Brokering the boundary between science and advocacy: the case of intermittent preventive treatment among infants

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The process of translating research into policy has gained considerable attention in recent years and a number of studies have investigated the nexus between the two 'worlds' of research and policy. One issue that has been little addressed is about the boundaries between research and advocacy: how far scientists do, or should, promote particular findings to policy makers and others. This article analyses a particular intervention in malaria control and the Consortium set up to accelerate its potential implementation. Using a framework that emphasizes the interplay of interests, institutions and ideas, it provides an example of how a network of committed researchers and funders attempted to follow a rational policy process, but faced conflicts and fundamental questions about their roles in generating scientific evidence and influencing global health policy. In an era of ever more and larger researcher groups and consortia, the findings offer insights and lessons to those engaged in the process of knowledge translation.

KEY MESSAGES

- There is an enduring tension within the policy process between perceptions of rigour, time urgency and the role of science vs advocacy.

- Research consortia, which include scientific investigators, policy makers and sponsors, need to recognize the potential development of tensions in the process of gathering evidence and advocating policy and therefore be prepared to manage what can be a complex process.

- Making review processes explicit and acknowledging the different pressures on actors' interests and institutions will help to broker disagreements about the boundaries between science and advocacy.

Introduction

The process of translating research or knowledge into policy has attracted great interest among researchers, funders and policy makers (Lavis 2006; Oxman *et al*. 2009). A number of models (from rational to enlightenment approaches) have been generated to describe how research can be translated into policy (Buse *et al*. 2012). Most observers agree that barriers to rational policy making abound (Walt 1994; Black 2001) and that few global health interventions are evidence based (Buekens *et al*. 2004). Even 'gold standard' evidence produced by randomized controlled trials is often undermined by factors such as bias or pressure (Davis and Howden-Chapman 1996;

Moher *et al*. 1999). Yet, many still aspire to following a rational process from evidence or knowledge production to policy formulation and implementation.

Although guidelines exist on competing interests (see e.g. The PLoS Medicine Editors 2008), and some studies have explored issues such as bias and selective reporting in research and publication of findings (e.g. Cook *et al*. 2007), fewer have looked at potential conflict of interests in research partnerships or networks (Stuckler *et al*. 2011) or raised questions about the boundaries between research and advocacy (Sufrin and Ross 2008). This is a neglected field. But in a current context where researchers increasingly work more closely with funders and policy makers, these become essential questions. As policy makers and funders invest substantial resources on research networks, play active roles within those networks and press for evidence to inform policy, the boundaries between science and advocacy may be challenged.

The case of IPTi: gathering the evidence

This article explores one case where contestation around the evidence on Intermittent Preventive Treatment among Infants (IPTi) led to a prolonged debate as to whether the intervention should be adopted as a policy. It serves as an example of how complex the demarcation between disseminating research results and advocating such results can be.

In 2001, the results of a randomized controlled trial in Tanzania using IPTi,[1] employing sulphadoxine–pyrimethamine (SP), delivered through the Expanded Programme on Immunisation showed that this could be a useful intervention. It reduced clinical malaria episodes by 59% and had other beneficial effects such as reduced anaemia and hospital admissions (Schellenberg *et al*. 2001). On the basis of this trial and others (Massaga *et al*. 2003), a group of researchers established the IPTi Consortium in 2003. Funded by the Bill and Melinda Gates Foundation, the Consortium set out to test the intervention in more settings. It was confident, based on the findings from the first trial, that further research would rapidly guide a global policy recommendation by the World Health Organization (WHO) on the appropriateness of IPTi for developing countries. A specific Policy Platform was established within WHO to facilitate the process of translating knowledge into action. However, by mid-2007, in spite of a wealth of evidence on IPTi (see Table 1 which provides a summary of the trials supported by the IPTi Consortium), the policy process appeared to be stalled as a WHO recommendation was not forthcoming. Between 2007 and 2009, when the WHO finally endorsed the adoption of IPTi, there was a flurry of activity to promote the intervention and to accelerate the process of reaching a global decision. Using the lens of interests, ideas and institutions, this article explores the process of moving from gathering and reviewing evidence to agreeing a global policy recommendation.

