Strengthening the expert review process: a case study of the WHO's global malaria programme

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This paper presents findings from a comparative 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 in 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 technical actors retain a concern over the legitimacy of the process by which technical evidence is brought to bear in the policy development process. Cash and colleagues[1] 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 bodies. While the WHO has principally focussed 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.

1. Introduction

The use of evidence has been a long established part of the policy process, and within public health, research evidence is widely considered the necessary foundation for many health policy decisions [2-4]. Whether in the form of peer validated research or defined more broadly as any type of knowledge that influences a decision, evidence can help to project rationality about a decision or an outcome [5, 6].

Why, when, and how research evidence is used in the development of public health policy can sometimes be difficult to discern [7, 8]; however, these questions are important to understand if the aim is to increase and improve evidence use in the policy process. A wide range of research has been done to better understand the linkages between researchers and policy makers, particularly in the area of "knowledge transfer and exchange" (KTE). This is a relatively new field, and one not specific to health policy, that has emerged to capture why, when, and how knowledge or evidence is used to inform policy [9-13]. However, the implied linear process between the knowledge produced by researchers and the policies developed by policy makers -already acknowledged as a weakness in the field [14, 15] - oversimplifies and does not adequately account for the complexities and political nature of policy making [16].

As noted by Smith [17], the evidence-based policy (EBP) movement has championed one particular idea which assumes that *more* use is *better* use, especially if that evidence comes from the tops of particular hierarchies. Parkhurst [18] and others [19, 20] have identified this approach as problematic due to the way it can, in the name of promoting technical effectiveness, work to depoliticise policy debates which need to reflect multiple competing social values of a population. They argue for a more explicit recognition of the nature of politics that has been missing from much previous work promoting evidence use. Parkhurst [18]

and Cairney [19] suggest that in order to address the politics of evidence - in all its forms - we need to move beyond past efforts focussing solely on knowledge transfer, recognising that social goals can be contested, and understanding how the pursuit of our values may manifest in biased uses of evidence. The main issue is not that hierarchies are inherently flawed, but rather that they are being incorrectly applied in many cases if they are used to prioritise policy choices. Over reliance on hierarchies also can obscure the importance of external validity, often failing to explicitly address questions of the applicability of findings across contexts [21] .

While some authors have noted the limitations of hierarchies of evidence in terms of policy usefulness [18, 22, 23], these ideas have yet to be taken up widely in the EBP movement. There still needs to be critical reflection of what hierarchies can be used for, and what 'good evidence for policy' would have to look like if single hierarchies do not meet the needs for evidence use within policy decisions [18]. Parkhurst [18] outlines that another relevant challenge to the EBP movement is in recognising the importance of the legitimacy of the decision making processes utilising evidence. The EBP literature seems to assume that evidence use is a universally embraced good thing, yet from a policy studies perspective, the process by which public policy decisions are made, and social outcomes achieved, must be accepted as legitimate by the population [15]. Instead, the concern has been over research 'use' or 'uptake', with competing political or cultural considerations simply classified as 'barriers' to be overcome, or with 'resistance' to evidence explained as due to lack of understanding of the science by the potential beneficiaries [13, 20, 24].

Parkhurst [18] has argued that democratic debate 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. Such an approach requires shifting thinking to consider 'systems of evidence advice' rather than just targeting individuals as knowledge brokers.

It is not unusual to expect that 'good evidence' and 'good use of evidence' will be viewed and interpreted differently by different actor groups [25, 26]. The experiences, composition, and professional status of actors within evidence advisory bodies influence how evidence is interpreted and how recommendations are formed [27]. These insights are part of a slowly growing literature on the role of evidence advisory bodies, and how to improve their inner workings, for example by including patient experience information [28] or economic information [29, 30] in order to promote the integration of evidence into health policy and practice. Some of the literature is concerned with exploring how such bodies deal with constructing or facilitating a deliberative process that is seen as legitimate [29-33].

However, what many of these studies have in common is that they tend to focus on national advisory bodies in particular, such as the National Institute for Health and Clinical Excellence (NICE) in England and Wales, which has direct influence over policy and practice for the National Health Service. At present, few studies examine the processes and perceptions of global health evidence advisory bodies, who advise institutions such as the WHO, on recommendations for global health policy.

