Facilitating Policy Formulation and Policy Implementation:

A Case Study of Policy on the Prevention of Mother to Child HIV Transmission in South Africa

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Abbreviations

AIDS	Acquired Immune Deficiency Syndrome
ANC	African National Congress
ARV	Antiretroviral
COSATU	Congress of South African Trade Unions
DA	Democratic Alliance
HIV	Human Immunodeficiency Virus
MCC	Medicines Control Council (RSA)
MEC	Members of the Executive Council
MTCT	Mother to Child HIV Transmission
MTCTP	Mother to Child HIV Transmission Prevention
NGO	Nongovernmental Organisation
PMTCT	Prevention of Mother to Child HIV Transmission
RDP	Reconstruction and Development Programme
SAINT	South African Intrapartum Nevirapine Trials
SAPA	South African Paediatricians Association
STD	Sexually Transmitted Disease
TAC	Treatment Action Campaign
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNICEF	United Nations International Children's Fund
WHO	World Health Organisation

Abstract

This case study explores the evolution of South African policy on prevention of mother to child HIV transmission (PMTCT). It employs the advocacy coalition framework developed by Paul Sabatier to analyse the factors that have hindered and facilitated the alteration and subsequent implementation of PMTCT policy. It provides a clear illustration of the impact that actors outside of the government can have on policy change and policy implementation. The Treatment Action Campaign (TAC) and a coalition of its partners exploited opportunities, taking action that led the South African government to change its PMTCT policy. After the government altered its PMTCT policy, TAC and its partners continued to take action, helping to facilitate the implementation of the PMTCT policy. The future of the implementation of PMTCT policy is dependent, in part, upon the future involvement of TAC and its partners.

Introduction

As of July 2004, the Joint United Nations Programme on HIV/AIDS (UNAIDS) estimated that South Africa was the country with the largest number of people living with HIV/AIDS.[1] South Africa has been severely impacted by the HIV/AIDS epidemic, posing major challenges to South African society. The South African government has been faced with the enormous challenge of responding to the epidemic. The government's response has been heavily criticised as being unresponsive and insufficient to meet the challenges posed by the epidemic. In particular, the government has been criticised for its reluctance to formulate and implement policy necessary to fight the HIV/AIDS epidemic in the country. This pessimistic view of the country's response overlooks the intensive efforts led by civil society to influence HIV/AIDS policy – efforts that, as will be demonstrated, have produced concrete results.

This examination will investigate the efforts of the Treatment Action Campaign (TAC) and its partners to facilitate policy change and policy implementation of South African prevention of mother to child HIV transmission (PMTCT) policy. This study will analyse the development and implementation of South African PMTCT policy using the advocacy coalition framework developed by Paul Sabatier. The advocacy coalition framework examines the roles that conflict between competing groups and changes in external events play in policy change and policy implementation. This analysis will demonstrate the influence that TAC and its coalition partners have had on PMTCT policy.

TAC and its coalition partners recognised the South African government's reluctance to plan and implement a comprehensive PMTCT programme in the public health care system. Initially, TAC and its coalition partners used public mobilisation campaigns in an attempt to influence PMTCT policy. When public mobilisation proved to be ineffective, they turned to the court system.

The courts acted as a broker in the conflict between the government and TAC and its partners over PMTCT policy. The court issued a handful of rulings favourable to TAC and its partners that ultimately lead the government to alter its policy. South African PMTCT policy now calls for a comprehensive PMTCT programme in the

[1] UNAIDS, *2004 Report on the Global AIDS Epidemic* (2004) [Online]. Available at http://www.unaids.org/bangkok2004/GAR2004_html/GAR2004_00_en.htm. [6 August 2006].

public health care system.

Methodology

This investigation provides an account of the South African government's PMTCT policy, identifying key events, their causes, and their impact on PMTCT policy. A variety of primary and secondary source documents were used to reconstruct the events that influenced PMTCT policy.[2] Primary source documents included South African government legislation, strategic plans, operational plans, frameworks, guidelines and discussion documents, as well as speeches, statements, legislative debates, press releases, and court rulings. Interest group newsletters, press releases, research reports and annual reports were also consulted. Secondary source documents included newspaper accounts, as well as academic discussions and analyses related to HIV/AIDS, PMTCT, and public policy. These documents were the foundation for a detailed, although inevitably selective, account of South African PMTCT policy.

[2] This case study did not use interviews as a data source. Unfortunately, due to logistical constraints, this case study was unable to include interviews with key actors who influenced PMTCT policy.

Chapter 1: Implementation Literature Review

Prior to examining and analysing of the formulation and implementation of South African prevention of mother to child HIV transmission (PMTCT) policy, it is important to understand of the operational definitions of and theoretical frameworks for examining implementation. This chapter will briefly discuss a number of operational definitions of "implementation." The chapter will explore the top-down model, the bottom-up model, and the advocacy coalition framework, which are used to interpret the implementation process. The advocacy coalition framework will provide the foundation for the analysis of South African PMTCT policy.

What Is Implementation?

An investigation of the academic literature on implementation requires an understanding of the concept of "implementation." Scholars studying policy implementation have offered operational definitions for the word, a handful of which will be briefly examined.

Policy studies scholars often disagree about the meaning of "implementation" because the word has two related, yet distinct meanings. J.E. Lane explains:

> *Webster's Dictionary* states that 'implementation' means either the act of implementing or the state of having been implemented; it presents the following key words for 'implement': to carry out: accomplish, fulfil; to give practical effect to and ensure of actual fulfilment by concrete measures, to provide instruments or means of practical expression.[3]

Similarly, "the *Oxford English Dictionary* discusses the two definitions: 'to complete, perform; to fulfil.'"[4] Notably, implementation can be a verb, connoting an action or process, or a noun, indicating an outcome. The dual meaning of the word has lead some to focus on implementation as a process, while others view implementation as a result or outcome.

Research in the area of policy implementation is a recent undertaking. Scholarly debates about implementation did not attract significant attention until the 1970's. Initial studies on the subject emerged as part of research on public administration. These researchers viewed implementation as an outcome, rather than an ongoing process. Paul Sabatier and Daniel Mazmanian point out that "to administer" and "to implement" were thought of as synonymous in research on public

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[3] J.E. Lane, *Public Sector* (London: Sage, 1995), p. 97.
[4] Ibid, p. 98.

administration in the 1970's.[5]

During this period, scholars assumed that the process of implementation occurred automatically, as part of the natural workings of the public administration. Implementation was the natural functioning of the public administration – a cog in the predictable, machine-like processes of the bureaucracy.[6] This conceptualisation of implementation solely as an outcome overlooked the process of implementation.

It quickly became evident to scholars that this understanding of implementation was far too simplistic. Contrary to the initial beliefs, policy implementation was rarely an easy or naturally-occurring process.[7]

Later research on implementation expanded its purview, considering implementation as both an outcome and as an ongoing process. The implementation process became the basis for evaluating the outcome. Lawrence Baum explains:

> Implementation is best defined as the relevant actions and inactions of public officials who are responsible for helping to achieve objectives contained in previously enacted policies. This is a relatively narrow definition, because it excluded extragovernmental activities that help to determine a policy's ultimate impact.[8]

Baum also notes:

> Students of the implementation process tend to share the same central interests. Scholars have been concerned primarily with the effectiveness of the process, both descriptively and as an outcome to be explained. Increasingly, attention has been focused on the goal of explanation. The imperfections of implementation no longer require documentation, so that the major goal of research has become one of understanding why these imperfections exist and on what bases they vary.[9]

Mazmanian and Sabatier elaborate a similar conceptualisation of implementation. They state:

> To understand what actually happens after a programme is *enacted* or *formulated* is the subject of *policy implementation*: those events and activities that occur after the issuing of authoritative public policy directives, which include both the effort to administer and the substantive impacts on people and events. This definition encompasses not only the behaviour of the administrative body which has responsibility for the programme and the compliance of target groups, but also the web of direct and indirect political, economic, and social forces that bear on the behaviour of all those involved, and ultimately the impacts — both intended and

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[5] Paul Sabatier and Daniel Mazmanian, "Policy Implementation," in Stuart Nagel, *Encyclopaedia of Policy Studies* (New York: Plenum, 1983), p. 143.
[6] Fanie Cloete and Henry Wissink (eds.), *Improving Public Policy* (Pretoria: Van Schaik Publishers, 2000), p. 167.
[7] Paul Sabatier and Daniel Mazmanian, "Policy Implementation," in Stuart Nagel, *Encyclopaedia of Policy Studies* (New York: Plenum, 1983), p. 143.
[8] Lawrence Baum, "Comparing the Implementation of Legislative and Judicial Policies," in Daniel Mazmanian and Paul Sabatier, *Effective Policy Implementation* (Lexington, Massachusetts: Lexington Books, 1981), pp. 39-40.
[9] Ibid, p. 40.

> unintended — of the programme.[10]

This notion of implementation acknowledges the influence of actors outside of the government sector.

Mazmanian and Sabatier provide an alternative, yet related, definition of implementation, stating:

> Implementation is the carrying out of a basic policy decision, usually incorporated is a statute but which can also take the form of important executive orders or court decisions. Ideally, that decision identifies the problem(s) to be addressed, stipulates the objective(s) to be pursued, and, in a variety of ways, "structures" the implementation process. The process normally runs through a number of stages beginning with passage of the basic statute, followed by the policy outputs (decisions) of the implementing agencies, the compliance of target groups with those decisions, the actual impacts — both intended and unintended — of those outputs, the perceived impacts of agency decisions, and, finally, important revisions (or attempted revisions) in the basic structure.[11]

Mazmanian and Sabatier note that policy decisions are not limited to legislative action, but can include executive orders or court decisions. They also acknowledge that implementation can lead to both intended and unintended results.

From these definitions, it is possible to abstract a number of key components of the concept "implementation." As a number of scholars have discussed:

- Implementation is the enactment of a policy decision.
- These policy decisions can include legislative action, as well as executive orders and court decisions.
- Implementation not only encompasses positive action, but also includes relevant inaction.
- Implementation includes both the intended and unintended consequences of action.
- Implementation encompasses not only the actions and inactions of government officials, but also those of actors outside of the government sector.
- Ideally, the process of implementation carries out the stipulated objectives of a policy decision.
- Implementation is never a final or static state, but rather is a constantly evolving process.

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[10] Daniel Mazmanian and Paul Sabatier, *Implementation and Public Policy* (Lanham, Maryland: University Press of America, Inc., 1989), p. 4.
[11] Ibid, pp. 20-21.

Recent Implementation Models

In 1980's and 1990's, two models for analysing implementation were predominant. The top-down model and the bottom-up model examine the difficulties encountered in the implementation process – aspects which were overlooked in early research. Both frameworks acknowledge these complications as an inherent and unavoidable part of the implementation process. The models analyse key players and mechanisms that facilitate implementation. Both paradigm implicitly offer methods for addressing the challenges encountered in the implementation process.

Top-Down Model

One of the most influential articulations of the top-down model was elaborated in the work of Mazmanian and Sabatier. The top-down model focuses on the policy decisions made by government officials, concentrating primarily on policy decisions by top officials in the central government.

Three key observations provide the basis for the top-down model. These observations state:

1. Policy making is an iterative process of formulation, implementation and reformulation, and the distinction between the three should be maintained.
2. The focus should be on the attainment of the stated policy goals, although outputs of the implementing agencies and the outcomes of the implementation process are both important.
3. Implementation can be viewed from three quite different perspectives — the initial policymaker or the centre, the field-level implementing officials or the periphery, and the actors at whom the programme is directed or the target group—but a centre-focused perspective to implementation is preferred.[12]

On the basis of these observations, Mazmanian and Sabatier seek to "identify the factors that affect the achievement of statutory objectives throughout the entire [policy] process." According to the top-down model, top government officials can facilitate implementation by formulating detailed policy, so as to ensure the greatest degree of control over street-level bureaucrats as they carry out implementation.

A number of case studies examined by Mazmanian, Sabatier, and various other academics have tested the empirical applications of the top-down model.[13] The case studies uncovered the strengths and weaknesses of the model.

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[12] Fanie Cloete and Henry Wissink (eds.), *Improving Public Policy* (Pretoria: Van Schaik Publishers, 2000), p. 172.

[13] For a list of case studies testing the empirical applications of the Sabatier and Mazmanian framework, see Table 1 in: Paul Sabatier, "Top-Down and Bottom-Up Approaches to Implementation Research: a Critical Analysis and Suggested Synthesis," *Journal of Public Policy*, 6:1 (1986), p. 26.

The evidence confirms the importance of legal structuring, or planning, disproving claims that planning is altogether unrealistic. The model stresses the manner in which legal structuring by top government officials can help to facilitate policy implementation.[14] This legal structuring is particularly critical for implementation of more difficult policies.

