

# The development of health policy in Malawi: The influence of context, evidence and links in the creation of a national policy for cotrimoxazole prophylaxis

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## Abstract

Within the health policy field, a growing literature is attempting to understand the diverse responses of policy makers to research, and to explain why certain research findings make their way into policy while others are effectively ignored. In this paper we apply a policy analysis framework to the development of cotrimoxazole prophylaxis national policy in Malawi. Arguing that Malawi was one of the early adopters of cotrimoxazole prophylaxis at a national level, we show how the research to policy process was influenced by national healthcare context, the networks of individuals involved, and the nature of the public health evidence itself.

## Introduction

Cotrimoxazole (CTX) is an antimicrobial drug that has been used as a prophylaxis against HIV related infection in Europe and North America since the early 1990s<sup>1</sup>. In 1999, two randomised controlled trials, demonstrated that cotrimoxazole prophylaxis (CPT) reduced morbidity for adults with HIV, and reduced morbidity and mortality for HIV positive adults co-infected with tuberculosis (TB) in Cote d'Ivoire<sup>2-3</sup>. In 2000, the World Health Organization (WHO) and United Nations AIDS Programme (UNAIDS) responded by releasing provisional recommendations that CPT be scaled up across Africa for HIV positive adults and children<sup>2-4</sup>. In 2004, the results of a trial on the efficacy of CPT for HIV positive children in Zambia demonstrated that CPT significantly reduced morbidity and mortality among children of all ages, at different stages of disease progression, and the effect was sustained beyond 12 months of use<sup>5</sup>. This resulted in a set of international paediatric recommendations that CPT be given to HIV infected and exposed children in Africa<sup>6</sup>. Finally, and at least in part in reaction to the recognition that scale-up of CPT was extremely slow across the continent, the WHO issued detailed guidelines on the use of CPT in resource poor settings in 2006 for both adults and children<sup>1</sup>.

Despite these international recommendations, concerns have been raised that routine use of CPT has only partially been translated into practice<sup>7-9</sup>. Since 2007, three papers have been published which question why it has taken so long for CPT to be implemented in resource-limited settings, and questions remain as to why policy making around CPT in these settings has varied, in terms of time taken to reach a decision on its implementation, and the content of the national policies<sup>7-9</sup>.

To understand this variation in timing and policy content, we conducted a three country study comparing national policy processes for CPT (across Malawi, Uganda and Zambia) focusing on the ways in which national context impacts on health policy making. This paper examines the findings of the Malawi study, and focuses on the creation of two sets of national policy on CPT in Malawi: the use of CPT for HIV positive TB patients in 2002, and the second, more

general policy on the use of CPT for HIV positive adults and children in 2005. The paper explores the ways in which the Malawian national policy development process for CPT was shaped by the healthcare context, the links between researchers and policy makers, and the evidence available.

It presents the model that we used and the methods employed before turning to consider our empirical evidence in two sections. The first section relates to the 2002 policy which was formed by the National Tuberculosis Control Programme (NTP) of the Ministry of Health and Population (MOHP), and the second relating to the 2005 policy which was formed by the HIV Unit of MOHP. The data demonstrate the importance of having a favourable policy context, but show how concerns about the power of the evidence available can be mitigated by the links and actions of a policy entrepreneur – a key actor who supports a policy change and who is strategically connected to research and policy making networks. Conversely, the data shows that when the evidence base is exceptionally strong, there is less of a need for such an entrepreneurial role by policy actors.

## Methods

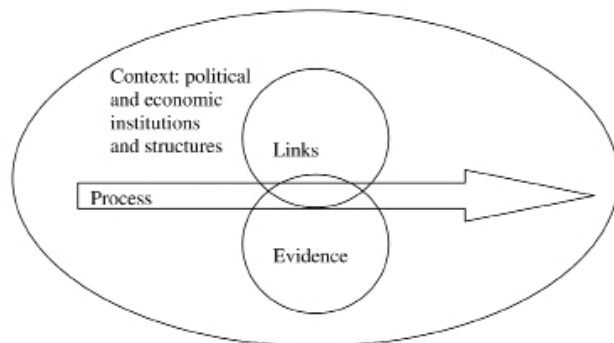
The field of policy analysis has shown that the ideal model of policy making in which research evidence is expected to follow a direct path into policy formation rarely exists in reality.