This paper focuses on one WHO department in particular, the WHO Global Malaria Programme (WHO-GMP), as an example of an influential international policy and guidance producer, and presents the findings from a comparative 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 anti-malarial drug given at a pre-specified time 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 some 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 [34], the process through which evidence was used to inform policy was seen as contentious and therefore less than ideal to those who were involved [35]. In comparison, SMC [36] was viewed by those involved as a model process due to its seeming efficiency [37].

In looking at the negative assessment of one process in relation to the positive assessment of the other, this paper explores the influences on the use of evidence in policy making for IPT according to those key stakeholders who were involved in their development.

2. Methods

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), who funded 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 evidence advisory bodies - 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 who were 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, 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 between March 2011 and October 2015 was also considered, but mainly as supplementary to the interview and document analysis. Data was organized and analysed with the help of Nvivo10.

The framework for analysis came from Cash and colleagues [1] work on the use of science and technology to inform policymaking within the field of sustainable development. They analysed environmental sustainability across a range of countries and 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 process of evidence generation and use has been unbiased and fair in its treatment of divergent stakeholder views and interests. 'Good evidence' for policy can be seen to capture the ideas of credibility and salience identified by Cash et al., as these concepts reflect the EBP movement's normative principles of fidelity to science and usefulness to achieve social goals. The concept of legitimacy can be seen to capture the principles of 'good use of evidence' for policy, as it reflects policy scholars' concerns that evidence-informed policy decisions remain democratically representative of multiple social interests.

3. Findings

3.1 A tale of two processes

In the context of increasing interest in malaria and greater availability of funding but few effective interventions [38], the results of the first IPTi study published in the *Lancet* [39] generated much enthusiasm among the core group of scientists involved in the trial. This research group along with others formed a cross-institutional global research partnership - the IPTi Consortium – that in its funding proposal 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 [40].

The IPTi Consortium was made up of a group of researchers and international policy makers including its funder, the BMGF, and staff at WHO and UNICEF [40]. To facilitate the review of evidence gathered through the Consortium's research groups, a concurrent Policy Platform was established in WHO-GMP [41]. Its role was to prepare the evidence as it became available from the IPTi studies for a WHO technical review process, so that WHO-GMP could reach a global recommendation on IPTi. This technical review process involved the assessment of evidence by a series of WHO committees – a Technical Expert Group (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 [42]. At the time of the 2006 review, three of the trials on efficacy and safety were not yet published. The recommendation of the 2006 TEG was positive provided that implementation would take place alongside rigorous monitoring and that as additional data on IPTi emerged, there would be further assessments of the intervention. This TEG recommendation then went to the TRAC in December 2006 where it was also endorsed. The next and 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 the availability of the final results of the pending trials in early 2007, which reported the occurrence of severe adverse reactions that had not been reported in the other previous trials. It was only in October 2007 that the second TEG meeting took place. Although this second TEG also recognized IPTi using sulfadoxine-pyrimethamine (SP) was a "promising intervention" it recommended another review be held in 2008 when new data became available [43].

In an attempt to drive forward the process, the BMGF commissioned a study from the Institute of Medicine (IoM) in mid-2007 to evaluate the IPTi results. A year later, in July 2008, the IoM review was finalized and provided a more positive conclusion on IPTi [44]. Finally, the closing meeting of the IPTi Consortium was held in January 2009. Given the turbulence of 2007 and 2008, its members were determined to see the policy process through to a final conclusion. They advocated the setting of a date for another TEG to review what was by then the complete set of trial data. In April 2009, eight years after the first IPTi study was published, this final and third meeting of the TEG endorsed a global policy recommendation on IPTi by WHO to member states [45].

The turbulent policy process for IPTi is widely used within the global malaria community as an example of a process where the inherent tension between researchers, their funders, and policy makers could have been better managed [35, 46]. In fact, the political fall-out from the IPTi policy process was among the factors that precipitated WHO-GMP to review its many existing policy setting mechanisms [47]. WHO-GMP recognized by 2010, under the leadership of a new director, that it needed to adapt its expert review process if it wanted to maintain and strengthen its global leadership role in policy-setting [47]. 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 insufficiently able to respond to a rapidly changing political, funding and epidemiological landscape [47].

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 [48]. The result was the evidence advisory body, MPAC, first convened in 2012, which meets twice a year 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" [48].

The first body of evidence to come under MPAC review was for SMC. SMC, previously referred to as IPTc, is defined as the intermittent administration (once a month, up to four months) of full treatment courses of an antimalarial medicine (Amodiaquine + SP) during the malaria season to prevent malarial illness by maintaining therapeutic antimalarial drug concentrations in the blood throughout the period of greatest malarial risk [36], which for SMC-relevant countries is essentially the rainy season.