The case studies underscore the need to consider the implementation over longer time periods. "... [T]he focus in the framework on the formulation-implementation-reformulation cycle encourage[s] many of our case authors to look at a longer time-frame than was true of earlier implementation studies (i.e. ten years instead of four)." The focus on the formulation-implementation-reformulation cycle would later lead academics to highlight learning as a key factor facilitating implementation over an extended timeframe.[15]

Ultimately, the focus on the legally mandated policy objectives, in combination with an expanded time span for assessing implementation, results in a more optimistic view of policy implementation.

> On one hand, the focus on legally-mandated objectives encouraged scholars to carefully distinguish the objectives contained in legal documents from both the political rhetoric surrounding policy formulation and the tendency of critics to evaluate a programme on the basis of what they mistakenly perceived to be its objectives.[16]

The evaluation of successes in carrying out legally mandated policy objectives over an extended period of time has led scholars to reconsider situations that were once labelled "policy failures."[17]

The case studies testing the empirical applications of the top-down model demonstrate two major flaws. First, the writers mistakenly emphasise the importance of clear and consistent policy objectives. The case studies verify the critics' claims that few programmes contain clear and consistent policy objectives. Rather, evidence demonstrates that the majority of policies contain a number of conflicting objectives.

Sabatier refutes this claim in part, noting:

> This does not... preclude the possibility of assessing programme effectiveness. Instead, it simply means that effectiveness needs to be re-conceptualised into 'acceptability space' demarcated by the intersection of the ranges of acceptable values on each of the multiple evaluative dimensions involved.[18]

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[14] Paul Sabatier, "Top-Down and Bottom-Up Approaches to Implementation Research: a Critical Analysis and Suggested Synthesis," *Journal of Public Policy*, 6:1 (1986), p. 27.
[15] Ibid, p. 27.
[16] Ibid, p. 28.
[17] Ibid, p. 30.
[18] Ibid, p. 29.

Second, the case studies demonstrate that while the model examines implementation over a longer time frame than previous studies, the framework is not specifically useful in examining policy implementation over a decade or more. Sabatier acknowledges that, "This is because... [the framework] focuses too much on the perspective of programme proponents, thereby neglecting the strategies (and learning) by other actors which would provide the cornerstone for a more dynamic model."[19]

Advocates of the bottom-up model weigh a number of key critiques against Mazmanian and Sabatier's framework. First, critics argue that the model's focus on officials in the top positions of the government is overstated and neglects to recognise the influence of the private sector, street level bureaucrats, and policymakers from other policy subsystems.[20]

Second, the model is accused of being "difficult to use in situations where there is no dominant policy (statute) or agency, but rather a multitude of governmental directives and actors, none of them pre-eminent."[21] In these situations, the presence of multiple, potentially conflicting directives makes it complicated for bureaucrats to determine which directives they should follow.

Third, it is contended that the model is "likely to ignore, or at least underestimate, the strategies used by street level bureaucrats and target groups to get around (central) policy and/or to divert it to their own purposes."[22] Lower level bureaucrats may find that policy is not fitting to the realities on the ground or to their personal interests. While the top-down model would argue that top government officials should carefully consider the situation on the ground, the reality is that they often cannot; thus, policies may need to be adjusted at the point of implementation to fit local circumstances.

As has been illustrated, the top-down model overemphasises the agency of actors at the upper levels of the policy making process, thereby ignoring or underestimating the influence of actors at lower levels. The model has not been discarded altogether, as certain elements offer valuable insights into the implementation process.

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[19] Ibid, p. 30.
[20] Ibid, p. 30.
[21] Ibid, p. 30.
[22] Ibid, p. 30.

The Bottom-Up Model

In contrast with the top-down model, the bottom-up model focuses on the lower levels of the government. According to this model, "the latitude of those charged with carrying out policy is so substantial that... policy is effectively 'made' by the people who implement it."[23] The model identifies "the networks of actors involved in service delivery in one or more local areas and asks them about their goals, strategies, activities, and contacts."[24] Street-level bureaucrats, rather than top government officials, are the key actors in the policy implementation process.

The model views policy as effectively being formulated by street level bureaucrats. Policy is but a collection of words before it enters the implementation process and is transformed into realities by street level bureaucrats. "Policy standards – establishing requirements for how policy goals shall be implemented – 'represent no more than exhortations: they are inanimate messages that must be communicated to those in charge of executing the policy.'"[25]

Like the top-down model, the bottom-up model is criticised for being an insufficient account of the implementation process. First, opponents claim that the bottom-up model overemphasises the importance of bureaucrats in relation to top government officials,[26] ignoring contributions by top government officials. It also may underestimate the indirect influence of top officials through their ability to affect the institutional structures in which bureaucrats operate.[27]

Second, "because [the bottom-up model] relies very heavily on the perceptions and activities of participants, it is their prisoner – and therefore is unlikely to analyse the factors *indirectly* affecting such behaviour which the participants do not realize." Social, economic, and legal factors that influence the perceptions, resources, and participation of individual bureaucrats must be accounted for.[28]

As has been demonstrated, the bottom-up model overemphasises the agency of

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[23] Lipsky, Michael, "Standing the Study of Public Policy Implementation on its Head," in Walter Burnham and Martha Weinberg (eds.), *American Politics and Public Policy* (Cambridge, MA: MIT, 1978).

[24] Paul Sabatier, "Top-Down and Bottom-Up Approaches to Implementation Research: a Critical Analysis and Suggested Synthesis," *Journal of Public Policy*, 6:1 (1986), p. 32.

[25] Giandomenico Majone and Aaron Wildavsky, "Implementation as Evolution," in J. Pressman and A. Wildavsky, *Implementation* (Berkeley: University of California Press, 1984), p. 164.

[26] Paul Sabatier, "Top-Down and Bottom-Up Approaches to Implementation Research: a Critical Analysis and Suggested Synthesis," *Journal of Public Policy*, 6:1 (1986), p. 34.

[27] Ibid, p. 34.

[28] Ibid, p. 35.

actors at the lower levels of the policy making process, thereby ignoring or underestimating the influence of actors in upper levels of the government. The model does provide valuable insights into influence of lower level bureaucrats on the implementation process, demonstrating how bureaucrats can play a key role in overcoming the impediments that surface as policy is translated into action.

The Advocacy Coalition Framework

Sabatier elaborates an alternative approach for analysing policy implementation that synthesises key contributions of the top-down and the bottom-up models. The advocacy coalition framework views implementation as the result of learning by actors involved in the policy process. In short, implementation occurs as actors find ways to overcome barriers and policy is revised in response.

The framework focuses on advocacy coalitions, defined as "actors from various public and private sectors who share a set of beliefs and who seek to realize their common goals over time."[29] The focus on advocacy coalitions erases the unnecessary division between top government officials and bureaucrats found in the top-down and the bottom-up models.

Sabatier incorporates elements from the bottom-up model into the advocacy coalition framework. He states:

> Consistent with the bottom-uppers, one needs to start from a policy problem or subsystem – rather than a law or other policy decision – and then examine the strategies employed by relevant actors in both the public and private sectors at various levels of government as they attempt to deal with the issue consistent with their objectives.[30]

Both top government officials and street level bureaucrats play a role in policy change and policy implementation, and in dealing the complexities encountered in the process.

Sabatier also incorporates elements of the top-down model into the advocacy coalition framework. He asserts:

> The manner in which legal and socio-economic factors structure behaviour options need[s] to be incorporated... This leads to a focus on (1) the effects of socio-economic (and other) changes external to the policy network/subsystem on actors' resources and strategies; (2) the attempts by various actors to manipulate the legal attributes of governmental programmes in order to achieve their objectives over time; and (3) actors' efforts to improve their understanding of the magnitude and factors affecting the problem — as well as the impacts of various policy instruments — as they learn

[29] Ibid, p. 39.
[30] Ibid, pp. 38-39.

from experience.[31]

Policies are influenced by both external changes and by internal manipulations. Actors seek to understand and react to these influences, with the ultimate goal of facilitating policy implementation.

Generally, the advocacy coalition framework is based on five basic premises. First, "the process of policy change – and the role of policy-oriented learning therein – requires a time perspective of a decade or more."[32] The focus on an extended time span allows learning to result in policy change. Policy change refers to the formal creation of new policies or the alteration of existing policies by top government officials, which one conventionally thinks of as "policy change." It also incorporates elements of the bottom-up model, referring to policy change resulting from alterations in the manner in which bureaucrats operationalise policy.[33]

Second, "the most useful way to think about policy change over such a time span is to focus on 'policy subsystems.'"[34] Sabatier defines a "policy subsystem" as: "The set of actors who are involved in dealing with a policy."[35]

Third, "policy subsystems will normally involve actors from all levels of government."[36] As was previously pointed out, this premise erases the unnecessary division of top government officials and bureaucrats. Sabatier asserts:

> ...our conception of policy subsystems should be broadened from traditional notions of iron triangles — limited to administrative agencies, legislative committees, and interest groups at a single level of government — to include two additional categories of actors: (1) journalists, researchers, and policy analysts, who play important roles in the generation, dissemination, and evaluation of policy ideas... and (2) actors at *all* levels of government active in policy formulation and implementation.[37]

The work of this larger range of actors is acknowledged.

Fourth, "public policies (or programmes) can be conceptualised in the same manner as belief systems, i.e. as sets of value priorities and causal assumptions about how to realize them."[38] Policies are merely beliefs formalised in a policy decision. Actors become involved in the policy process to promote their belief system with the

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[31] Ibid, p. 39.
[32] Paul Sabatier, "An Advocacy Coalition Framework of Policy Chance and the Role of Policy-Oriented Learning Therein," *Policy Sciences*, 21 (1988), p. 131.
[33] Ibid, p. 131.
[34] Ibid, p. 131.
[35] Ibid, p. 138.
[36] Hank Jenkins-Smith and Paul Sabatier, "Evaluating the Advocacy Coalition Framework," *Journal of Public Policy*, 14:2 (1994), p. 179.
[37] Paul Sabatier and Hank Jenkins-Smith, "The Advocacy Coalition Framework: An Assessment," in Paul Sabatier, ed., *Theories of the Policy Process* (Boulder, CO: Westview Press, 1999), p. 119.
[38] Ibid, p. 131.

goal of having their beliefs incorporated into policy decisions.[39]

Fifth, "theories of the policy process or policy change need to address the role played in the process by technical information concerning the magnitude and facets of the problem, its causes, and the probable impacts or various solutions."[40] Technical information of this sort plays a notable role in the policy process, influencing administrative agency and legislative decision-making.

Based on these five premises, the advocacy coalition framework examines the evolution of a policy and its implementation. The framework focuses on advocacy coalitions operating in the policy subsystem. "Within the subsystem, it is assumed that actors can be aggregated into a number of advocacy coalitions composed of people from various organisations who share a set of normative and causal beliefs and who often act in concert."[41] Advocacy coalitions are held together by shared beliefs.

Coalitions are united by shared core beliefs. Members within a coalition may differ to some degree in their secondary beliefs. The framework holds that the "core" of the shared beliefs of an advocacy coalition is quite resilient and is not changed easily[42]; thus, the foundational beliefs that unite an advocacy coalition are consistent over time. As a result, advocacy coalitions tend to be rather consistent over time.

Sabatier states, "While belief systems will determine the *direction* in which an advocacy coalition (or any other political actor) will seek to more governmental programmes, *its ability to do so* will be critically dependent upon its resources." Coalitions mobilise, using available resources, to advocate their particular policy beliefs. Coalitions adopt strategies that allow them to assert their policy beliefs.[43]

In a policy subsystem, advocacy coalitions compete with the goal of transforming their policy beliefs into policy decisions. Competition among coalitions is mediated by what Sabatier calls "policy brokers," who seek to minimise conflict between coalitions and facilitate compromise between competing policy beliefs. The role of policy broker is often played by certain elected officials, such as a chief executive, courts, or blue ribbon commissions.[44] The mediated outcome of conflict between advocacy coalitions forms the basis on which policy and governmental

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[39] Ibid, p. 132.
[40] Ibid, p. 118.
[41] Paul Sabatier, "An Advocacy Coalition Framework of Policy Chance and the Role of Policy-Oriented Learning Therein," *Policy Sciences*, 21 (1988), p. 133.
[42] Ibid, p. 141.
[43] Ibid, p. 143.
[44] Ibid, p. 141.

programmes are built.[45]

Once causal theory and a course of action are agreed upon, a governmental programme is implemented. Policy outputs are the operational incarnations of these governmental programmes. In other words, policy outputs are governmental programmes translated into action. Policy outputs produce policy impacts. Policy impacts include both intended and unintended impacts that occur as the policy is operationalised.[46]

Policy outputs and policy impacts are observed by advocacy coalitions who continue to be concerned with a policy issue. Sabatier states:

> On the basis of perceptions of the adequacy of governmental decisions and/or the resultant impacts, as well as new information arising from search processes and external dynamics, each advocacy coalition may revise its beliefs and/or alter its strategy.[47]

This process is referred to as policy-oriented learning, which comprises "relatively enduring alterations of thought or behavioural intentions which result from experience and which are concerned with the attainment (or revision) of policy objectives."[48]

Policy-oriented learning is shaped by "internal feedback loops"[49] from both policy outputs and policy impacts. Policy-oriented learning allows actors to re-evaluate the secondary aspects of a coalition's belief system. It is the "ongoing process of search and adaption [sic] motivated by the desire to realize core policy beliefs."[50]

Policy-oriented learning of this type is vital to the evolution of a policy, facilitating policy implementation over an extended period of time.

