48e] the findings here illustrate the importance of process legitimacy in addition to concern over outputs and outcomes.

5. Conclusion

In the case of the policy development processes for IPTi and SMC, the findings show that "good evidence" from a purely technical (credibility) perspective was not sufficient to ensure universal agreement and uptake of recommendations, even within a highly technocratic body such as the WHO-GMP. The findings suggest that evidence also needed to be relevant (salient) to the policy question being asked, and technical actors retained a concern over the legitimacy of the process by which technical evidence was brought to bear in the policy

development process. Cash and colleagues findings from the field of sustainable development,^[18] that evidence must be credible, salient, and legitimate to be accepted by the public, appears to equally apply within scientific advisory committees, albeit nuanced by their specific contextual realities.

While the WHO has principally focused on technical criteria for evidence inclusion in its policy and guideline development processes, the study of the MPAC suggests that the design and functionality of its scientific advisory committees might also have a role to play within its overarching evidence advisory system. Scientific advisory committees should consider enabling transparent, responsive, and credible processes of evidence review, to ensure that they are effective in producing advice that ultimately leads to policy recommendations by WHO. Such legitimacy may also be important to implementation of recommendations by WHO member states, particularly considering the current funding environment in which WHO is highly reliant on external sources of funding, both for programmatic work, as well as for funding research that aims to ultimately inform policy and practice.

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Conflict of Interest

The authors declare no conflict of interest.

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