In the case of SMC, there too was a positive first study also published in the *Lancet* [49]. However, unlike with IPTi, here an official consortium with an overt policy agenda was never formed. Instead, a series of informal meetings with policy makers and programme managers to identify outstanding priorities for research relevant to a SMC policy decision took place in 2008 [50]. These were followed by several large-scale evaluation studies in 2009 to address these questions [51-53]. 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 [50]. 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 [54]. 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 [36].

3.2. Strength and quality of evidence

Although there were several questions about the efficacy of IPTi (e.g. around the extent to which IPTi merely delayed the onset of malaria and how much that mattered), the main concern of several respondents was that the positive results from the first trial were not reproduced to the same high levels in later trials. 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 all studies results were similarly and consistently highly efficacious [55]. The difference in measures of, in particular, effectiveness and repeatability, were often described as proxy measures for the relative higher "quality" and "strength" of the SMC evidence base. This is striking because by traditional measures of judgement stemming from the EBP movement, the IPTi evidence base was at least similar to evidence bases for other malaria prevention and control interventions [56].

The concern for strength and quality level overlaps with Cash et al.'s [1] concept of 'credibility', defined as reflecting the scientific adequacy of the technical evidence. While in political debates there may be disagreement over which policy outcomes are most important, there is agreement on the need to adhere to scientific good practice for any given piece of evidence that may be utilized [57]. Parkhurst [18] suggests that a different way to look at or define 'good evidence for policy' is essentially to view it as appropriate evidence (i.e. policy-relevant evidence constructed in ways that would be useful to inform relevant policy concerns, which are also applicable to the local policy context) that is of high quality. He notes however, that quality must be judged by the methodological principles relevant to the evidence base, as well as adherence to broad principles of good scientific practice. So in short, quality still matters, even if the hierarchy of evidence, with randomised controlled trials (RCTs) at or near the top [23], does not always provide the definitive measure of quality, or even of certainty, as evidenced by the IPTi group of studies. Unlike with IPTi, the SMC set of studies had a consistently large effect in all its study sites [54, 55]. Many interviewees seemed to conflate consistency with certainty, which in turn might have helped the evidence base for SMC appear "stronger" and of higher quality compared to IPTi.

This perception of "strength" might have been compounded by the fact that the SMC study sites in the sub-Sahel region of Africa were also the proposed implementation sites for the SMC policy, which resulted in an unusual situation for the TEG to consider – the evidence base they were reviewing 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.

Some interviewees found the quality of both evidence bases to be comparable, with some even suggesting that the evidence for IPTi was "better" due to the volume of data. Nevertheless, the "quality" of the evidence seemed to be less of a concern, or more of a secondary consideration, when the size of the intervention effect was large. In the case of SMC, studies showed that it had a 75% protective effect in children [36], compared to a 30% protective effect in infants for the IPTi set of studies [34].

> *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*

Many of those involved with the policy decision felt that, unlike with SMC, IPTi didn't do what it was supposed to do, which was demonstrate that it saved the lives of infants.

> *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 effect than IPTi. – KI51*

One explanation for this difference in results is that the SMC portfolio was 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 policy-relevant results. This lead to the perceived level of evidence being high. This is ironic, since delivering a complete and robust package of results was the explicit purpose of the IPTi consortium.

> *Well I think the evidence base on SMC was more robust. 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*

3.3. Policy relevance

SMC researchers asking the "right" questions is a theme that came up often in interviewee responses. In fact, in comparison IPTi was often described as "the wrong drug, at the wrong dose, at the wrong time" to the extent that responding to this pervasive belief was part of a Q&A briefing pack prepared for Consortium spokespeople following one of their Lancet publications [58]. In reality, the programmatic feasibility of IPTi was recognised as being extremely important by the IPTi Consortium. The large operational study in six African countries led by UNICEF and the community effectiveness study in Southern Tanzania explored operational issues and how IPTi would work within the existing health system. Results from Tanzania showed that overall IPTi was safe, affordable, acceptable and possible

to deliver within the existing health system [59-62]. While these findings were examined by the third WHO TEG, and probably contributed to the decision to recommend IPTi, various respondents still expressed concerns about implementation.