> Policy-oriented learning normally entails experimenting with a variety of implementing mechanisms over time. Dissatisfaction with the performance of a specific mechanism — in terms of either its policy outputs at the operational level or its resultant inability to ameliorate the problem — will lead programme proponents to re-examine their strategy.[51]

Policy-oriented learning drives the cycle of policy formulation, policy implementation, and policy reformulation.

The policy process is not only shaped by policy-oriented learning. It is also shaped by external events and by system parameters, which have yet to be discussed.

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[45] Ibid, p. 133.
[46] Ibid, p. 133.
[47] Ibid, p. 133.
[48] Ibid, p. 133.
[49] Ibid, p. 133.
[50] Ibid, p. 151.
[51] Ibid, p. 151.

Sabatier points out that, "Policy-making in any political system or policy subsystem is constrained by a variety of social, legal, and resource features of the society of which it is a part."[52] Sabatier divides the external factors affecting policy change within a subsystem into two main categories: 1.) relatively stable parameters, and 2.) dynamic system events.

Sabatier identifies four relatively stable parameters: 1.) basic attributes of the problem area (or good); 2.) basic distribution of natural resources; 3.) fundamental cultural values and social structure; and 4.) basic legal structure. Relatively stable system parameters are extremely difficult to change; therefore, it is not feasible for actors in a policy subsystem to alter these parameters.[53]

Sabatier highlights three dynamic system events: 1.) changes in socio-economic conditions and technology; 2.) changes in subsystem governing coalitions; and 3.) policy decisions and impacts from other subsystems. In contrast to the relatively stable parameters, the dynamic system events are those elements external to a policy subsystem that can change over time. As these aspects change, they affect the opportunities and the constraints that actors face. Changes in dynamic system events can either hinder or facilitate the ability of actors in a policy subsystem to assert their policy beliefs.[54]

According to Sabatier, changes in factors external to a policy subsystem can shake the foundation of the subsystem. Policy-oriented learning that results from internal feedback loops tends to lead actors to revise secondary beliefs. By contrast, changes in factors external to a policy subsystem can lead actors to reconsider core beliefs – beliefs which are very difficult to change as they are foundational to the existence and to the efforts of a policy coalition.[55]

Sabatier provides a diagram (Figure 1.1) summarizing the basic elements of the advocacy coalition framework, which were discussed briefly above. This framework will be the foundation for the subsequent examination of the formulation and implementation of South African policy on prevention of mother to child HIV transmission (PMTCT).

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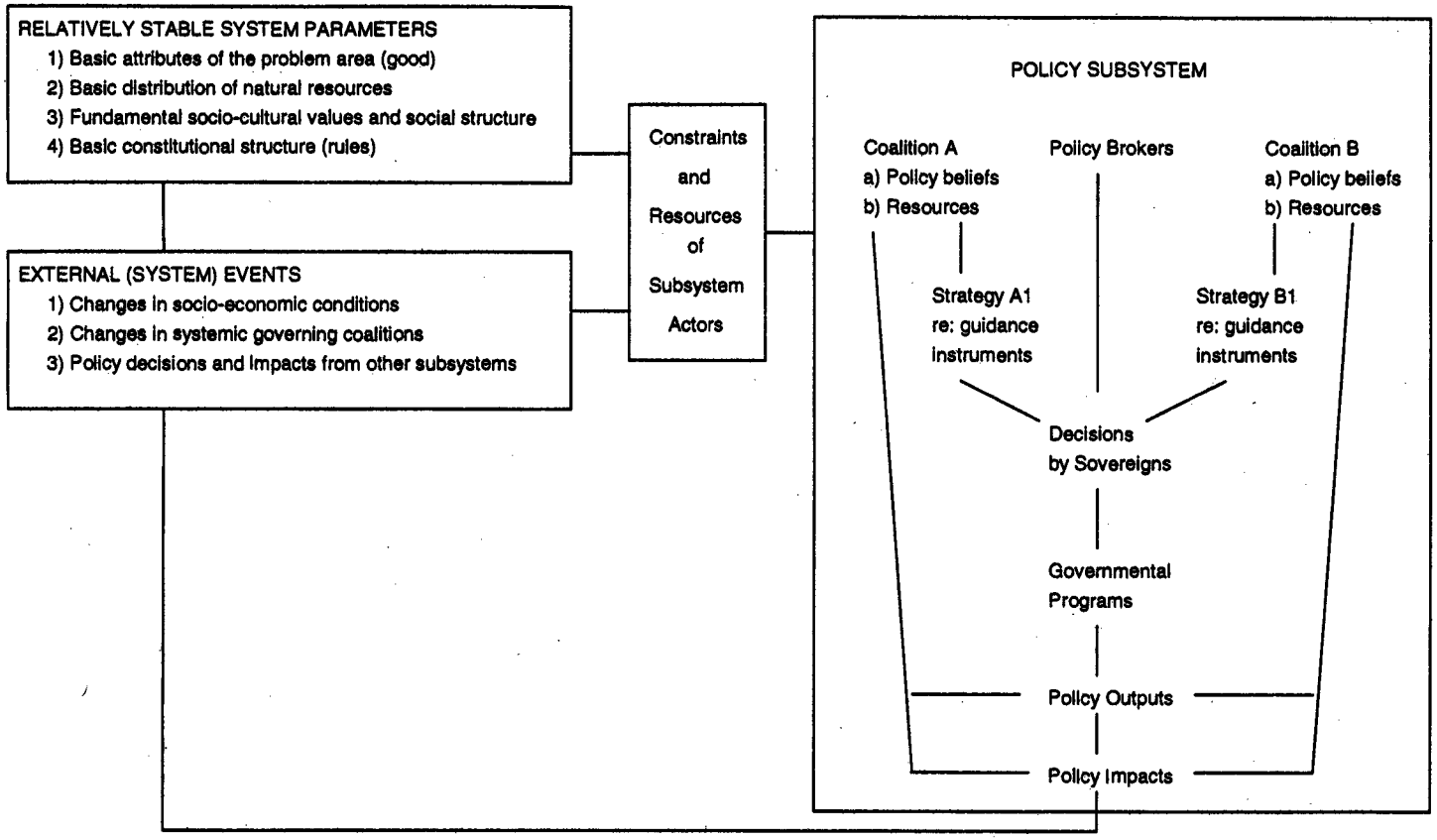
[52] Ibid, p. 134.
[53] Ibid, p. 134.
[54] Ibid, p. 136.
[55] Ibid, p. 134.

Figure 1.1: The advocacy coalition framework of policy change



Source: Sabatier, 1993[56]

[56] Paul Sabatier, "Policy Change over a Decade or More," in Paul Sabatier and Hank Jenkins-Smith, eds., *Policy Change and Learning: An Advocacy Coalition Approach* (Boulder, CO: Westview Press, 1993), p. 18.

Chapter 2: Prevention of Mother to Child HIV Transmission and the South African Government

The HIV/AIDS epidemic in South Africa is extremely complex, multifaceted, and rapidly evolving. Responses to the epidemic have been correspondingly complicated, and ever changing. Prevention efforts, including prevention mother to child HIV transmission (PMTCT) efforts, lie at the core of the response. This chapter will provide a brief sketch of the HIV/AIDS epidemic in South Africa, focusing on the HIV prevalence statistics among women of childbearing age, and the implication of high infection rates among this population. The chapter will discuss mother to child HIV transmission, highlighting medical interventions that can be employed to prevent HIV transmission from mother to child. The discussion will subsequently address the key policy decisions made by the South African government on PMTCT, tracking the evolution of the policy stances related thereto. Lastly, the discussion will consider the many controversies pertaining to PMTCT efforts and the government's contentious policy decisions.

The narrative provided in this chapter is an inevitably selective account of HIV/AIDS and PMTCT policy in South Africa; however, a basic account of the situation is a necessary foundation for the subsequent analysis of the evolution of the South African government's PMTCT policy.

HIV/AIDS in South Africa and Mother to Child HIV Transmission

The HIV/AIDS epidemic in South Africa has grown at a rapid pace. In 2003, the Joint United Nations Programme on HIV/AIDS (UNAIDS) estimated that approximately 5.3 million people in South Africa were living with HIV.[57] As of July 2004, UNAIDS estimated that South Africa was the country with the largest number

[57] UNAIDS, "South Africa: Epidemiological Fact Sheets," (2004) [Online]. Available at http://www.unaids.org. [1 October 2004], p. 2. The exact statistics for prevalence of HIV/AIDS are unknown. UNAIDS estimates that between 4.5 million (low estimate) and 6.2 million (high estimate) South Africans were living with HIV in 2003. UNAIDS acknowledges: "The current estimates do not claim to be an exact count of infections. Rather, they use a methodology that has thus far proved accurate in producing estimates that give a good indication of the magnitude of the epidemic in individual countries. However, these estimates are constantly being revised as countries improve their surveillance systems and collect more information" (UNAIDS, *2004 Report on the Global AIDS Epidemic*, 2004: 2). In South Africa, "Reliable statistics on HIV/AIDS deaths in South Africa are not available despite Government's extensive, and largely successful, efforts to improve the national vital registration system" (Dorrington et al., *The impact of HIV/AIDS on adult mortality in South Africa*, 2001: 5).

of people living with HIV/AIDS. The HIV/AIDS epidemic in South Africa is a generalised epidemic, affecting all segments of society. In South Africa, the vast majority of HIV infections are in people in their prime reproductive years.[58] The large number of people living with HIV/AIDS has and will continue to pose a major challenge for South African policy makers.

UNAIDS estimates on HIV prevalence in countries with generalised epidemics are based largely on data from pregnant women attending antenatal clinics.[59] In South Africa, HIV prevalence statistics from antenatal clinics have been collected in since 1990. The antenatal clinic data have shown a steady and notable increase in HIV infection rates among women attending public antenatal clinics.[60] Infection rates among pregnant women grew from 0.55 percent in major urban areas and 0.38 percent outside major urban areas in 1990; to 12.03 percent in major urban areas and 8.3 percent outside major urban areas in 1995; to 24.3 percent in major urban areas and 22.9 percent outside major urban areas in 2000.[61]

The high prevalence among females in their prime reproductive years is problematic because HIV can be transmitted from mother to child during pregnancy, labour and delivery, and after delivery through breast milk. According to the United Nations International Children's Fund (UNICEF), in the absence of intervention to prevent mother to child HIV transmission (MTCT), approximately 35 percent of children born to HIV-positive mothers will be infected with HIV through mother to child transmission. Each year, approximately 700,000 children worldwide are infected with HIV through MTCT. These infections account for over 90 percent of paediatric infections. Of the 700,000 paediatric infections, approximately 15 to 20 percent are infected during pregnancy, approximately 50 percent during delivery, and approximately 33 percent through breast milk.[62] In South Africa, an estimated 70,000 children are infected each year through MTCT.[63]

Advances in medical technology have made it possible to prevent mother to

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[58] Clive Evian, "Policy Guideline and Recommendation for Feeding of Infants of HIV Positive Mothers," n.d. [Online]. Available at http://www.doh.gov.za/aids/docs/feeding.html. [22 April 2005].
[59] UNAIDS, *2006 Report on the Global AIDS Epidemic* (2004) [Online]. Available at http://data.unaids.org/pub/GlobalReport/2006/2006_GR_CH02_en.pdf. [6 August 2006], p. 10.
[60] UNAIDS, "South Africa: Epidemiological Fact Sheets," (2004) [Online]. Available at http://www.unaids.org. [1 October 2004], p. 2.
[61] Ibid, p. 4.
[62] UNICEF, "Prevention of parent-to-child transmission of HIV/AIDS," n.d. [Online]. Available at http://www.unicef.org/aids/index_preventionMTCT.html. [6 August 2006].
[63] Louise Stack and Kenneth Hlela, *Enhancing Policy Implementation: Lessons from the Health Sector* (Centre for Policy Studies: Johannesburg, 2002), p. 55.

child HIV transmission. As of 2000, PMTCT strategies included:

- Voluntary counselling and testing of the mother during pregnancy;
- Termination of pregnancy;
- Therapeutic interventions, such as
  - Provision of vitamin A to prevent vitamin A deficiencies,
  - Immunotherapy, and
  - Treatment of sexually transmitted infections;
- Obstetric interventions, such as
  - Avoidance of invasive tests
  - Birth canal cleansing, [and]
  - Caesarean section delivery;
- Modification of infant feeding practices, including
  - The choice to avoid breastfeeding
  - Early cessation of breastfeeding
  - Heat treatment of expressed breast milk, [and]
  - Exclusive breast feeding rather than mixed feeding;
- Anti-retroviral therapy, including
  - ARVs (antiretroviral drugs) to the mother to reduce the viral load in the mother's blood
  - AZT or Nevirapine to both the mother and child to reduce the rate of MTCT.[64]

Through these interventions, it is possible reduce to reduce the chances that an HIV-positive mother will transmit HIV to her child.