Recognising this, a number of frameworks and theories have been put forward to enable an analysis of what drives and shapes national and international policy process, looking in particular at the influence of political, economic and social context<sup>10-12</sup>. The majority of these frameworks have focused on policy making in high income countries, but over the last ten years a number of analysts have sought to understand the particular issues pertaining to policy making in resource poor settings<sup>13-14</sup>.

Walt and Gilson argue that the analysis of health policy in developing countries has been dominated by a consideration of the technical content of the policy, with little emphasis on understanding the central influence that policy actors, context and process have on policy formation<sup>14</sup>. In their model they posit that policy actors negotiate context, content and process in order to realise policy change, and that these factors should be mapped to enable a detailed understanding of health policy development<sup>14</sup>. Crewe and Young present a framework to understand the uptake of research into policy, which sees policy formation as a function of the interaction between: context (including local politics as well as the formal policy making institutions in a country), evidence (seen to reflect the credibility of evidence and communication of it) and links (seen to encompass the influence and legitimacy of key actors presenting research findings)<sup>13</sup>. Developing this framework further, Court and Young stress the importance of considering influences which are apparently beyond the national context when focusing on the case of developing countries<sup>15</sup>. In particular they point to the impact that international political agreements and policy; donor development policies; and donor research

and funding have on policy creation and implementation<sup>15</sup>. Both Crewe and Young and Court and Young conceptualise context, evidence and links as having overlapping elements.

For the purposes of our research we combined the analysis of context, evidence and links with Walt and Gilson's focus on the policy process as a dynamic concept. Importantly we also considered the relationships between the elements of the framework. Context, for instance, is conceptualised as having overarching impact on all other aspects. Within the context, policy actors interact with evidence (producing and/or interpreting it; accepting or rejecting it), while the links between policy actors shape the way in which evidence is made available and responded to. Diagrammatically our framework is represented in Figure 1:



This exploration of the research to policy process for CPT in Malawi was conducted as a case study. Published and unpublished documents relating to efficacy, evidence and national policies were reviewed. This was supplemented with in-depth interviews carried out with fifteen local policy makers. Initial key informants were selected from previously identified influential policy bodies, and snowball sampling methods were used to identify further actors who were involved in, and linked to the policy process around CPT. Interviews were conducted via telephone, recorded and then transcribed by the lead researcher (EH), with data analysis facilitated through the use of the Nvivo qualitative analysis software package. Ethical clearance was obtained from the London School of Hygiene and Tropical Medicine, and the Malawi National Health Sciences Research Committee.

## Results

### Evidence for the policy development process

Much of the Malawian research conducted on the efficacy and feasibility of introducing CPT addressed CPT as a potential intervention for HIV positive tuberculosis patients and was conducted in collaboration with the National Tuberculosis Programme (NTP). In 1999, when the results of the research from Cote d'Ivoire were published, concerns about their generalisability across Africa were raised by senior Malawian researchers in a letter to the *Lancet*<sup>2-3 16-17</sup>. At this stage, a Malawian randomised controlled trial conducted by the College of Medicine (COM) examining the benefits of CPT for HIV infected TB patients was in its infancy. The letter warned of high rates of bacterial resistance to CTX in Malawi in comparison to Abidjan, and the potential that widespread use of CTX as a prophylaxis might increase resistance to Malawi's first line malaria treatment<sup>16</sup>.