From WHO's perspective, the operational feasibility of an intervention was reported to be as important as its effectiveness and safety. For example, clear guidelines to country programme managers were and still are considered to be crucial. WHO and some other respondents were 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. WHO guidelines 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 indoor residual spraying and SMC among others), the actual relevance of IPTi was also questioned in countries where its delivery mechanism, the Expanded Programme on Immunisation (EPI) coverage was low, or malaria seasonal, as IPTi would have a very small effect [63].

Perhaps more importantly in terms of implementation, some interviewees suggested that IPTi was of middle to low priority in Ministries of Health. This 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. 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.

SMC, in comparison to IPTi, was described as having higher "practicability" and "generalisability" beyond just a research setting. This also seemed to contribute to the "strength" of its evidence base.

> *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*

In fact, for IPTi, this lack of generalisability appears to have contributed to the study results seeming to appear not as "good" or relevant.

> *One of the problems with IPTi, is that when they did the [first] study in Ifakara, it was an intense transmission setting, when they did it. And the same study published how the transmission went down over five years. So in fact, what [they] found five years ago, may not be there now, because the transmission [is going] down.- KI32*

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 (targeting infants less than nine months for IPTi versus from six to sixty months for SMC), and also study location. The SMC studies were focussed only in areas of highly seasonal transmission (basically a geographical band across the widest part of Africa, just under the Sahel desert) 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 (unsurprising) variability in results, compared to the (also unsurprising) relative homogeneity of the SMC study results due to the homogeneous transmission settings.

By conducting the SMC RCTs in the very countries where the intervention, if successful, would be eventually rolled out, 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 relevant.

3.4. Legitimacy of process

At the time of the IPTi Consortium, the evidence review process at WHO-GMP involved the assessment of evidence by a series of committees at different levels – the TEG, TRAC, and STAG [47]. Interventions involving vaccines (such as IPTi, which was to be delivered through the EPI programme) also need 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 [47]. In contrast, by the time for

evidence review of the SMC set of studies in 2011, and benefiting from a restructure that was intended to make the policy process more "transparent, responsive, and credible" [48], there were just two levels – the TEG and the MPAC which the TEG reported to.

3.4.1 A difference in 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 rational policy process. 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 …." (p. 11) [40]. It was clear 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." (p. 15) [40]. 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." (p. 2) [40].

It was thus planned that policy engagement would take place alongside the process of generating the evidence on IPTi. A strategy was devised (known within the IPTi Consortium as 'the green lines') which set out a clear schedule that by 2006 the Consortium would have generated a substantive body of evidence on IPTi-SP (efficacy, EPI interactions, community effectiveness, costing, acceptability, rebound, immunology, safety and drug resistance) to inform a policy recommendation; and that by 2008 it would produce further scientific evidence on IPTi as related to the above areas but using other drugs than SP [41]. 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

3.4.2 Conflicting agendas

Supporting a decision to "go ahead" was the reason the IPTi Consortium was designed to draw on its strengths as a group of researchers, funders and policy makers to support, analyse and synthesize the findings from a number of studies across various disciplines, and through the Policy Platform to inform the review process to get a global policy decision [40]. However, the Consortium was made up of actors from different institutions with different primary objectives ranging from a focus on science to a concern with delivering programmes and agreeing global malaria policy. One thing they did all have in common though were high expectations that IPTi knowledge transfer would be quick and that a policy recommendation would be possible without complication [40]. Unfortunately, perceptions of the IPTi Consortium, in addition to contestation over the evidence itself, did appear to affect how the evidence was viewed. This appears to have led to the perception of "two sides" pitted against the other. One IPTi Consortium member 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 a tension within the research community as well. Some IPTi Consortium members were strongly committed to contributing to public health by reducing malaria morbidity and mortality and this included a clear engagement in the policy process. Others felt, however, that scientists had to stay neutral and focus on the research. Still others in the Consortium were torn between science and advocacy, feeling compelled to generate robust evidence and also responsible for acting upon the policy process.

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.

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 within their epistemic community, caused this set of actors to lose their structural power and so undermined their

legitimacy within the IPTi policy development process. This was a consistent reflection across the various groups of interviewees – funder, researcher, and WHO staff.

> *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*

In comparison, the researchers who were part of the SMC studies were perceived to have played their neutral role - a form of their structural power - which helped maintain their legitimacy.

> *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 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 seeming legitimacy undermining missteps.