Development of Antiretroviral Drugs for Preventing MTCT

Antiretroviral drugs, such as AZT and Nevirapine, have provided the greatest promise in the fight against MTCT. Antiretrovirals reduce the chances that a woman will transmit HIV to her child during pregnancy, labour and delivery. Antiretroviral drugs (ARVs) are useful in PMTCT for two reasons:

1. ARVs will lower the viral load of the mother, thereby reducing the risk of transmission in the womb, during labour and during birth. The duration of treatment would determine how low the viral load in the breast milk will be and could therefore also reduce the risk of transmission through breastfeeding.
2. ARVs can by used as a post-exposure prophylaxis for an infant who has contracted the virus in the womb, during labour, during birth or to a limited extent through breastfeeding.[65]

Major studies examining the use of AZT for PMTCT commenced in 1994 in the United States, with a number of key studies following in 1996 in Thailand, Burkina Faso and Côte d'Ivoire, and later in South Africa, Tanzania and Uganda. The studies concluded:

> A range of AZT regimens can significantly reduce MTCT of HIV. Each individual regimen has a variety of advantages and disadvantages with respect to potential toxicity. Regimens also differ in degrees of practicality and feasibility for implementation. On the

[64] Anneke Meerkotter, Susie Bullington, Taryn Young, Amanda Swawr, and Caron Heyes, *Mother-to-Child Transmission of HIV: A Guide for Health Workers and HIV/AIDS Trainers* (2000) [Online]. Available at http://www.tac.org.za. [16 June 2005], pp. 10-20.
[65] Ibid, p. 20.

> question of toxicity it is important to note that the World Health Organisation (WHO) considers AZT to have an acceptable clinical safety profile. For the prevention of MTCT, the WHO specifically places AZT on its essential drug list, as an indispensable drug that should be made available at all times, in adequate amounts and in the appropriate dosage formulations.[66]

The studies of AZT demonstrated the potential for preventing MTCT.

AZT, however, was not simple to administer. The AZT regiment for PMTCT required patients to adhere to a rather intensive medication regimen. The standard regimen of AZT for PMTCT required the mother to take the medication daily from the fourteenth week of pregnancy, and required the baby to take the medication daily for the first six weeks after birth. In situations where this regimen was too expensive or too difficult to administer, two pills could be administered daily to the mother from the thirty-sixth week of pregnancy, and one pill every two hours during labour. Combining AZT with caesarean section delivery and exclusive formula feeding helped reduce the chances of transmitting HIV from mother to child to almost nothing.[67]

By the late 1990's, AZT was available on the global market; however, a regimen of AZT was extremely expensive. In 1999, the price of treating one woman with AZT and formula to replace breast milk in South Africa was R500 for a single treatment package.[68] In the context of resource-limited developing countries, the expense of administering AZT was a cost that constrained health care systems would find difficult to bear.

By 1998, the Ugandan HIVNET012 trial uncovered the potential of a second drug, Nevirapine, for preventing MTCT. HIVNET012 researchers concluded that Nevirapine was promising because it was simple, cheap and could be used widely.[69] Nevirapine was easier to administer than AZT, requiring a simple regimen of one pill administered to the mother during labour, and one pill administered to the child between 24 and 72 hours after birth. Furthermore, a dose of Nevirapine was significantly cheaper than AZT. After 8 January 2001, one dose of Nevirapine cost a mere R10, providing hope for a financially feasible means of preventing MTCT.

The HIVNET012 study revealed the promise for Nevirapine, coupled with

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[66] Ibid, pp. 20-23.
[67] Virginia van der Vliet, "AIDS: Losing 'The New Struggle'," *Daedalus*, 130:1 (2001), p. 166.
[68] Judith Soal, "I'll Be There In the Front," *Cape Times*, 26 March 1999.
[69] Anneke Meerkotter, Susie Bullington, Taryn Young, Amanda Swawr, and Caron Heyes, *Mother-to-Child Transmission of HIV: A Guide for Health Workers and HIV/AIDS Trainers* (2000) [Online]. Available at http://www.tac.org.za. [16 June 2005], pp. 27.

exclusive formula feeding, in preventing mother to child HIV transmission.[70] In a situation where an HIV-positive pregnant women is not given Nevirapine and where she breastfeeds her child, approximately 29 out of 100 babies would be HIV-positive if the mother breastfed the child for six months, and approximately 31 out of 100 babies would be HIV-positive if the mother breastfed the child for 12 months.[71] In other words, without Nevirapine or exclusive formula feeding, the transmission rate from mother to child is approximately 30 percent. Nevirapine and exclusive formula feeding help to reduce this 30 percent transmission rate.

In a situation where Nevirapine was administered to 100 HIV-positive, pregnant women, and where the mothers breastfed, approximately 20 out of 100 babies would be HIV-positive after six months of breastfeeding, and approximately 22 out of 100 babies would be HIV-positive after 12 months of breastfeeding. Alternatively, in a situation where 100 HIV-positive pregnant women were properly administered Nevirapine and where replacement formula feed was used exclusively, approximately 13 out of 100 babies would be HIV-positive.[72] Nevirapine, coupled with exclusive formula feeding, reduced the rate of mother to child HIV transmission from approximately 30 percent in the absence of both interventions, to approximately 13 percent with the use of both Nevirapine and exclusive formula feed. This represents a decrease in the rate of HIV transmission of approximately 50 percent.

The testing of Nevirapine both in the HIVNET012 trial and later in the South African Intrapartum Nevirapine Trials demonstrated that the medication had very few side effects. Trials found that Nevirapine occasionally caused skin disease and liver problems; however, these side effects were rare. The trials eased fears for many that Nevirapine would lead to drug resistant mutations of the virus. The studies concluded that Nevirapine did not lead to permanently resistant mutations in either the mother or the child. While the single dose of Nevirapine caused resistant mutations to appear in the body, the resistant mutations only remained in the body for a short period of time and were harmless.[73]

With both AZT and Nevirapine, the drugs needed to be coupled with an effective HIV counselling and testing programme. In order to intervene to prevent

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[70] Ibid, p. 27.
[71] David McCoy, Mitch Besser, Ronel Visser and Tanya Doherty, *Interim Findings on the National PMTCT Pilot Sites: Lessons and Recommendations* (Durban: Health Systems Trust, 2002), pp. 25-27.
[72] Ibid, pp. 25-27.
[73] High Court of South Africa, Transvaal Provincial Division, *Minister of Health vs. Treatment Action Campaign* (2001) Case No. 21182/2001.

MTCT, a pregnant woman must first know her HIV status. Women who test HIV-positive would then need to be counselled about PMTCT interventions. HIV counselling and testing programmes require additional trained staff, leading to additional costs for the health care system.

As part of a counselling programme, an HIV-positive woman also would need to be informed that AZT or Nevirapine alone cannot prevent the HIV transmission from mother to child. While AZT and Nevirapine significantly reduce MTCT during labour and delivery, the drugs are not effective in preventing MTCT through breast milk. As was demonstrated in the statistics cited above, a child born HIV negative due to the provision of AZT or Nevirapine can be infected with HIV through breast milk. Thus, a comprehensive PMTCT programme should include provision of formula feed to replace breast milk. Exclusive use of formula feed, in lieu of breastfeeding, can completely prevent MTCT through breast milk. Notably, the provision of formula feed also raises the cost of PMTCT and raises a number of other more complicated issues.

Despite the challenges, in January 2001, the World Health Organisation (WHO) recommended the drug for use in PMTCT.[74] This recommendation marked the official endorsement of the drug by the international medical community.

Given that advances in medical technology had made MTCT largely preventable, and given the promising evidence about the efficacy of Nevirapine and exclusive formula feeding for PMTCT, the South African government faced the challenge of how to address MTCT generally and the use of Nevirapine specifically.

Early National Department of Health Policy on PMTCT

The Medicines and Related Substances Control Amendment Act passed by the South African government in 1997 contained provisions that would later have implications for PMTCT policy. In an effort to reduce the costs of pharmaceuticals, the Act permitted parallel importation of medicines to South Africa. Parallel importation lowers the costs through the importation of goods produced by other countries at lower prices. The Act was particularly pertinent to the pricing of antiretroviral medications, including those antiretroviral medications developed for use in PMTCT.

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[74] Constitutional Court of South Africa, *Minister of Health vs. Treatment Action Campaign* (2002) Case No. CCT 8/02, p. 10.

As early as 1998, the South African National Department of Health took a formal stance on the use of AZT for PMTCT. On 2 October 1998, the Members of the Executive Council (MECs) for Health decided not to introduce an AZT regimen for PMTCT, a decision which was endorsed by the Inter-Ministerial Committee on AIDS. A statement issued by the Department of Health noted, "A detailed study in South Africa [had] shown that introduction of the drug would cost about R80 million, resulting in a further strain on an already limited health budget. Consideration would also have to be given to the high dependence on breast-feeding in South Africa."[75]

In May 2000, the government released the *HIV/AIDS/STD Strategic Plan for South Africa, 2000-2005*. The Strategic Plan set out to reduce HIV transmission from mother to child, calling for the implementation of clinical guidelines to reduce MTCT and improvements in HIV counselling and testing and family planning services for HIV-positive women.[76] It invited the government to review and revise policy on antiretroviral use for PMTCT. It required the government to review, monitor and evaluate current research, identify additional areas of related research, and review and update national policies to reduce MTCT.[77] Notably, the Strategic Plan did not discuss the provision of antiretroviral medication for PMTCT in the public health care system.

Prevention of Mother-to-Child HIV Transmission and Mamanagemenof [sic] *of HIV Positive Pregnant Women,* released by the Department of Health in May 2000, elaborated the government's PMTCT policy. The policy guideline targeted at health professionals, discussed strategies for managing and reducing MTCT. The guideline examined various PMTCT interventions, and discussed challenges that HIV-positive pregnant women pose for care efforts.[78] The documents provided a summary of possible PMTCT interventions,[79] with the notable omission of AZT and Nevirapine.

The 13th International Conference on HIV/AIDS, held in Durban in July 2000, focused national and international attention on PMTCT. Following the

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[75] Department of Health, "Government Continues to Focus on AIDS Prevention," (1998) [Online]. Available at http://www.doh.gov.za/mediaroom/index.html. [29 April 2005].
[76] Department of Health, *HIV/AIDS/STD Strategic Plan for South Africa: 2000-2005* (Pretoria: National Department of Health, 2000), p. 19.
[77] Ibid, p. 22.
[78] Department of Health, *Prevention of Mother-to-Child HIV Transmission and Mamanagemenof* [sic] *HIV Positive Pregnant Women* (Pretoria: National Department of Health, 2000).
[79] Department of Health, "Prevention of Mother-to-Child HIV Transmission and Management of HIV Positive Pregnant Women" (2000) [Online]. Available at http://www.doh.gov.za/aids/docs/mtct.html. [22 April 2005].

Conference, the South African government introduced a pilot PMTCT programme in the public health care system. The pilot programme provided Nevirapine and free milk formula to HIV-positive pregnant and lactating women served by the public health care system. The programme would be implemented at 18 pilot sites – two sites in each of the nine provinces. Of the two sites per province, one site would be in an urban location, and one site would be in a rural location. The availability of Nevirapine in the public health care system, however, was limited to the two test sites per province.

One of the main objectives of the pilot project was to collect data that could be used to plan and implement a future, national PMTCT programme in the public health care system.[80] After the first year of implementation, the 18 site pilot programme covered some 193 health facilities, including hospitals, midwife obstetric units, community health centres and clinics. The programme served approximately 6,090 antenatal bookings each month, approximately nine percent of the country-wide bookings in the public health care system.[81]

Controversy over Mother to Child HIV Transmission

The National Department of Health's PMTCT policies attracted a significant attention from actors outside of the government. Between 1998 and 2001, a great deal of controversy surrounded the government's PMTCT policy.