Despite these concerns, funding by UNAIDS for the Malawian trial was halted, and in 2000, the publication of WHO recommendations (based on the Abidjan data)

resulted in the Malawi government considering that placebo controlled trials on the efficacy of CPT were no longer ethical<sup>17-18</sup>. The government maintained, however, that the evidence base for the WHO's recommendations from 2000 was not powerful enough to warrant the implementation of CPT within the country<sup>18</sup>.

Although the initial Malawian trial had been halted, research into the efficacy of CPT for HIV positive TB patients continued. The COM adapted their trial to analyse efficacy of two different doses of CTX in HIV positive patients with TB and then compared these with historical controls<sup>17</sup>. Two further projects examining efficacy and feasibility were conducted in collaboration with the NTP, one in Karonga in the north of the country, and one in Thyolo in the south<sup>18-19</sup>. The results of these studies were released in 2002 demonstrating that CPT reduced mortality among HIV positive TB patients, and supporting the implementation of CPT for HIV positive TB patients. During the same year the ProTEST initiative<sup>1</sup>, which had piloted the provision CPT for HIV positive TB patients within Lilongwe District, reported their findings that it was feasible to provide CPT for this group of patients<sup>20</sup>. That year, government approved a national policy of providing adjunctive CPT for HIV positive TB patients during and following their TB treatment<sup>21</sup>. The Malawi 2002 policy specifically recommended that:

- TB patients who test seropositive for HIV will be offered cotrimoxazole for the duration of anti-TB treatment (i.e. 8 months).
- Patients should continue to take cotrimoxazole once they have completed the TB treatment, but the procurement, distribution, supervision and monitoring of CTX treatment post TB treatment would not be the responsibility of the NTP.

Following the publication of the policy, two further, smaller pieces of research demonstrated that the provision of CPT for HIV positive TB patients could be scaled up and was associated with good treatment outcomes in Malawi<sup>22-23</sup>. In addition, a further study examining the incidence of CTX preventable infections in HIV positive adults in Blantyre found high levels of malaria and invasive bacterial infections<sup>24</sup>.

Between 2004 and 2005 studies from Zambia, South Africa and Uganda provided evidence that:

CPT reduced morbidity and mortality (among HIV positive children) in areas of high bacterial resistance to CTX (Zambia); CPT may help to reduce mortality in individuals with TB in an area of high HIV prevalence (South Africa); and that daily CPT was associated with reduced morbidity and mortality and had beneficial effects on CD4-cell count and viral load (Uganda)<sup>5,25-26</sup>. This prompted the HIV Unit at the Ministry of Health to adopt a broader national CPT policy<sup>27</sup> (MKI 2:27/01/09).

The 2005 Malawi national policy was then written, specifically recommending the following:

- CPT should be offered to HIV-positive adults (aged 15 years and above) in stages II, III or IV of HIV disease; all people with a CD4 count of 500/mm<sup>3</sup> or less (regardless of symptoms); pregnant women after the first trimester who fall into one or both of the previous two categories. CPT prophylaxis should be taken for life, even if the patient is taking ARVs.

• CTX should be offered to children aged 6 weeks or above, born to an HIV-positive woman (irrespective of whether the woman received antiretroviral therapy in pregnancy) until HIV can be confidently excluded; any child of 6 weeks or more who is HIV-positive

regardless of symptoms. CPT prophylaxis should be taken for life, even if the patient is taking ARVs<sup>27</sup>.

### ***The 2002 Policy Processes***

While the above provides the description of the policy content, as well as the development of the body of evidence and the overall timeline, it does not explain why or how particular processes were followed, or why Malawi was so swift in its development of the 2002 policy. In order to explain the use and uptake of research evidence in Malawi, the following section of this paper examines the influence of national context, the nature of the evidence, and the links between key actors.

### ***Context***

Interviews conducted identified three elements of the existing political context as particularly important in influencing how the 2002 policy process unfolded: the history of HIV and AIDS programming in Malawi, the established role of the National TB Control Programme, and the existing issues facing the national Malaria Control Programme. In terms of national HIV and AIDS programming, the national response to HIV and AIDS was initially (from 1988) coordinated by the National AIDS Control Programme (NACP), established at the Ministry of Health and Population (MOHP)<sup>28</sup>. From its initiation through the 1990s, attention was primarily paid to prevention rather than treating those who were already infected.