A big perceived misstep was the creation of the IPTi Policy Platform, which was part of the Consortium, but also part of WHO-GMP [41]. One of its first actions was to support the independent TEG held in 2006, but when the reports of potential serious adverse events were made, the WHO staff who were part of the Policy Platform were caught between strongly convinced Consortium members and uncertainty about safety from researchers and programme managers within and outside the Consortium. It appears that a key assumption in the original concept of the Policy Platform turned out to be mistaken – that the IPTi Consortium-WHO cohesion would remain high, and that the Policy Platform would direct the policy development process rapidly towards a decision [41]. In reality, the Policy Platform was unable to negotiate the tensions over the distinctly different expectations of the various actors involved.

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 pushing platform; that this was a conflict of interest and detracted from the legitimacy of the process and the independent 'balancing act' that is a WHO policy recommendation.

> *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 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 viewed 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 rather that it was in everyone's interest to make the process smooth while still maintaining institutional integrity via independence and transparency.

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

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

4. Discussion

In the case of IPTi and SMC, the factors that appear to have edged the SMC evidence base over the evidence base for IPTi was that it was ultimately 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. The study findings also suggest that the breakdown in consensus and trust in the policy process, due to the perceived biases and conflicting agendas of the actors involved, might have led to the perception of a weak evidence base and policy for IPTi, in comparison to SMC. The contestation around the IPTi policy process appears to have contributed to negative perceptions of its policy value.

However, contestation, as a form of deliberation and consensus building, is not necessarily a "bad" thing, particularly when built into 'institutional arrangements' that ensure governing processes reflect deliberation [64]. Indeed, some scholars have seen the need for deliberation as

particularly important when public policy relies on delegation to expert advisory bodies, such as MPAC, that serve to provide scientific advice [65, 66]. Institutional approaches in the policy sciences recognise that institutions can be thought of not just in terms of formal structures, but also the rules that shape how decisions are made, as well as the established practices or norms in existence that further direct outcomes [67, 68]. In the case of IPTi and SMC, it appears that transparency of the evidence consideration and policy making steps was more critical, and potentially more important, than achieving consensus.

A number of scholars reflecting on the balance between scientific expert advice and democratic principles such as transparency draw on the work of Jürgen Habermas, a social theorist who is particularly known for his discussions on the importance of democracy and deliberation within the 'public space' [69]. The atypical 'technocratic model' of the relationship between science and policy, which can supress deliberation and debate in deference to expert rationality, reflects some of the core objections by critics of the EBP movement who are concerned with the depoliticisation of decision making [70]. In the case of IPTi, it seemed that in their attempt to depoliticize decision making, IPTi researchers inadvertently ended up politicising their evidence base, raising objections within the global malaria community. This tension between a desire to achieve the best possible social goals from a body of evidence, and respect for a democratic decision making process, cuts to the core of the question of what constitutes the 'good use of evidence' when a desire to avoid technical bias and maximise the potential of evidence to achieve social goals risks depoliticisation and a trend towards technocracy and rationality, in what many argue is inevitably, and perhaps even appropriately, an irrational process [18].

IPTi was introduced as an innovation that was enthusiastically pursued by a group of committed public health practitioners and researchers and internally framed along the lines of

a rational approach. The Consortium's idea of 'planning ahead' underlined the proposal to BMGF which included a clear schedule (green lines) and a Policy Platform to facilitate the policy making process of generating the evidence. The Consortium members believed that more evidence delivered in a timely way would persuade policymakers to recommend IPTi. However, over time, as IPTi was questioned, this internal expectation and framing of IPTi gave way to a breakdown in consensus and a different portrayal of a battle between those who set boundaries between science and advocacy, and those who believed scientists had a role in promoting the findings from their research.

In contrast, the SMC policy process was never viewed as a battle between the actors involved; 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 [48]. Efforts of these kinds – active communication via open access meeting reports, open consultation and participation in meetings, and transparency throughout the evidence-utilisation process, for example by making all MPAC meeting background documents available online [48] – may have contributed to WHO-GMP and MPAC's legitimacy during the SMC policy process.

5. Conclusion

In the case of the policy processes for IPTi and SMC, the findings show that 'good evidence' from a purely technical perspective, though important, 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 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 [1] 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 expert technical advisory bodies.

While the WHO has principally focussed on technical criteria for evidence inclusion in its guideline development processes, the study of the MPAC suggests that the design and functionality of evidence advisory bodies must also enable transparent, responsive, and credible processes of evidence review to ensure these bodies are effective in producing advice that engenders change in policy and practice.

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