Analytical framework and methods

Rather than assume a rational approach to the research–policy process, the study started from the viewpoint that the process of funding, undertaking and communicating research is a messy and iterative process (Weiss 1979). This was a retrospective case study, and we analysed our data by drawing on concepts from Walt and Gilson (1994) on context, actors and process and from Shiffman and Smith (2007) on the role of ideas and how issues are framed. We brought these concepts together and organized our findings under a framework of interests, institutions and ideas (Howlett *et al*. 2009), highlighting the interests (of the different actors), institutions and ideas (research evidence). The concept of institutions is used in two ways. One, to denote organizations such as WHO, and two, as the sets of 'formal and informal rules, enforcement characteristics of rules and norms of behaviour that structure repeated human interaction' (North 1989, p. 1321) as well as the strategies adopted by such organizations (Ostrom in Sabatier 2007). The interplay of these factors has been usefully illustrated by others (e.g. Sumner *et al*. 2011). In talking about the actors, we refer to a malaria network and policy community. The latter is defined as the group of scientists, researchers, policy makers and funders specifically interested in IPTi, who made up the IPTi Consortium. The concept of network is used more broadly, to include malarialogists involved in other interventions, scientific journalists, malaria programme managers and other organizations involved in malaria.

We used qualitative methods of investigation, combining an analysis of global-level issues with insights from national-level processes. Observational data were gleaned from international meetings and conferences between December 2008 and January 2009, including the last annual meeting of the IPTi Consortium. Participation in these meetings offered the opportunity for informal interviews with 20 participants, including country malaria programme managers and researchers. A total of 62 documents and papers informed the final write up of this study: these focused on malaria, the research–policy nexus and IPTi. We conducted a search on PubMed of all studies published on IPTi (as well as other malaria interventions) to develop a timeline on the accumulation of evidence on IPTi and to contextualize key events in the policy process.

Specific guides for semi-structured interviews were constructed for both global- and country-level interviews. The sample of interviewees followed a purposive approach combined with a snowball technique. Global-level informants were formally interviewed between January and June 2009. In total, we interviewed 22 individuals at global level: 9 researchers, 7 policy makers, 4 researcher/policy makers and 2 funders.

Country interviews were largely generated through two embedded case studies, in Ghana and Tanzania between March and April 2009. The total number of interviews conducted in both countries was 22, which involved 29 individuals: 8 from research, 8 from Ministries of Health and 13 from donor agencies. More details are available from Oliveira-Cruz and Walt (2009).

Before discussing findings, we provide a narrative background, providing the context within which research and policy occurred.

Background

Context matters: global attention for malaria

Malaria is a highly complex disease, demanding wide-ranging research that includes molecular and genetic science, modelling