In the late 1990's, an international disputeemerged concerning the procurement of antiretroviral drugs. The resulting conflict would have far reaching implications for the use of antiretroviral drugs for PMTCT. In 1998, the South African government became embroiled in a legal battle with the multinational pharmaceutical companies and in a diplomatic battle with the United States over international intellectual property rights and parallel importation. As was previously noted, 1997 Medicines and Related Substances Control Amendment Act authorised parallel importation of pharmaceutical drugs to South Africa. The legal and diplomatic battle effectively prevented South Africa from purchasing pharmaceuticals through parallel importation for some time. The high prices of antiretroviral drugs made it difficult for the South African government to afford PMTCT pharmaceuticals

[80] Health Systems Trust, *Interim Findings on the National PMTCT Pilot Sites: Lessons and Recommendations* (Durban: Health Systems Trust, 2002), p. 1.
[81] Ibid, p. 1.

during the conflict.

In January 1999, the political rift over PMTCT in the South African government widened when the Western Cape, the only province under the control of the Democratic Alliance (DA) party,[82] broke with the national government's PMTCT policy and commenced the country's first comprehensive PMTCT programme in the public health care system. The programme began at two midwife obstetric units in Khayelitsha, a township outside of Cape Town. The programme provided HIV-positive, pregnant women with AZT monotherapy with the aim of reducing rates of mother to child HIV transmission by approximately 50 percent.[83]

A comprehensive HIV counselling and testing programme, established at both midwife obstetric units, accompanied the provision of AZT. In addition, follow up care programmes, established at nine clinics in the areas surrounding the midwife obstetric units, provided mothers with advice about the benefits of formula feeding in lieu of breastfeeding and offering formula feed free of charge. The follow up care programmes included follow up check-ups for babies born to HIV-positive mothers, checking for signs of HIV infection and performing HIV tests on the babies at nine and 18 months after birth. The Western Cape PMTCT programme openly challenged the national government's stance on the use of antiretroviral drugs for PMTCT. The programme demonstrated the feasibility of a PMTCT programme using antiretroviral medications.

Despite the Western Cape PMTCT programme, cost of antiretroviral drugs continued to be a major impediment to the use of antiretroviral drugs for PMTCT. To fight the high cost of AZT, the government and members of AIDS organisations, including the Treatment Action Campaign (TAC), joined in an unlikely alliance to challenge major international pharmaceutical companies and their drug prices. Pressure from the alliance led Glaxo Wellcome, makers of AZT, to offer a 70 percent price reduction for AZT to the South African government. The government and activists, however, were not satisfied with the offer. Both parties wanted Glaxo Wellcome to make AZT available at or near cost.[84]

In the second half of 1999, the results from the HIVNET012 trial

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[82] The Western Cape was the only provincial government not under the control of the African National Congress. The Democratic Alliance was not bound to national policy by party loyalty, as the other provincial governments were.

[83] Fareed Abdullah, "The Complexities of Implementing Antiretroviral Treatment in the Western Cape Province of South Africa," *Development Update*, 5:3 (2004), p. 249.

[84] "Make AZT Affordable for All", *Cape Argus*, 28 April 1999.

demonstrated the potential of the cheaper drug, Nevirapine, for PMTCT. In light of the ongoing stalemate between the South African government and the international pharmaceutical companies, a more affordable alternative to AZT was incredibly promising.

In mid-1999, following South Africa's second democratic election, Dr. Manto Tshabalala-Msimang replaced Dr. Nkosazana Dlamini Zuma as Minister of Health. Dr. Zuma had refused to include antiretrovirals in the government's PMTCT programme and Dr. Tshabala-Msimang represented hope for policy change. Within weeks of her appointment, the new Minister organised a trip to Uganda for a briefing on the HIVNET012 trials of Nevirapine. Upon return, the Minister proclaimed, "We came back as a South African delegation absolutely inspired, absolutely motivated. If Uganda can do it, so can South Africa. We have fought many battles. We can't be defeated by a virus."[85] As will later be demonstrated, this optimistic stance would not continue for long.

In September 1999, the South African government reached an agreement with the United States government about international intellectual property right and parallel importation. The agreement allowed South Africa to import patented medicines from countries that produced them at the lowest cost. Despite the promising news, Dr. Ian Roberts of the Gauteng Health Department noted, "The government would still not be able to commence with plans to acquire cheap medicines unless pharmaceutical companies withdrew the court case they had brought against the government, or the court decided on the case."[86] The ongoing legal battle meant that the diplomatic agreement had little bearing on pharmaceutical prices.

In July 2000, the 13th International Conference on HIV/AIDS drew attention to the affordability of antiretroviral drugs and South African government's controversial response to the AIDS crisis. President Mbeki's personal affinity for dissident views on HIV/AIDS exemplified the government's response. In his speech opening the conference, the President spoke about poverty and its effects on disease, but refused to acknowledge the link between HIV and AIDS.[87] The President's views agitated national and international actors, attracting negative attention to the government's response to HIV/AIDS and PMTCT.

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[85] "Health Minister Holds News Conference on Return," *Pulsetrack* (22 June 1999).
[86] Robert Herbert and Thembisile Makgalemele, "US Settles Drug Row with SA," *Saturday Star*, 17 September 1999.
[87] "AIDS Lobby Furious At 'Dustbin' Crack," *The Mercury*, 4 July 2000.

Despite the negative reaction incited by the President's controversial remarks, the conference was a source of great hope for efforts to combat HIV/AIDS and MTCT. The results of the South African Intrapartum Nevirapine Trials were announced at the conference, demonstrating the potential of Nevirapine. The spotlight on HIV/AIDS in South Africa prompted Boehringer Ingelheim, the manufacturer of Nevirapine, to offer Nevirapine for the South African public health care system at no cost for five years. The government, however, declined the offer.[88]

Despite the promising developments, the government's reluctance to take action to formulate a comprehensive PMTCT programme in the public health care system continued, and activists became increasingly impatient. In July 2000, TAC threatened the government with legal action if the government did not make antiretroviral medication for PMTCT available in the public health system.[89] In the wake of these threats of legal action, the government agreed that it would formally discuss Nevirapine.[90] TAC was limited in its pursuit of legal action by the fact that the Medicine Controls Council had not registered Nevirapine for PMTCT.[91] TAC decided to delay court action, giving the government time independently to consider the use of Nevirapine.

Despite the threats of legal action, TAC was also reluctant to take the government to court because it was unsure that the court would issue a favourable ruling. In October 2000, legal action became more promising when the Constitutional Court issued a ruling in the case of the *Republic of South Africa vs. Grootboom.* The Grootboom case addressed the claims of Irene Grootboom, a woman whose family was living in "deplorable conditions" in a squatter camp in the Western Cape. Ms. Grootboom felt that the government was not taking reasonable measures to ensure the progressive realisation of the right to access to housing provided for in the Bill of Rights.[92]

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[88] Mark Heywood, "Preventing Mother-to-Child HIV Transmission in South Africa: Background, Strategies and Outcome of the Treatment Action Campaign Against the Minister of Health," *South African Journal of Human Rights,* 19 (2003), p. 285.

[89] "AIDS Group Threatens Mbeki with Court Action." 13 July 2000 [Online]. Available at www.int.iol.co.za/index.php?set_id=13&art_id=qw963505981288B232. [15 December 2004].

[90] Helen Schneider, "On the Fault-Line: the Politics of AIDS Policy in Contemporary South Africa," *African Studies,* 61:1 (2002), p. 149.

[91] Des Parker, Elija Mhlanga, Vince Gilbey, Ismail Suder, and Phindile Ngubane, "Judge Does Turnaround on AIDS Comments," *Daily News,* 21 July 2000.

[92] Joan Fitzpatrick and Ron Slye, "Republic of South Africa v Grootboom. Case No. CCT 11/00. 2000 (11) BCLR 1169 and Minister of Health v Treatment Action Campaign. Case No CCT 8/02," *The American Journal of International Law,* 97:3 (July 2003), pp. 669-670.

The Grootboom case addressed many of the same provisions contained in the Bill of Rights at issue in the conflict over the use of antiretroviral medication for PMTCT. The Grootboom case dealt with section 26 of the Bill of Rights, discussing the right of access to adequate housing (section 26, paragraph 1). The case addressed the obligation of the state to take reasonable legislative and other measures to ensure the progressive realisation of this right within its available resources (section 26, paragraph 2). The case also considered section 28 of the Bill of Rights, granting children the right to shelter (section 28, paragraph 1(c)).

In October 2000, the Constitutional Court issued a ruling in favour of Ms. Grootboom. The Court found, "'No provision in the nation-wide housing programme as applied within the Cape Metro for people in desperate need.' Since that programme made no provision for the relief of such persons, the government's policy was not reasonable."[93]

The Grootboom case was extremely significant for TAC's efforts because it established that socio-economic rights are justiciable,[94] and that the court had a right to intervene in instances where the government was clearly acting in opposition to the provisions of the Bill of Rights. The case would be the basis for TAC's subsequent pursuit of legal action against the government.

In 2001, the Western Cape PMTCT programme provided encouraging evidence of the potential for a successfully implemented PMTCT programme in South Africa. The Western Cape rolled out the programme to antenatal and child health clinics throughout the province. By late 2001, the PMTCT programme reached approximately 50 percent of pregnant women in the province, with plans to reach 90 percent of pregnant women by June 2002, and 100 percent of pregnant women by March 2003.[95] The success of the rollout set an example for a future, nation-wide, PMTCT programme throughout the rest of the country. Furthermore, the programme provided a stark contrast to the inaction in the rest of the country.

In March 2001, the conflict between the South African government and multinational pharmaceutical companies was set to come to a head. The government, joined by TAC, Medicins sans Frontières, the Congress of South African Trade Unions (COSATU), and other international actors, attempted to resolve the conflict

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[93] Ibid, p. 672.
[94] Ibid, p. 670.
[95] High Court of South Africa, Transvaal Provincial Division, *Minister of Health vs. Treatment Action Campaign* (2001) Case No. 21182/2001.

over pharmaceutical pricing. The dispute drew national and international attention, as the alliance spearheaded an international campaign to draw attention to unaffordable pharmaceutical prices. In the face of international criticism, the pharmaceutical companies withdrew from the court case in April 2001.[96] The victory enabled the South African government to purchase antiretroviral drugs at reduced costs through parallel importation.

Each of the events outlined above, which occurred between 1998 and 2001, influenced the interaction by the two main parties involved in the debate over policy on PMTCT. The subsequent discussion will highlight the role that each of these events played in the debate over the formulation and evolution of South African PMTCT policy.

[96] Andy Gray, Thulani Matsebula, Duane Blaauw, Helen Schneider, and Lucy Gilson, *Policy Chance in a Context of Transition: Drug Policy in South Africa 1989-1999* (Johannesburg: Centre for Health Policy, 2002), pp. 39-40.

Chapter 3: The Origin and Development of a Policy Subsystem

Chapter 2 discussed the advances in medical technology that made prevention of mother to child HIV transmission (PMTCT) possible. The chapter also discussed the controversial policy decisions made by entities of the South African government that inhibited the full utilisation of available PMTCT interventions. Lastly, the chapter highlighted some of the controversy that surrounded the government's reluctance to take firm action to plan and implement a comprehensive PMTCT programme in the public health system.

This chapter will incorporate the previous discussion about the medical technology that made PMTCT possible. The chapter will emphasise how advances in medical technology helped to draw attention to PMTCT, leading to what the advocacy coalition framework identifies as the creation of a policy subsystem.

This chapter will describe the formation of opposing groups, or "advocacy coalitions." The chapter will examine the formation of a Treatment Action Campaign (TAC)-led advocacy coalition and the reactionary formation of a government-led coalition. The discussion of the government-led coalition will delve into key beliefs that formed the basis for the coalition's policy decisions.

A Policy Subsystem Emerges

In his discussion of the advocacy coalition framework, Paul Sabatier discusses the creation of a policy subsystem. He states, "The most likely reason for the emergence of a new subsystem is that a group of actors become dissatisfied enough with the neglect of a particular problem by existing subsystems to form their own."[97] This description reflects the situation that evolved in South Africa concerning PMTCT.

Throughout the early and mid-1990's, the South African government did not take action to address PMTCT. The primary reason for government inaction was the lack of viable, effective methods for preventing mother to child HIV transmission (MTCT). Initially, the MTCT was grouped in with the general issue of HIV/AIDS, as there was no impetus for MTCT to receive significant, isolated attention. As we saw in Chapter 2, the situation did not remain static.

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[97] Paul Sabatier, "An Advocacy Coalition Framework of Policy Chance and the Role of Policy-Oriented Learning Therein," *Policy Sciences*, 21 (1988), p. 139.

Amidst a growing global HIV/AIDS pandemic, medical community and pharmaceutical companies began to study methods for preventing MTCT. Over time, a number of PMTCT strategies were identified, including the use of antiretroviral drugs and replacement formula feed. As was previously discussed, major studies examining the use of AZT and Nevirapine in PMTCT took place between 1994 and 1999. The data collected from the studies demonstrated the promise for the fight against MTCT. Both drugs significantly reduced the chances that an HIV-positive mother would transmit HIV to her child during pregnancy, labour and delivery.