According to one interviewee:

*“The HIV programme did not have any say on cotrimoxazole, and they didn't have any strong views. I do remember that at that time the HIV programme was emphasising HIV prevention.... but without offering them any medication ..... they had other priorities and so this is what we saw from the HIV programme, it was more about the preventive aspect, use of condoms and safe blood. (MKI 12/11/ 2009)*

In 2001, the National AIDS Control Programme was transformed into the National AIDS Commission (NAC) and later moved from MOHP to the Office of the President and Cabinet.

While an HIV Unit at the MOHP was in existence, staffing was reduced to one official (until 2003/2004 see below). Many of the HIV AIDS programming activities were therefore undertaken by the NAC, institution which had a multi-sectoral national role rather than a medical focus (MKI 10:20,02,09)

In contrast to HIV and AIDS Programming in Malawi, the NTP had long term key characteristics that made it a highly favourable environment for CTX research, policy making and implementation. The NTP had a much longer history (running since 1964) and was a well funded (receiving support from several donor agencies), and well established programme with a treatment orientation for TB patients, of whom it was estimated in 2001, 70% were co-infected

with HIV (MKI1, MKI6)<sup>2,30</sup>. The high mortality rates among HIV positive TB patients were of great concern to those within the NTP. Furthermore, the pilot ProTEST project was being run in collaboration with the NTP, and it had a particular interest in establishing joint TB/HIV integrated services. Finally, part of the NTP's budget was set aside for operational research, which was highly valued by those working within the programme in providing evidence to influence national policy and address programmatic issues. As will be shown, this proved particularly important for CPT research and policy development<sup>3</sup>.

The final key political contextual element identified as important was the concerns of the existing national Malaria Control Programme. The Malaria programme was particularly concerned about the chemical interaction between CTX and Sulfadoxine/Pyrimethamine (SP).

They considered that widespread use of CTX would generate resistance to SP, which was the first line drug for Malaria treatment at the time.

### ***Evidence***

The above contextual factors set the stage in which CPT evidence was developed and understood. The second element of our conceptual framework was to look at the nature of the evidence itself, and how it is understood, to explain its use in policy formulation. As mentioned, the weight of the evidence behind the WHO/UNAIDS provisional recommendations on CPT of 2000 was enough to lead to the halting of the randomised controlled trial which was underway in Blantyre, yet the Government of Malawi did not see the evidence as definitive enough for areas with high bacterial resistance to CTX and different disease burdens to Cote d'Ivoire<sup>17,22</sup>. The publication of international recommendations based on evidence from Cote d'Ivoire alone was considered by some medical researchers to have had hindered national policy development. As one interviewee explained:

You should go back to 2000, the letter written [by Malawian researchers] to the Lancet.

It said that this was completely, the wrong decision of UNAIDS, because there were studies going on in Malawi, Cape Town, and Senegal. All three of those studies stopped.... I think that UNAIDS held up the implementation of CPT in Africa ... we said that we cannot use the Cote d'Ivoire evidence, we don't have toxoplasmosis, or we didn't think that we had toxoplasmosis; and the resistance rates are different.. (MKI 2).

Other research, however, was soon to be conducted which was seen to have much more immediate national relevance. Three new studies began in Malawi specifically looking at CPT for HIV positive TB patients starting between 1999 and 2000. One was the re-designed trial comparing the efficacy of two different doses of CPT to historical controls, while the other two were operational cohort studies conducted simultaneously and in collaboration with the NTP.

The operational nature of this work meant that the potential for the research results to have local policy relevance was established before the research began. In addition, under the ProTEST pilot project, the feasibility of implementing CPT for HIV positive TB patients was examined.