Table 1 IPTi Consortium trials

Study site/year published	Study period	Main funding sources	Transmission and EIR per year	No. of infants enrolled, placebo/IPTi drug	Study design	Age at drug dosing	Protective efficacy[a] [% (95% CI)]
Ifakara, Southern Tanzania (Schellenberg et al. 2001)	08/1999 to 04/2001	WHO Tropical Diseases Research	Perennial (29)	Placebo 351 SP = 350	Individually randomized control trial	2, 3, 9 months (at time of DP2, DPT3 and measles)	59.4% (41.7% to 71.7%)
Manhiça, Mozambique (Macete et al. 2006)	09/2002 to 02/2004	IPTi Consortium; Banco de Bilbao, and Vizcaya, Argentaria Foundation	Perennial with seasonal peaks (38)	Placebo = 755 SP = 748	Individually randomized control trial	3, 4, 9 months (at time of DPT2, DPT3 and measles)	20.8% (3.5% to 35.0%)
Navrongo, Ghana (Chandramohan et al. 2005)	09/2000 to 06/2004	UK government (DFID)	Highly seasonal (418)	Placebo = 1225 SP = 1221	Cluster randomized control trial	3, 4, 9, 12 (at time of DPT2, DPT3, and measles + extra at 15 months)	30.3% (17.8% to 40.9%)
Kumasi, Ghana (Kobbe et al. 2007)	01/2003 to 09/2005	German government	Perennial with seasonal peaks (400)	Placebo = 535 SP = 535	Individually randomized control trial	3, 9, 15 (at time of DPT3 and measles + extra at 15 months)	20.7% (8.7% to 31.2%)
Tamale, Ghana (Mockenhaupt et al. 2007)	03/2003 to 07/2005	German government and Charite (University Medicine Berlin)	Perennial with seasonal peaks (NA)	Placebo = 600 SP = 600	Individually randomized control trial	3, 9, 15 (at time of DPT3 and measles + extra at 15 months)	32.4% (19.6% to 43.2%)
Lambaréné, Gabon (Grobusch et al. 2007)	12/2002 to 08/2006	IPTi Consortium and German government	Perennial with seasonal peaks (50)	Placebo = 504 SP = 507	Individually randomized control trial	3, 9, 15 months (at time of DPT3 and measles+extra visit at 15 months)	22.6% (−24.2% to 51.7%)
Kisumu, Kenya (Odhiambo et al. 2010)	03/2004 to 03/2007	IPTi Consortium	Perennial (7)	Placebo = 337 SP-AS3 = 339 AQ3-AS3 = 347 CD3 = 342	Permuted block randomized control trial	2, 3, 9 months (at time of DP2, DPT3 and measles)	25.7% (6.3% to 41.1%)
Korogwe (K) and Same (S), Tanzania (Gosling et al. 2009)	2004–2008	IPTi Consortium	K: Perennial with seasonal peak S: low transmission	K/S Placebo = 320/284 SP = 319/283 CD3 = 317/285 MQ = 320/284	Individually randomized control trial	2, 3, 9 months (at time of DP2, DPT3 and measles)	−6.7% (−45.9% to 22.0%)[b]

Sources: adapted from Conteh *et al.* (2010); and site-specific publications and Aponte *et al.* (2009) for values reported on the protective efficacy (except for the last two trials on the table where we used the site-specific publication for the values for protective efficacy).

[a] Refers to the combined values for the protective efficacy offered by IPTi with SP against clinical malaria dose from 1 to 12 months of age.

[b] Efficacy was measured at 2–11 months of age.

EIR, entomological inoculation rate.

and applying specific interventions for prevention and treatment. In 2009, >3.3 billion people were at risk of malaria transmission (WHO 2010a,b). Most confirmed cases occur in Africa, and >80% are among children below 5 years of age (WHO 2008).

Global attention for malaria shifted from grand aspirations in the 1960s (when eradication was the goal) to neglect in the 1970s and 1980s, to a recovered vision in the 1990s (Bradley 1999). Resurgence in attention was accompanied by a huge rise in the funds available for both research and control. From approximate expenditure of US\$ 20 million in the 1980s, malaria funding grew in 1995 to US\$ 85 million, reaching US\$ 4 billion by 2009 (Global Fund 2009).

The increase in funding brought new and more investigators into the malaria field, providing opportunities for research, and led to greater discussion about the paucity of interventions against malaria. At the end of the 1990s, there were limited tools that were recommended by WHO and that countries could implement for malaria treatment and control. Chloroquine was still the most utilized drug for treatment of malaria in Africa, in spite of known, large-scale resistance (Shretta *et al*. 2000). But moves by African Ministries of Health towards using SP, which was widely available, inexpensive and more efficacious, were slow (Shretta *et al*. 2000; Williams *et al*. 2004). Tanzania, for example, only introduced SP in 2001. Thus, when the positive findings were reported in 2001 from the IPTi study in Ifakara, Tanzania, there were only a few interventions for malaria control (see Figure 1).