In light of the advancements in medical technology, various actors began to express their dissatisfaction with the South African government's inaction on PMTCT. The medical technology capable of preventing MTCT created an opening for the emergence of a new PMTCT policy subsystem. Civil society groups led efforts in the new policy subsystem to influence PMTCT policy.

The Creation of the TAC-Led Coalition

As early as 1997, civil society began to show dissatisfaction with the South African government's failure fully to address PMTCT. Actors began to pressure the government to take action. Organisations such as the AIDS Law Project at the Centre for Applied Legal Studies, the AIDS Consortium, and the Perinatal HIV Research Unit at the University of Witwatersrand lobbied the Minister of Health and the Department of Health to develop PMTCT policy. The goal was "to pressure the government to implement the 'steps to be taken to prevent peri-natal transmission of HIV' listed in the 1994 National AIDS Plan."[98]

On 10 December 1998, the Treatment Action Campaign was founded, grouping together a handful of previously separate activist organisations. The principal objectives of TAC, as outlined in the organisation's Constitution, were to:

> 4.1 Campaign for equitable access to affordable treatment for all people with HIV/AIDS;
> 4.2 Campaign for and support the prevention and elimination of all new HIV infections;
> 4.3 Promote and sponsor legislation to ensure equal access to social services for and equal treatment of all people with HIV/AIDS;
> 4.4 Challenge by means of litigation, lobbying, advocacy and all forms of legitimate social mobilisation, any barrier or obstacle, including unfair discrimination, that limits access to treatment for HIV/AIDS in the private and public sector;

[98] Mark Heywood, "Preventing Mother-to-Child HIV Transmission in South Africa: Background, Strategies and Outcome of the Treatment Action Campaign Against the Minister of Health," *South African Journal of Human Rights*, 19 (2003), p. 280.

> 4.5 Educate, promote and develop an understanding and commitment within all communities of developments in HIV/AIDS treatment;
> 4.6 Campaign for access to affordable and quality health care for all people in South Africa;
> 4.7 Train and develop a representative and effective leadership of people living with HIV/AIDS on the basis of equality and non-discrimination irrespective of race, gender, sexual orientation, disability, religion, sex, socio-economic status, nationality, marital status or any other ground;
> 4.8 Campaign for an effective regional and global network comprising of organisations with similar aims and objectives.[99]

Based on these goals, TAC focused its initial efforts on "raising awareness among people with HIV of treatments, campaigning for lower medicine prices, and advocating the right to treatment using antiretroviral drugs."[100]

Through these efforts, TAC created a unified lobbying force. The TAC-led coalition included, but was not limited to, other nongovernmental organisations, such as the AIDS Law Project, the Legal Resources Centre, the AIDS Consortium, and Medicins sans Frontières[101]; health professionals; academics; university students; and individuals affected by and living with HIV/AIDS.[102] While it is possible to paint a broad picture of participation in the TAC-led coalition, the inner workings of the TAC-led advocacy coalition were likely more complex is apparent on the surface. Current information does not provide a deep enough account into the dynamic among TAC and its allies to reveal the deeper complexities.

Early in its existence, TAC and its allies used public action campaigns to assert their policy beliefs, with the ultimate objective of having these beliefs translated into public policies. TAC quickly assumed the position as leader of the advocacy coalition, taking up PMTCT as its first campaign issue.[103] Initial public action campaigns targeted the government. An additional public action campaign targeted pharmaceutical companies to reduce the price of antiretroviral medications.

The endeavours of TAC and its allies were numerous and varied. Between 1999 and 2001, the TAC led a sustained lobbying effort focusing on PMTCT. Mark

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[99] Treatment Action Campaign, *Constitution of the Treatment Action Campaign* (2004) [Online]. Available at www.tac.org.za. [5 May 2005], pp 2-3.
[100] Mark Heywood, "The Price of Denial," *Development Update*, 5:3 (2004) [Online]. Available at www.interfund.org.za. [22 May 2005], p. 98.
[101] Treatment Action Campaign. *Treatment Action Campaign (TAC) Report for January 2002 - February 2003* (2003) [Online]. Available at www.tac.org.za. [5 May 2005], p. 2.
[102] TAC also enjoyed the support of the Congress of South African Trade Unions (COSATU), although COSATU was not directly involved in the conflict over PMTCT policy. COSATU's partnership with TAC was based on the recognition of the major impact that HIV/AIDS was having on workers.
[103] Helen Schneider, "On the Fault-Line: the Politics of AIDS Policy in Contemporary South Africa". *African Studies*, 61(1) (2002), p. 148.

Heywood, Head of the AIDS Law Project – a major TAC partner – recalled that, "There were meetings with the first and second Ministers of Health, demonstrations, the drafting of memoranda, a 50,000 person petition to the President and a campaign that targeted pharmaceutical companies to reduce the prices of essential anti-retroviral medicines and particularly Glaxo Wellcome's drug, Zidovudine (AZT)."[104]

The TAC-led coalition initially drew its influence through the public mobilisation. The coalition had little or no formal political power to influence the government's policy; however, the intense, public pressure placed on the government made it difficult for the government to ignore the groups.

The Government Coalition Solidifies

As the TAC-led coalition began to mobilise and apply pressure on the government to address PMTCT, members of the government consolidated an advocacy coalition of their own. The government-led advocacy coalition, as it shall now be referred to, was a natural extension of the existing government structure and the party system. The government-led coalition included key players in positions of decision-making power in the government, such as the Minister of Health and the provincial Members of the Executive Council (MECs) for Health from all provinces, except the Western Cape.[105] The coalition enjoyed the support of Thabo Mbeki, who held the position of Vice-President from 1994 to 1999, and assumed the Presidency in 1999.

While the government-led coalition encompassed a number of key government players, it is important to note that the coalition was not inclusive of all members of the government. Members of the government had a wide range of perspectives on PMTCT and available information suggests that there was some degree of disagreement within the government over PMTCT. Despite the absence of total support or a unified position, the government-led coalition's say in the debate over PMTCT was extremely strong because the government is the formal state policy-maker.

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[104] Mark Heywood, "Preventing Mother-to-Child HIV Transmission in South Africa: Background, Strategies and Outcome of the Treatment Action Campaign Against the Minister of Health," *South African Journal of Human Rights*, 19 (2003), p. 281.

[105] The Democratic Alliance party ruled the Western Cape province for a short period in 2001 and thus was not bound to follow the party line of the African National Congress, which ruled the national government and all other provincial governments.

The Debate Begins over PMTCT

As the government-led coalition solidified, it also began to defend its position. During the initial period of debate over PMTCT, members of the government cited a multitude of reasons as to why they were reluctant to proceed with a comprehensive PMTCT programme in the public health care system. Generally, these concerns were related to fears that problems would arise as a programme was implemented. While some concerns were hinted at previously, the justifications for concerns about implementation difficulties expressed by the government now will be examined in greater detail.

First, members of government cited cost as a major factor inhibiting the use of the drug AZT for PMTCT. In a press release dated 27 October 1998, the Department of Health stated, "[The] government has come out in support of the Department of Health's decision not to administer the AZT drug to pregnant women." The Department added, "A detailed study in South Africa has shown that the introduction of the drug would cost about R80 million resulting in a further strain on an already limited health budget."[106]

In March 1999, the Minister of Health reiterated concerns about the price of AZT in an encounter with members of TAC at a Health Portfolio Committee Meeting. Dr Nkosazana Zuma stated, "We cannot afford the [PMTCT] programme because of the high cost of the drugs... It would cost R500 to treat just one pregnant woman and that is too much."[107]

In April 1999, the government appeared to have a change of heart. Following a meeting between Minister Zuma and TAC, the two parties released a joint statement that affirmed that "affordable treatment for HIV/AIDS and all medical conditions is a basic human right." In the statement, Minister Zuma appeared to change her stance, promising, "The government would name an affordable price for the implementation of AZT to pregnant mothers and report within six weeks on the price and other issues pertaining to the prevention of mother to child transmission." The Minister and TAC joined together to call for multisectoral cooperation to pressure on the pharmaceutical companies to reduce the price of HIV/AIDS medications.[108]

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[106] Department of Health, "Government Continues to Focus on AIDS Prevention" (1998) [Online]. Available at http://www.doh.gov.za/mediaroom/index.html. [29 April 2005].
[107] Judith Soal, "I'll Be There In the Front," *Cape Times*, 26 March 1999.
[108] Minister of Health and Treatment Action Campaign, "Joint Statement of the Minister of Health and TAC," 30 April 1999.

TAC actively collaborated with the government to pressure pharmaceutical companies to reduce the prices of AZT and Nevirapine. At a TAC-led protest targeting Glaxo Wellcome, the manufacturer of AZT, Mark Heywood, head of the AIDS Law Project, stated that "We are not the government's friend on this issue, but Glaxo Wellcome could be doing more to make AZT available at cost price. We are fighting for the interests of people living with HIV and for those HIV-positive women who are pregnant."[109]

Both the government-led coalition and the TAC-led coalition refused to make concessions in the fight for lower pharmaceutical prices. When Glaxo Wellcome offered a 70 percent reduction in the price of AZT, both parties rejected the offer, holding out for pricing that they deemed to be appropriate and affordable for the South African context. As was discussed in Chapter 2, the alliance worked together to fight international pharmaceutical companies in a court case concerning parallel importation of pharmaceuticals. The uncomfortable alliance over the pricing of antiretroviral medicines endured as the battle played out against the pharmaceutical companies.

Second, the government expressed fears about the safety and side effects of antiretroviral drugs. In October 1999, President Mbeki ushered in a new debate regarding PMTCT when he questioned the safety of AZT. In a speech to the National Council of Provinces, Mbeki pointed out that there was one court case in the United States and one in the United Kingdom pending, both of which dealt with the safety of AZT. The President claimed that, "The toxicity of [AZT] is such that it is, in fact, a danger to health." Mbeki ordered the Minister of Health to investigate the safety of AZT, adding that the drug would not be used in South Africa until its safety had been confirmed.[110] Rather than reflecting evidence from scientific studies, the concerns expressed by the President reflected a penchant for the views of AIDS dissidents.

On 5 April 2000, the Minister of Health, Dr. Tshabalala-Msimang, made a speech to Parliament, in which she further questioned the safety of antiretroviral drugs for use in PMTCT. The Minister noted that there had been five deaths in South African clinical trials of Nevirapine. In light of the deaths, the Minister called for an investigation into the causes of the deaths. She also called for an investigation into

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[109] Marco Granelli and Vivian Warby, "Mbeki Wants Lower Price for Anti-AIDS Drug," *The Star,* 29 April 1999.

[110] Thabo Mbeki, "Address to the National Council of the Provinces," 28 October 1999, [Online]. Available at http://www.anc.org.za/ancdocs/history/mbeki/1999. [30 June 2005].

the potential links between the deaths and the potential toxicity of Nevirapine, focusing on the high incidences of liver toxicity observed in the trials.[111]

Third, the government noted the need to consider HIV transmission through breast milk. In October 1998, the Department of Health issued a statement stressing that a comprehensive PMTCT programme would need to account for the high dependence on breastfeeding in South Africa.[112] The 13th International Conference on HIV/AIDS focused attention on MTCT through breast milk. The Department of Health noted that, "The research results coming from Durban which suggest[ed] some benefits and reduced rate of transmission in those [HIV-positive mothers] who exclusively breastfed." The Department expressed caution that, "In most of our rural communities, breastfeeding is crucial for infant and young child survival. In these communities, early weaning leads to early death from waterborne diseases."[113]

The government highlighted the need to consider "the implications of the reversal of some of the benefits that attends continued breastfeeding in mothers who have been given antiretrovirals."[114] It was argued that the use of antiretrovirals, such as AZT or Nevirapine, was pointless if not accompanied by efforts to prevent MTCT through breast milk.