However, the fact that the research was produced locally and was of policy relevance did not mean that it was accepted by all of the local actors. During the policy meeting which led to the 2002 policy, three concerns were raised about the evidence base: the strength of the operational research

given the use of historical controls; the lack of evidence on whether widespread use of CTX would increase resistance to SP, and the lack of evidence as to whether CTX would be needed if anti-retroviral therapy became available<sup>21,4</sup>.

### **Links**

The final element of the framework used to explain policy change is to understand the key roles played by networks of actors (or groups of actors) and the links between them. Two key, sometimes overlapping, networks were identified: researchers (involved in the local CPT research from the College of Medicine in Blantyre), and policy makers (from the MOHP's HIV Unit, NTP and Malaria control programme). Within the national context, and when there is uncertainty about international and national evidence, key actors are often needed to mobilise opinion or push policy change forward. Interviews identified one key individual a 'policy entrepreneur' (identified by 11 of the 15 interviewees) whose actions were critical to taking the policy forward. In addition a group of 'policy champions' (actors particularly motivated about an issue with power or authority to lend to it) who surrounded him were also identified. This individual and the supporting network were able to use their links and influence to overcome lingering concerns about the evidence of CPT, and to identify the policy channels needed to finally establish the 2002 component of the national policy. The strategic position of the policy entrepreneur arose from his background as a medical researcher as well as a programme officer. One informant explained that the policy entrepreneur involved senior MOHP personnel in the discussions about CPT very early in the process, explaining: (MKI 12). .... the TB programme had prioritised its own research, it made sure that there was a coownership process among the stakeholders ..... I personally think that this is a key step when we run operational research to facilitate policy transfer. It was very different when someone from an academic institution goes to the MOH and says here is a study here are the results and would you like to implement it (MKI 12).

Entrepreneurs cannot bring about change on their own, however. They link important networks and groups, or identify key contextual features providing opportunities for change, but policy change is ultimately still driven by interests and groups with power. In this case, while the policy entrepreneur was certainly central to driving the policy process forward, he was also surrounded by several supportive policy champions, including senior researchers involved in local CPT studies and senior members of staff at the NTP – a group with the power and legitimacy to provide support for policy change. The importance of this group and their links finally culminated in the 2002 meeting that led to the first national CPT policy. As discussed above, there were concerns about the strength of the evidence base. Yet the local researchers (the policy champions), were passionate about their results, defending their research model when its validity was questioned.

### **The 2005 policy process**

The above text details the elements of the conceptual framework which were seen to explain the uptake of research into policy in 2002. However, by 2005, a second, broader national CPT policy had been developed. Our analysis found that the same conceptual elements were important to explaining this second policy development process, yet the details of each element had changed. The

field of policy analysis recognises that policy development is a dynamic and social process. Over time, shifts within the national and international healthcare context and in the body of international evidence available, reshaped the policy environment.

### **Context**

Between 2003 and 2004, there was an increasing attention paid to biomedical interventions for HIV treatment. The HIV Unit in the Ministry of Health was established with four (senior) members of staff recruited (MKI10:20,02,09), and a national plan for anti-retroviral therapy in the public sector was developed in 2004 (with financial support from The Global Fund to Fight AIDS, Tuberculosis and Malaria)<sup>32</sup>. In addition, the national Malaria Control Programme agreed to phase out SP use for first-line treatment for uncomplicated Malaria. While it remained in use for intermittent presumptive therapy in pregnancy and people living in remote areas where it is difficult to access ACT, this shift in Malaria policy meant that concerns about cross resistance were not longer so profound.