Moreover, the policies recommending the various interventions were supported by different levels of evidence. For example, WHO in 2000 recommended (WHO 2000) an intervention for the Intermittent Preventive Treatment of Pregnant Women (IPTp) on the basis of very limited evidence (Parise *et al*. 1998; Shulman *et al*. 1999) and within a short time frame between results and recommendations. This contrasted with a much slower policy process on the efficacy of insecticide-treated bed nets, for which there was ample evidence (Alonso *et al*. 1991; Lengeler 2004) but which took much longer to be recommended by WHO—only in 2003 (WHO 2003). In this case, the reason seemed to be a more cautious approach following the rapidity and limited evidence underlying the IPTp policy recommendation. By the mid-2000s, WHO had restructured its global malaria policy to recommend countries focus on case control using ACTs, long-lasting insecticide-treated bed nets, IRS and IPTp.

However, although these interventions were advocated by WHO, country uptake was slow and uneven. Cliff *et al*. (2010),

for example, show how disparate interests and ideas slowed the uptake of bed nets in Mozambique and Zimbabwe. Countries also lacked clear scientific guidance as to which intervention to choose in the absence of evidence on the effectiveness of treated bed nets vs indoor residual household spraying with insecticides (Woelk *et al*. 2009). Slow adoption is not particular to malaria interventions. As suggested by Shearer *et al*. (2010), the adoption of Hib vaccine in resource-poor countries was slow until certain factors were in place: financing, advocacy efforts, interpersonal contact with national decision makers and technical support.

The combination of the resurgence in effort and interest in malaria, plus the impetus towards research collaboration through partnerships, meant that malaria policy was being implemented in a highly dynamic environment, making the resulting scientific and policy discourses less predictable and fast changing.

Developing the evidence: the IPTi Consortium and review process

In the context of increasing interest on malaria and greater availability of funding for malaria, but few effective interventions, the results of the first IPTi study reported in 2001 (Schellenberg *et al*.) generated enthusiasm among the core group of scientists involved in the trial. This research group alongside others formed the IPTi Consortium in 2003 following new trials that were initiated in Gabon, Ghana and Mozambique in 2002 and 2003 to test the intervention.

The primary aim of the IPTi Consortium was to generate scientifically robust evidence that would inform policy and practice on IPTi in Africa (IPTi Consortium 2003). The Consortium was made up of a group of researchers and international policy makers. Members included a number of research groups; its funder, the Bill and Melinda Gates Foundation; staff in the Tropical Diseases Research programme at the WHO (who had funded and supported the Ifakara trial) and UNICEF, which saw potential benefits in adding IPTi to its Child Survival-Immunisation Plus strategy (IPTi Consortium 2003).

To facilitate the review of evidence gathered through the Consortium's research groups, a Policy Platform was established in WHO (2006). Its role was to prepare the evidence from the IPTi studies for a WHO technical review process, so that the Organization could reach a global recommendation on IPTi.
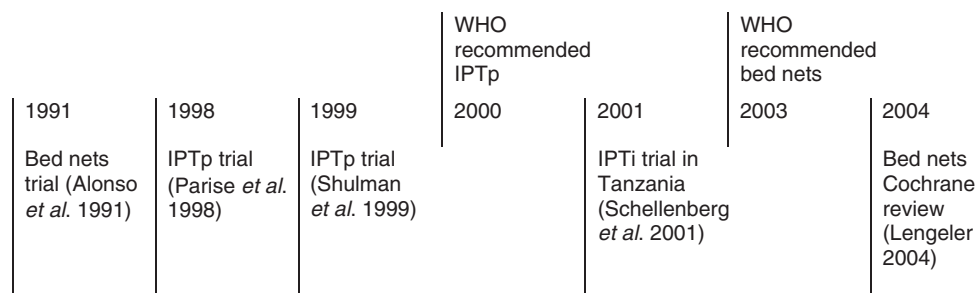
			WHO recommended IPTp		WHO recommended bed nets	
1991	1998	1999	2000	2001	2003	2004
Bed nets trial (Alonso *et al.* 1991)	IPTp trial (Parise *et al.* 1998)	IPTp trial (Shulman *et al.* 1999)		IPTi trial in Tanzania (Schellenberg *et al.* 2001)		Bed nets Cochrane review (Lengeler 2004)

Figure 1 Timeline of selected malaria control interventions: evidence and policy recommendations