Fourth, the government drew attention to the development of resistance to antiretrovirals in newborn child who received the drugs for PMTCT. The Department of Health pointed out that, "Another fact that needs to be critically analysed is the risk of resistance to Nevirapine that formed the [World Health Organisation's] earlier reluctance to recommend Nevirapine for wide scale use in MTCT."[115] The government called for an investigation of resistance documented in the HIVNET012 study in Uganda.[116]

Fifth, as the two sites per province pilot programme began, the government

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[111] Manto Tshabalala-Msimang, "Statement on Nevirapine Drug," Debates of the National Assembly Hansard, 5 April 2000, p. 2023.
[112] Department of Health, "Government Continues to Focus on AIDS Prevention," (1998) [Online]. Available at http://www.doh.gov.za/mediaroom/index.html. [29 April 2005].
[113] Department of Health, "The 13th International AIDS Conference," (2000) [Online]. Available at http://www.doh.gov.za/mediaroom/index.html. [29 April 2005].
[114] Department of Health, "The South African Government's Response to the HIV/AIDS Epidemic: Controversies and Priorities," (n.d.) [Online]. Available at http://www.doh.gov.za/aids/docs/gov-aids.html. [22 April 2005].
[115] Department of Health, "The 13th International AIDS Conference," (2000) [Online]. Available at http://www.doh.gov.za/mediaroom/index.html. [29 April 2005].
[116] Department of Health, "The South African Government's Response to the HIV/AIDS Epidemic: Controversies and Priorities," (n.d.) [Online]. Available at http://www.doh.gov.za/aids/docs/gov-aids.html. [22 April 2005].

began to express concerns about capacity. In August 2000, Dr. Tshabalala-Msimang, the Minister of Health, remarked, "We believe that we should expand the research sites on Nevirapine to all of the provinces so that we can improve our understanding of the operational challenges that would attend any introduction of antiretrovirals to prevent mother to child transmission in the public health system."[117]

Following the United Nations Special Session on HIV/AIDS in 2000, the Department of Health expressed further concerns about the capacity of the public health system to manage the rollout of antiretroviral drugs for PMTCT. The Department explained that there were a number of issues:

> [the Department had] been trying to explain with not much success to those who advocate the wholesale use of antiretroviral drugs in our country without considering the lack of capacity to procure, administer and monitor these drugs in the public health sector. These are no excuses but real challenges facing almost every developing country, and South Africa is no exception.[118]

Generally, the truth and validity of the South African government's claims as to why it was reluctant to proceed with a comprehensive PMTCT programme in the public health care sector have been highly contested. On numerous occasions, the government has been accused of running in the face of scientific evidence, and of bowing to the theories of dissident science.[119] The government has been accused of stalling and wasting time, rather than taking direct, concerted action to prevent MTCT. Furthermore, the government has been accused of prioritising political strategy at the expense of human life.[120] Questioning the truth and the validity of the government's concerns should not lead to an exaggeration of the reality of the situation, as many of the concerns raised by the government were very real.

The formal policy-making power of the government-led coalition allowed the government's concerns to block the formulation of a comprehensive PMTCT programme in the public health care system. The TAC-led coalition's strong disagreement with the government's position on PMTCT would fuel a protracted conflict over PMTCT policy, which will be examined in detail in the subsequent chapters.

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[117] Melanie-Anne Feris, "Health Minister Holds Back AIDS Drug," *The Star*, 13 August 2000.
[118] Department of Health, "Comment on UN Special Session on HIV/AIDS," (2001) [Online]. Available at http://www.doh.gov.za/mediaroom/index.html. [29 April 2005].
[119] Mark Heywood, "Preventing Mother-to-Child HIV Transmission in South Africa: Background, Strategies and Outcomes of the Treatment Action Campaign Case Against the Minister of Health," *South African Journal on Human Rights*, 19 (2003), pp. 298.
[120] S V Kalyan, "Statement on Nevirapine Drug," Debates of the National Assembly Hansard, 5 April 2000, p. 2027.

Chapter 4: The Evolution of a Policy Subsystem

Chapter 3 discussed the emergence of the prevention of mother to child HIV transmission (PMTCT) policy subsystem, the formation of the Treatment Action Campaign (TAC)-led and government-led advocacy coalitions, and the initial debate over PMTCT policy. As was demonstrated, the initial efforts by the TAC-led coalition to convince the government to change its PMTCT policy were largely fruitless. This chapter will delve deeper into the increasingly intense debate in the PMTCT policy subsystem, identifying the static and dynamic factors at play in the battle over PMTCT policy.

This chapter will employ the advocacy coalition framework to highlight the most significant factors influencing the PMTCT policy subsystem. The chapter will discuss the relatively stable system parameters and the dynamic system events that shaped the PMTCT policy subsystem. The discussion of the relatively stable system parameters and the dynamic system events will demonstrate the impact of both on the TAC-led coalition's ability to influence PMTCT policy. Ultimately, key dynamic system events created an opportunity for the TAC-led coalition to involve the court as a policy broker in the conflict over PMTCT policy.

Influence of Key External Factors

Throughout the conflict between the TAC-led coalition and the government-led coalition, a number of factors external to the PMTCT policy subsystem influenced the prospects for policy change in the PMTCT policy subsystem. Paul Sabatier's advocacy coalition framework acknowledges the influence that external factors have on policy change in a policy subsystem. He acknowledges that two sets of external factors – relatively stable parameters and dynamic system events – are of particular influence to policy change in a policy subsystem. These factors "affect the constraints and opportunities of subsystem actors."[121]

Relatively Stable Parameters

The first set of external factors that affect policy change are the "relatively stable parameters," which include:

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[121] Paul Sabatier, "An Advocacy Coalition Framework of Policy Chance and the Role of Policy-Oriented Learning Therein," *Policy Sciences*, 21 (1988), p. 132.

1. the basic attributes of the problem area;
2. the basic distribution of natural resources;
3. the fundamental socio-cultural values and social structure; and
4. basic constitutional structure.

Although these relatively stable system parameters are extremely difficult to change, they have a significant impact on the constraints and opportunities of actors in pursuing policy change.[122]

First, the basic attributes of the problem area influence policy change in a policy subsystem. Sabatier notes, "Public choice theorists have shown how various characteristics of goods, such as excludability, affect institutional (policy) options."[123] He adds:

> ... aspects of the good or problem/issue area affect the degree of learning likely to take place. For example, a problem's susceptibility to quantitative measurement affects the ability to ascertain performance gaps. The extent of learning is likewise contingent upon the ease of developing good causal models of the factors affecting the problem.[124]

PMTCT programmes lend themselves well to policy-oriented learning. The successes or failures of a PMTCT programme can be measured quantifiably and qualitatively.[125] The initial implementation of a PMTCT programme can be evaluated by examining quantitative data, such as:

- the number of health facilities offering PMTCT programmes;
- the number of women accessing HIV counselling and testing;
- the number of women accessing antiretroviral prophylaxis;
- the number of women accessing replacement formula feed; and
- estimated number of infant infections averted.

For example, data on the percentage of women offered HIV counselling and testing services, who agreed to be tested, can be used to monitor and evaluate the success of implementation efforts. Additionally, programme implementation can be gauged by quantitative data on the number of HIV-positive women who were administered antiretroviral prophylaxis to prevent mother to child HIV transmission (MTCT).[126]

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[122] Ibid, p. 134.
[123] Ibid, p. 135.
[124] Ibid, p. 135.
[125] The availability of data on PMTCT programmes is varies from country to country. Regular, reliable data on the health system can be difficult to come by some developing countries where consistent monitoring and evaluation is beyond both capacity and financial means. However, where data is available, the PMTCT problem issue lends itself well to both quantitative and qualitative measurement. In South Africa, health care personnel, government officials and research organizations have teamed together to improve the quality of data gathering, and monitoring and evaluation in the health care system since the democratic transition in 1994.
[126] David McCoy, Mitch Besser, Ronel Visser, and Tanya Doherty, *Interim Findings on the National PMTCT Pilot Sites: Lessons and Recommendation* (Durban: Health Systems Trust, 2002).

Longer term quantitative data on a PMTCT programme can be used to monitor and evaluate of a programme. For example, mother to child HIV transmission rates for PMTCT interventions can be compared to projected rates of infection of HIV in the absence of PMTCT interventions. On a national level, mother to child HIV transmission rates can be compared among provinces and among health facilities to demonstrate the effectiveness of a province or a facility's PMTCT programme.[127]

Additionally, qualitative data collected through surveys of both patients and health care personnel can be used to assess the extent and the quality of PMTCT services. The relative ease with which a PMTCT programme can be measured permits analysis of performance gaps.

Second, the basic distribution of natural resources influences policy change in a policy subsystem. Sabatier states, "The present (and/or past) distribution of natural resources strongly affects a society's overall wealth and viability of different economic sectors, many aspects of its culture, and the feasibility of options in many policy areas."[128]

The link between natural resources and a society's overall wealth is extremely complex. It was once assumed that natural resources enhanced the economic performance of countries; however, a significant body of literature has questioned this assumption, demonstrating that natural resources detract from economic performance in resource rich developing countries. Research has found that the economies of resource rich developing countries often grow slower than the economies of resource poor developing countries.[129,130] Given the extremely complex link between natural resources and a society's overall wealth, it would be presumptuous to assume a direct, or even indirect, link between natural resources in South Africa and the government's PMTCT policy. An examination of the link between natural resources and policy options in South Africa would need to be the subject of a more detailed economic analysis.

In identifying natural resources as a relatively stable parameters, it seems that

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[127] Ibid.

[128] Paul Sabatier, "An Advocacy Coalition Framework of Policy Chance and the Role of Policy-Oriented Learning Therein," *Policy Sciences*, 21 (1988), p. 135.

[129] R. M. Auty and R. Mikesell, *Sustainable Development in Mineral Economies* (Clarendon Press: Oxford, 1998).

[130] Jeffery D. Sachs and Andrew M. Warner, "Natural Resource Abundance and Economic Growth," National Bureau of Economic Research Working Paper 5398, (Cambridge, MA: National Bureau of Economic Research, 1995).

Sabatier is in essence highlighting the link between resources and policy options. The importance of resources to policy is undeniable. Without having to hypothesise about the complex link between South Africa's natural resources and the government's PMTCT policy, it is possible to examine the impact of resources much more generally on the government's PMTCT policy.

As was discussed briefly in Chapters 2 and 3, human resources in the South African public health care system are limited. South Africa faces a number of human resources challenges, including an overall shortage of health care personnel, an unequal geographic distribution of available personnel, an unequal distribution of personnel between the public and private sectors, and the significant attrition of trained personnel from the country.[131] Limited human resources in the public health care sector severely constrained the government's ability to plan and implement a comprehensive PMTCT programme in the public health care system.

Third, the fundamental cultural values and social structure influence policy change in a policy subsystem. In South Africa, PMTCT policy appears to have been fundamentally shaped by the social structure and by a handful of influential cultural values.

Policy-making and policy change in South Africa is fundamentally affected by the social structure entrenched by the system of apartheid. Between 1948 and 1994, the apartheid system created an unequal, segregated society. During the 50 years of the apartheid government, the government carefully planned and implemented policies of "separate development," attempting to segregate all aspects of society.

Inequalities in a country are expressed by the Gini coefficient, which measures inequality on a scale of 0 to 1, with greater inequality as the coefficient approaches 1. Estimates of the Gini coefficient for South Africa in 1994 ranged between 0.54 and 0.65. Gini coefficients for other middle-income countries generally range between 0.45 and 0.63, making South Africa one of the most unequal societies in the world.[132]

Apartheid health care policies created an extremely inequitable public health care system. The inequalities in the South African health care system were firmly entrenched by apartheid policies that prioritised health care for rich, urban whites and

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[131] Ashnie Padarath, Antoinette Ntuli, and Lee Berthiaume, "Human Resources," in Health Systems Trust, *South African Health Review, 2003-2004* (Durban: Health Systems Trust, 2004), p. 300.
[132] D. McIntyre, G. Bloom, J. Doherty, and P. Brijlal, *Health Expenditure and Finance in South Africa* (Durban: Health Systems Trust and the World Bank, 1995), pp. 23-24.

neglected health care for poorer non-white and rural populations.[133] In 1992 and 1993, the inequalities between health care resources in the poorest districts compared to the richest districts the public health care system were striking. Table 4.1 illustrates the extent of the disparities at the time.[134]

Table 4.1: Indicators of the availability of public sector health care resources between magisterial districts (1992/93)

Indicator	"Poorest" Districts	"Richest" Districts
Hospital beds/1,000 population	2.1	3.8
Population per clinic	16,260	12,442
Outpatient visits per capita	1.0	2.6
Doctors (general and specialist) per 100,000 population	5.5	35.6
Nurses per 100,000 population	188.1	375.3
Health Inspectors per 100,000 population	1.1	6.7
Pharmacists per 100,000 population	0.5	5.4

Source: McIntyre et al., 1995[135]

In the 10 years since the democratic transition, inequalities in the public health care system have been reduced; however, the legacy of the apartheid past continues to impact the public health system. Inequalities in infrastructure, human resources, education, and financing continue to have an effect on the public health care system and people's ability to access health care through the public sector. Poorer and rural areas continue to have fewer public health care resources available to them than wealthier, urban areas.

The democratic government has been left with the difficult task of addressing the legacy of apartheid in the public health care system. Prior to the democratic transition, the Freedom Charter of the African National Congress (ANC) called for "a

[133] National Health Accounts Project, "The Need for Health Care," in *Health Financing and Expenditure in Post-Apartheid South Africa* (2001) [Online]. Available at http://www.doh.gov.za/docs/reports/2001/hfe/chap02.pdf. [20 March 2005].