### **Evidence**

By 2005 there had been an increase in evidence on the efficacy of CPT for HIV related opportunistic infection. Of very high significance were the results of a paediatric randomised control trial in Zambia, which demonstrated that CPT reduced mortality by 43% and hospitalisation by 23% in HIV positive children in an area with high bacterial in-vitro resistance to CTX<sup>5</sup>. Research from South Africa, with similarly high rates of bacterial resistance to CTX, concurred with the Malawian results showing a reduction in mortality among TB patients taking CPT in an area with high HIV prevalence<sup>25</sup>. In Uganda, research results showed that CPT was associated with reduced morbidity and mortality, had a beneficial effect on CD4 cell count and viral load among HIV positive adults, again in an area of high bacterial resistance to CTX<sup>26</sup>. Further, a study on the incidence of CTX preventable infections in HIV positive adults in Malawi demonstrated that these patients had high levels of malaria and invasive bacterial infections<sup>24</sup>. Given the weight of the new evidence base, the discussions surrounding the evidence for a new broader CPT policy in 2005 were reported by interviewees to have been much less contentious than those in 2002.

### **Links**

In 2004, as the HIV Unit at the MOHP was developed, four new members of staff were recruited to begin the scale up of the treatment and care programme. The policy entrepreneur from the TB programme, who had been highly influential for the 2002 policy, was recruited into the HIV Unit, and began to organise meetings to prepare for a more general CPT policy. His role in the policy development process in 2005 was, however, quite different. Whereas before he had been central in gathering support for CPT, ensuring local ownership and bridging the policy and research networks, in 2005 he was central in driving forward meetings, and following MOHP endorsement, and making sure that the policy was written. None of the informants identified the former policy champions as needing to play an advocacy role in the development of the 2005 policy process.

### **Discussion**

The insights to be gained from critical analysis of policy making processes have been highlighted many times by policy analysts working in low-income settings<sup>13,15,33</sup>. Malawi offers an interesting, and perhaps rare, case of policy making processes on a single intervention that occurred at two points in time, and through two policy making bodies (the NTP or the national HIV Unit). Utilising a conceptual framework that highlights the importance of context, evidence and networks have illustrated how changes in the nature of some of these elements can affect the roles of key actors, and lead to different policy making processes. In terms of the 2002 policy, the context of the NTP showed that it was well funded, with a focus on bio-medical intervention; and was specifically looking for a means to reduce deaths among TB patients co-infected with HIV. As evidence was lacking in areas of high bacterial resistance to CTX, operational research was conducted on the efficacy and feasibility of CPT, providing evidence that was particularly relevant to influencing policy and change practice. However, this research did not provide answers to key areas of concern identified at the policy meeting, namely the potential to create cross resistance with SP and whether CPT would be needed if HAART was introduced. With these potential barriers, the activities of a well positioned policy entrepreneur, supported by a group of influential champions, was needed to achieve policy change. By 2005, changes in the context and evidence base could be seen. The HIV programme was focussing on treatment, care and support issues, and evidence on the efficacy of CPT for HIV positive patients in areas of high bacterial resistance to CTX had been gathered. Along with the reduction in the reliance on SP, there were no longer barriers to the development of a CPT policy for all HIV infected individuals, and no longer a need for an influential network to press it forward. The same policy entrepreneur was involved in the second policy development process, but he played a different role - shifting from bridging the researcher and policy making communities, to a much more straightforward process of facilitating discussions about the evidence that ultimately led to the adoption of CPT for a much wider group of patients.

## Conclusion

Despite idealised models, there is no simple or single way in which evidence gets taken up into policy. Instead, multiple factors work together to shape the ways this can be done. In the case of CPT a number of studies on the drug's efficacy in Africa were published between 1999 and 2005, providing several pieces of evidence on which decisions could be made<sup>2-3,5,16,18-19,25-26,34</sup>. Yet, as numerous authors have pointed out, there has been varied and, at times, slow uptake of CPT across African settings<sup>7-9</sup>. This study has shown how a policy analysis lens can provide a powerful lens through which the policy change process can be explained and understood. Policy decisions are never value-free simple assessments of epidemiological evidence, but are a result of competing ideas, and having key actors using evidence to support positions they promote. The framework used here to look at context, evidence, and links has shown how this played out in Malawi over CPT for HIV affected individuals, and can help to guide other investigations of the research to policy process.

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