Table 2 Dates and decisions of the WHO review process

2006	• In October, the first TEG meeting recommended IPTi
	• In December, the Technical Research Advisory Committee endorsed the first TEG recommendation
2007	• In May, the Scientific Technical Advisory Committee meeting was cancelled as WHO assessed new evidence on IPTi which reported severe skin reactions to SP in Ghana
	• In June, the Gates Foundation commissioned an independent review of IPTi by the IoM to review all evidence, including the latest data from Ghana
	• In October, the second TEG meeting did not recommend IPTi in view of a number of uncertainties
2008	• In June, the IoM review presented the results of its review, concluding that IPTi merited further investment
2009	• In April, the third TEG meeting recommended IPTi as a policy with some caveats and TRAC endorsed this recommendation
	• In October, the IPTi recommendation was reviewed and endorsed by the Strategic Advisory Group of Experts

This technical review process involved the assessment of evidence by a series of WHO committees at different levels (see Table 2).

The first Technical Expert Group (TEG) meeting in October 2006 assessed the results of 11 studies on the efficacy and safety of IPTi in infants and children (WHO TEG 2006). All were conducted in Africa in areas of different transmission patterns. The studies included six IPTi-SP trials, one IPTi trial with an alternative drug combination (amodiaquine and artesunate) and four other IPT trials (either for children with anaemia or for children in areas of seasonal malaria[2]). At the time of the 2006 review, three of the six trials on efficacy and safety were not yet published—two were complete and one was still on-going (WHO TEG 2006; IPTi Consortium 2009). The recommendation of the 2006 TEG was that:

> In settings where 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 TEG 2006, p. 11).

The two provisos for this recommendation were that: (1) implementation would take place alongside rigorous systems of monitoring and not at the expense of other malaria control interventions and (2) as additional data on IPTi emerged, there would be further assessments of the intervention.

This TEG recommendation went to the Technical Research Advisory Committee in December 2006 where it was endorsed. The next and final level of review, before going to the WHO Director General, was at the Scientific Technical Advisory Committee 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 Kumasi and Tamale IPTi-SP trials in Ghana in early 2007, which reported some rebound effects of anaemia and the occurrence of severe adverse reactions (potentially Stevens–Johnson syndrome). It was only in October 2007 that the second

TEG meeting took place. It reviewed the existing evidence, including data from the completed and published (or in press at the time) trials, and assessed additional data and analysis requested at the first TEG review in October 2006—which the IPTi Consortium had provided in April 2007.

Although this second TEG recognized IPTi using SP as a '. . . promising intervention . . .' it recommended another review be held in 2008 when new data became available (WHO TEG 2007, p. 7):

> 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 TEG 2007, p. 7).

Many in the Consortium felt the review process had stalled after the TEG in 2007 and questioned the generalizability of the findings that had led to its cautious conclusion. In an attempt to drive forward the process, the Gates Foundation 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:

> [There is] substantial evidence indicating that IPTi-SP significantly diminished the incidence of clinical malaria in infants living in areas of high and moderate intensity transmission . . . a wealth of data supports the . . . safety of SP dosages currently recommended for these age groups . . . . [and] . . . that an intervention with results of this magnitude is worthy of further investment (Institute of Medicine 2008, pp. 2 and 61).

The last meeting of the 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 new and emerging evidence from the UNICEF multi-country study and others. As a new director of Global Malaria Programme (GMP) was expected imminently, the acting director agreed to convene a third TEG meeting. This meeting reviewed evidence presented to the two previous WHO reviews as well as additional data on: severe skin reactions to SP, the study in Southern Tanzania and the multi-country pilot implementation studies led by UNICEF and finally, two trials (in Kilimanjaro and Kisumu) that used other additional anti-malarial drugs (WHO TEG 2009).

The recommendation of the third TEG was that 'SP-IPTi delivered through EPI be considered for implementation as an additional malaria control intervention . . . in areas with moderate to high transmission' (WHO TEG 2009, p. 5). In April 2009, the fourth TEG endorsed a global policy recommendation on IPTi by WHO to member states seeking to control malaria (WHO 2010a,b). WHO guidelines on the adoption of IPTi were completed and disseminated to countries in 2011 (WHO and UNICEF 2011).

Why did a research process start as consensual, but end up as one of high tension between members of the Consortium? What split the tightly knit policy community of different actors who had coalesced around agreed research questions and a belief that the knowledge generated through research would result in a rapid global policy recommendation? The findings that emerged from the analysis of events around the process of moving from research to a policy recommendation are best understood as an interplay between ideas, interests and institutions. In the discussion below, institutions and interests are presented together because they are closely inter-linked. Actors' interests (or agency) are often closely aligned with the institutions (or structures) they belong to and abide by (Buse *et al*. 2012). Interests thus represent different levels of power, whether of resources (financial or knowledge), status or position, or ability to mobilize others.

Findings

Institutions and interests

Working within institutional norms and rules are the actors who have particular interests and who create knowledge, promote and advocate change. The WHO review process to reach a global decision on IPTi reflected the tensions between different interests and institutional norms. WHO's rules, norms and strategies include ways of achieving consensus among experts (technical and programmatic) to reach global recommendations on a variety of health matters, and then providing global guidelines to assist countries in their implementation. Although the evidence-gathering process within WHO has been criticized (Oxman *et al*. 2007), views differ on the extent to which assessment of evidence has improved and the exigency with which it is followed by different departments (Lancet 2007). Few, however, would disagree that the process is strongly underpinned by public health and ethical values ('do no harm') and by the need to include low-income country perspectives and realities. In this regard, respondents from the case study countries and other representatives from sub-Saharan countries confirmed that WHO's technical advice was highly regarded in their countries. And given the divergence of opinion on findings expressed at the various technical review meetings (Table 2), a number of interviewees from developing countries were sympathetic to WHO's caution in making a recommendation. Others have recognized that disagreements over appropriate malaria strategies at national level are not uncommon (Woelk *et al*. 2009).

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. The Policy Platform was an innovative idea, perceived to be a mechanism for research translation and policy adoption. However, the Consortium was made up of actors from different organizations, with different institutional norms, even if the members were united in their aim to test a specific intervention that would reduce morbidity and mortality from malaria, especially among children. The primary objectives of their organizations ranged from a focus on science to a concern with

delivering programmes and agreeing global malaria policy. These organizations also had different levels of power and influence, as judged by the resources they could draw on and their scientific status, among other things.

One of the Consortium's most influential members was the Gates Foundation, credited with inaugurating a new era of scientific commitment to global health problems through its energetic advocacy (Lancet 2009) and research (Black *et al*. 2009). Its support for the IPTi Consortium formed part of this investment. As a 'hands-on' funder, the Foundation's participation in key meetings of the Consortium was largely seen as positive and helpful, particularly in the instance of the 'lost year' of 2008 when frustrations among Consortium members had reached a peak because they perceived the WHO review process to have stalled. In their view, the review process lacked transparency (review body members were not always perceived to be appropriate) and was too influenced by the director at the time—who was also believed to have reservations about IPTi-SP as a prevention tool. This period, thus, exposed tensions as to whose mandate it was to translate evidence into practice. WHO felt pressurized by the Foundation to move faster than it deemed reasonable. The Foundation responded to other Consortium members' perceptions of a stagnant process, by, for example, commissioning the IoM review. This was then criticized by some as challenging WHO's TEG review system without taking into sufficient consideration the responsibilities the Organization had towards its country members when providing a global policy recommendation.

Certainly, a number of respondents observed that there was a potential basic tension between the Foundation's close involvement in the research and policy processes and speculated about the extent to which this might influence scientific proceedings. For example, some researchers noted a potential conflict of interest where their institutions were being funded by Gates Foundation grants for research other than their own, or where they were involved in other projects supported with resources from the Foundation. Others feared that discussion, especially where there was contention, might not be openly expressed or that less experienced or senior researchers would be intimidated by questioning procedures or entering into debates.

WHO, on the other hand, has long struggled to maintain its global role and reputation (Frenk 2008). It has had to compete with many other organizations for resources. The re-design of the malaria programme in 2005 with the appointment of a new director was observed to have led to an infusion of strategic focus to GMP by separating it from the Roll Back Malaria programme and rejuvenating and streamlining internal WHO processes, including the system for reviewing evidence before approving policy decisions. This could be said to have been an attempt to regain lost ground as more actors (the Global Fund, the Gates Foundation, the Roll Back Malaria initiative) entered the malaria field. As for the Policy Platform, from its foundation, it was in an ambiguous relationship within the organization. It was the brainchild of the Consortium, but part of the GMP. One of its first actions was to support the independent TEG held in 2006. But when the reports of potential adverse responses were made, the Policy Platform was caught between strongly committed and convinced Consortium members and uncertainty about safety emanating from

researchers and programme managers within and outside the Consortium. Thus, a key assumption embedded in the original concept of the Policy Platform did not materialize: that policy community cohesion would remain high and the Policy Platform would direct the policy process rapidly towards a decision. In the event, the Policy Platform was unable to negotiate the tensions over the distinct expectations and institutional strategies of the various actors involved in the policy community.

Ideas

The ways ideas are framed and understood both within policy communities and networks or by the wider public can make a difference to the political support they engender and their translation into policy and practice. In the light of the positive results from Ifakara, the policy community presented IPTi enthusiastically and consensually as a promising intervention to address malaria among infants. The Consortium framed its activities as part of a rational process to translate research into policy by setting up the Policy Platform in parallel to evidence-gathering and in order to accelerate the policy process.

There were thus high expectations among Consortium members 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). Although none of the trials subsequent to the Ifakara study achieved the same high level of efficacy (Aponte *et al.* 2009), the 2006 TEG nevertheless recommended IPTi be introduced where appropriate. Had this recommendation been endorsed, the internal framing of a rational policy process would have been vindicated. However in 2007, it was overturned, reflecting unanticipated tensions created by contestation over evidence and differences within the policy community.

In addition, many in the Consortium perceived that the stalling of what was expected to be a rational review process between 2007 and 2009 introduced a tension between scientific independence and advocacy. On the one hand, some inter-viewees suggested that such was the optimism after the Ifakara results that advocating for IPTi almost took precedence over generating the evidence. The confidence in the initial results and the investment in the Consortium were suggested to have led to pressure to show results and get the policy endorsed. The majority of respondents pointed out that the first results were exciting at a time of very limited alternatives. Nevertheless, one respondent wondered whether this enthusiasm may have led to the perception of 'a party line' supporting IPTi which could not be breached. And another observed that 'once you champion something you cease to see other people's points of view', implying that advocates became reluctant to take seriously any shortcomings in IPTi.

Some 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.

> As a physician I was trained to 'do no harm'. But doing nothing can do harm...I always saw the end of the process as being not just the production of evidence but with the policy process.

> It is unrealistic to think scientists are dispassionate. It is unavoidable to have a relationship with policy and...not to advocate an intervention that proved to be effective. But obviously it is necessary to have independent systems of review.

Others within the Consortium felt, however, that scientists had to stay neutral and focus on the research.

> Scientists have a role in assisting, not leading the policy process.
> I think it is very dangerous when the scientists start getting too involved in pushing their own interventions...ethically scientists have a responsibility within countries to present results in a dissemination meeting, submit a formal report to the ministry of health, and publish to the academic audience. The process after that is for policy makers to take forward. In settings with weak capacity scientists can help a step further, but scientists should not become advocates. It should not be the Consortium's role, but of a different group of people, to get the evidence translated into a policy.

Yet 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.

> I found myself in the difficult position where I thought...it's on my own conscience whether or not I can just generate information.... [or] do I have some sort of moral obligation to push for the policy decision....

In short, some noted that the tension between producing the evidence (which should be an independent process) and advocating for it was a major conflict of interest. The role of the Gates Foundation was particularly noted in this regard. Some felt that the Foundation's behaviour in using its influence to accelerate the policy process was questionable, given its role as both funder (wanting to see positive outcomes and returns on investment—in this case a WHO recommendation) and member of the Consortium (co-ordinating and assessing the results from the various studies). Others were more pragmatic, seeing this as a struggle between institutional norms: between a globally led organization desirous of moving fast towards policy and a more deliberative bureaucracy taking heed of its country members. Such tensions are common to other issues as well. A study of the tobacco control policy community noted that although some members considered themselves as pure advocates and others as pure scientists, the majority assumed multiple roles along this spectrum and accepted the role of advocacy in translating evidence into policy (Mamudu *et al.* 2011). However, in contrast to the IPTi experience, consensus among members had developed over a very long time period, and the policy community had to exercise vigilance in the face of industry attempts to question scientific evidence.

Conclusions

The IPTi story illustrates enduring tensions within the policy process, between perceptions of time urgency and rigorous

review and between the role of science and advocacy. Relating the narrative to the framework of institutions, interests and ideas, it demonstrates how 'contextual factors' aligned favourably to shape the process of moving from evidence to policy. The raised global attention and resources for malaria boosted the potential for IPTi as a malaria strategy. This dynamic environment affected a network of 'interests' and enabled the core policy community of researchers to seize the opportunity provided by a successful study in Tanzania to establish the Consortium to further evaluate the intervention. We traced how policy community cohesion was affected by dissension over evidence and the technical review process and how institutional norms, values, and power affected the actions of interests and organizations within the policy process. Finally, we recognized two sets of 'ideas' held by members of the IPTi Consortium that affected the process of moving from research to policy: one was expecting the process to be rational—a planned, linear route from research to a WHO policy decision, and the other was assuming an advocacy role for the Consortium which was not endorsed by all of its members.

This article suggests that in an era where it has become commonplace for diverse groups (researchers, funders, policy makers) to collaborate in large research projects, a number of factors need to be taken into account. Although goals may be shared—providing the rationale on which the collaboration is based—each group or organization will have their own particular values and institutional norms. Consensus on common goals does not obviate groups or organizations having different levels of power and exercising that power at different stages of the process, whether in collecting, recording and interpreting data (where dissension may arise) or in overriding objections to the early promotion of results or in promoting particular findings over others. Individuals may be bound by organizational rules and values which are at variance with aspects of the research goals or may feel tensions between scientific claims and promotion of those claims. There may also be tensions between national vs global level members of a network relating to different local realities.

In other words, the policy process from research to evidence to policy is not rational. Weathering some of the exigencies mentioned above is part of managing the process of knowledge translation. The key is in the management of the process, which will differ from context to context, case to case and over time. First, seeking to understand and taking account of the norms and values of different members of a group or partnership and making them explicit may improve brokerage between reaching consensus among groups with different perceived responsibilities and goals. This is not something that is often explicitly encouraged, yet it could provide useful pointers to those who wish to turn policy into practice. Buse (2008) makes the case for the need for more systematic prospective policy analysis.

Second, making review processes as explicit and transparent as possible should be a governance aim of all organizations: this includes open acknowledgement of any potential conflicts of interest, rigorous consultation processes about who sits on various bodies in selecting research proposals as well as in reviewing evidence. Confidence that such processes are as fair and equitable as possible will allow, and not stifle, scientific debate and dissension. And confidence in processes will help to explore and broker any arguments about transgressing the boundaries between research and advocacy.

Finally, understanding the context and the competencies of the health system are also key to managing expectations. The results from an evaluation of implementing IPTi in five districts in Southern Tanzania showed no effects on child survival attributable to the intervention (Schellenberg *et al*. 2011). Translating evidence into practice depends on systems and situations that are different from trial conditions. As Schellenberg *et al*. say (2011), there are 'real-life' challenges in health systems (e.g. low coverage, late administration) that can act as significant constrain to the replication of trial results. Acknowledging the demands of the research and review process and understanding expectations and contextual elements are helpful in managing the delicate boundaries between research and advocacy and those between science and policy as well as practice.

Acknowledgement

Endnotes

[1.] IPTi is defined as '…the administration of a full course of an effective anti-malarial treatment at specified time points to infants at risk of malaria, regardless of whether or not they are parasitaemic, with the objective of reducing the infant malaria burden" (WHO TEG, 2006:1).

[2.] Not always with SP.

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