[134] While the data examines disparities between the poorest districts and the richest districts, the system of apartheid created a society in which there was a high correlation between race and class. The 1995 Health Expenditure Review (McIntyre et al., 1995) found that approximately half of the South African population fell into the poorest two quintiles, and that most of the people in the poorest two quintiles were Africans, most of whom resided in the former homeland areas (National Health Accounts Project, 2001, 17).

[135] D. McIntyre, G. Bloom, J. Doherty, and P. Brijlal, *Health Expenditure and Finance in South Africa* (Durban: Health Systems Trust and the World Bank, 1995).

preventive health scheme... run by the state," adding that "free medical care and hospitalisation shall be provided for all, with special care for mothers and young children."[136] In practice, the ANC has found that the legacy of apartheid in the health care system and the realities of limited financial resources have made this ideal an impossibility.

Cultural values promoting breastfeeding also appear to have affected policy on MTCT. As has been previously noted, breastfeeding is problematic for HIV-positive mothers because HIV can be transmitted through breast milk. However, breastfeeding is a strongly engrained practice in a number of South African cultures, linked to cultural values about the role of women as mothers and caregivers.[137] The use of replacement formula feed, in lieu of breastfeeding, as a means of preventing MTCT runs counter to these cultural practices that encourage breastfeeding.

Values promoting breastfeeding were reinforced by the United Nations International Children's Fund (UNICEF) and the World Health Organisation (WHO), and later by the South African government. In 1990, UNICEF and the WHO adopted the *Innocenti Declaration on the Protection, Promotion and Support of Breastfeeding.* The Declaration stated:

> As a global goal for optimal maternal and child health and nutrition, all women should be enabled to practice exclusive breastfeeding and all infants should be fed exclusively on breast milk from birth to 4-6 months of age. Thereafter, children should continue to be breastfed, while receiving appropriate and adequate complementary foods, for up to two years of age or beyond. This child-feeding ideal is to be achieved by creating an appropriate environment of awareness and support so that women can breastfeed in this manner.

In order to attain this goal, the Declaration called for "the reinforcement of a 'breastfeeding culture' and its vigorous defence against incursions of a 'bottle-feeding culture.'"[138] The Declaration shaped the breastfeeding policies of governments throughout the world.

South African policy on breastfeeding was informed by the recommendations contained in the Innocenti Declaration. In 1995, the new democratic government created the Maternal Child and Women's Health Policy, which called for the promotion of exclusive breastfeeding as a priority of the Reconstruction and

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[136] African National Congress, *Freedom Charter* (1955) [Online]. Available at www.anc.org.za/ancdocs/history/charter.html. [13 June 2005].
[137] Liz Walker, Reid Graeme and Morna Cornell, *Waiting to Happen: HIV/AIDS in South Africa* (Boulder, Colorado: Lynne Rienner Publishers, Inc., 2004), p. 50.
[138] UNICEF, *Innocenti Declaration on the Protection, Promotion and Support of Breastfeeding* (1990) [Online]. Available at http://www.unicef.org/nutrition/index_24807.html. [31 August 2005].

Development Programme (RDP). The policy drove government-sponsored campaigns aimed at promoting exclusive breastfeeding.[139] The combined effect of cultural values, international declarations and government policy favouring breastfeeding solidly reinforced breastfeeding as common practice in South Africa.

Forth, the basic legal structure influences policy change in a policy subsystem. "Basic legal norms are quite resistant to change... Basic legal traditions... tend to be rather stable over periods of a decade or more."[140] In South Africa, the Constitution of the Republic of South Africa is the foundation of the basic legal system. While the current South African Constitution only dates back to 1996 with the democratic transition, it is likely that the current Constitution will be the foundation of the South African legal system for a long time to come.

A number of provisions found in the Constitution shaped policy change in the PMTCT policy subsystem. In particular, provisions found in the Bill of Rights allowed the TAC-led advocacy coalition to assert its policy beliefs, while hindering the policy beliefs of the government-led coalition.

Section 27 and section 28 of the Bill of Rights were the foundation for the TAC-led advocacy coalition's policy beliefs. Section 27 of the Bill of Rights states:

> 27. (1) Everyone has the right to have access to -
> (a) health care services, including reproductive health care...
> (2) The state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realization of each of these rights.[141]

Section 28 of the Bill of Rights states that "(1) Every child has the right - ... (c) to basic nutrition, shelter, basic health care services and social services."[142] These two sections buttressed the position advocated by the TAC-led advocacy coalition.

Section 7(2) and section 8(1) of the Bill of Rights created an opportunity for the TAC-led coalition to assert its policy beliefs. Sections 7(2) states that "The state must respect, protect, promote and fulfil the rights in the Bill of Rights."[143] Section 8(1) states, "The Bill of Rights applies to all law, and binds the legislature, the executive, the judiciary and all organs of the state."[144] These sections allowed the TAC-led advocacy coalition to take legal action against the government to compel the

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[139] Department of Health, *Maternal Child and Women's Health Policy* (Pretoria: National Department of Health, 1995), p. xi.
[140] Paul Sabatier, "An Advocacy Coalition Framework of Policy Chance and the Role of Policy-Oriented Learning Therein," *Policy Sciences*, 21 (1988), p. 136.
[141] Constitution of the Republic of South Africa, 1996, Chapter 2, Section 27.
[142] Constitution of the Republic of South Africa, 1996, Chapter 2, Section 28.
[143] Constitution of the Republic of South Africa, 1996, Chapter 2, Section 7.
[144] Constitution of the Republic of South Africa, 1996, Chapter 2, Section 8.

Development Programme (RDP). The policy drove government-sponsored campaigns aimed at promoting exclusive breastfeeding.[139] The combined effect of cultural values, international declarations and government policy favouring breastfeeding solidly reinforced breastfeeding as common practice in South Africa.

Forth, the basic legal structure influences policy change in a policy subsystem. "Basic legal norms are quite resistant to change... Basic legal traditions... tend to be rather stable over periods of a decade or more."[140] In South Africa, the Constitution of the Republic of South Africa is the foundation of the basic legal system. While the current South African Constitution only dates back to 1996 with the democratic transition, it is likely that the current Constitution will be the foundation of the South African legal system for a long time to come.

A number of provisions found in the Constitution shaped policy change in the PMTCT policy subsystem. In particular, provisions found in the Bill of Rights allowed the TAC-led advocacy coalition to assert its policy beliefs, while hindering the policy beliefs of the government-led coalition.

Section 27 and section 28 of the Bill of Rights were the foundation for the TAC-led advocacy coalition's policy beliefs. Section 27 of the Bill of Rights states:

> 27. (1) Everyone has the right to have access to -
> (a) health care services, including reproductive health care...
> (2) The state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realization of each of these rights.[141]

Section 28 of the Bill of Rights states that "(1) Every child has the right - ... (c) to basic nutrition, shelter, basic health care services and social services."[142] These two sections buttressed the position advocated by the TAC-led advocacy coalition.

Section 7(2) and section 8(1) of the Bill of Rights created an opportunity for the TAC-led coalition to assert its policy beliefs. Sections 7(2) states that "The state must respect, protect, promote and fulfil the rights in the Bill of Rights."[143] Section 8(1) states, "The Bill of Rights applies to all law, and binds the legislature, the executive, the judiciary and all organs of the state."[144] These sections allowed the TAC-led advocacy coalition to take legal action against the government to compel the

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[139] Department of Health, *Maternal Child and Women's Health Policy* (Pretoria: National Department of Health, 1995), p. xi.
[140] Paul Sabatier, "An Advocacy Coalition Framework of Policy Chance and the Role of Policy-Oriented Learning Therein," *Policy Sciences*, 21 (1988), p. 136.
[141] Constitution of the Republic of South Africa, 1996, Chapter 2, Section 27.
[142] Constitution of the Republic of South Africa, 1996, Chapter 2, Section 28.
[143] Constitution of the Republic of South Africa, 1996, Chapter 2, Section 7.
[144] Constitution of the Republic of South Africa, 1996, Chapter 2, Section 8.

government to fulfil the provisions contained in the Bill of Rights.

The relatively stable system parameters set the context of PMCTC policy subsystem. The parameters created both opportunities and barriers to policy change. Given that these parameters are by nature difficult, if not impossible, to change, advocacy coalitions had to navigate the landscape, using positive system parameters to their advantage and downplaying parameters that were detrimental to their beliefs.

Dynamic System Events

Sabatier's second set of external factors affecting policy change are "dynamic system events." The dynamic system events that Sabatier highlights include:

1. changes in socio-economic conditions and technology;
2. changes in systemic governing coalitions; and
3. policy decisions and impacts from other subsystems.

Sabatier states:

> By altering the constraints and opportunities confronting subsystem actors, they constitute one of the principal dynamic elements affecting policy change. They also present a continuous challenge to subsystem actors to learn how to anticipate and to respond to them in a manner consistent with their basic beliefs and interests.[145]

The key dynamic system events in the PMTCT policy subsystem will be highlighted briefly.

First, changes in socio-economic conditions and technology influence policy change in a policy subsystem. Sabatier observes, "These [changes] can substantially affect a subsystem, either by undermining the causal assumptions of present policies or by significantly altering the political support of various advocacy coalitions."[146]

As has been previously noted, a number of changes in socio-economic conditions and technology affected policy change in the PMTCT policy subsystem. Of particular note among these changes were the development and endorsement of AZT and Nevirapine. The two drugs made it possible to use medical interventions to prevent MTCT during pregnancy, labour and delivery.

Second, changes in systemic governing coalitions bring a new governing coalition to power with a new approach to a policy issue.[147] During the time period under consideration, there was no major change in the national governing coalition.

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[145] Paul Sabatier, "An Advocacy Coalition Framework of Policy Chance and the Role of Policy-Oriented Learning Therein," *Policy Sciences*, 21 (1988), p. 136.
[146] Ibid, p. 136.
[147] Ibid, p. 137.

Since the democratic transition in 1994, the ANC has enjoyed the solid support of the vast majority of the South African voters. Electoral support for the ANC in national elections has been on the rise. The ANC won 62.6 percent of the national vote in 1994,[148] 66.35 percent of the national vote in 1999,[149] and 69.69 percent of the vote in 2004.[150]

In 2000, the Western Cape experienced a short-lived change in political power. In 2000, the Democratic Party joined with the New National Party to form the Democratic Alliance (DA), which took control of the provincial government of the Western Cape. The alliance only lasted into 2001, but the short change in political power provided the province with an important window of opportunity to break with national PMTCT policy. When the national government began the two sites per province rollout of Nevirapine, the Western Cape, under DA control, refused to limit the provision of the drug to the two test sites.[151] The Western Cape rollout became a shining example of a successful South African PMTCT programme involving antiretrovirals. It highlighted the viability of a multi-phased rollout. Furthermore, it demonstrated that a comprehensive PMTCT programme in the public health care system could have successes in the South African context.

Third, policy decisions and impacts from other subsystems affect a policy subsystem. Sabatier points out that "[s]ubsystems are only partially autonomous. In fact, the decisions and impacts from other policy subsystems are one of the principal dynamic events affecting specific subsystems."[152] A significant number of policy decisions and impacts from other subsystems affected policy change in the PMTCT policy subsystem, the majority of which were mentioned in Chapter 2. These policies had an impact on three key areas: the affordability of antiretroviral medication, the use of Nevirapine for PMTCT, and the court system's ability to enforce provisions of the Bill of Rights.

The Medicines and Related Substances Control Amendment Act in 1997

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[148] Independent Electoral Commission, (1994). "Elections '94," [Online]. Available at http://www.elections.org.za/Elections94.asp. [13 July 2005].
[149] Independent Electoral Commission, "National Election '99: National Results Per Party," (1999) [Online]. Available at http://www.elections.org.za/Results/natperparty.asp. [13 July 2005].
[150] Independent Electoral Commission, "National and Provincial Elections 2004," (2004) [Online]. Available at http://www.elections.org.za/elections2004_static.asp. [13 July 2005].
[151] Nico Steytler, "Federal Homogenity from the Bottom Up: Provincial Shaping of National HIV/AIDS Policy in South Africa," *Publius*, 33:1 (2003).
[152] Paul Sabatier, "An Advocacy Coalition Framework of Policy Chance and the Role of Policy-Oriented Learning Therein," *Policy Sciences*, 21 (1988), p. 137.

promised more affordable medications in South Africa, purchased through parallel importation. The controversy and legal battle with the U.S. Government and multinational pharmaceutical companies prevented the South African government from purchasing pharmaceuticals through parallel importation, a practice which would have driven down the cost of medications. The ensuing legal battle over parallel importation effectively kept the prices of pharmaceuticals, such as AZT, at an unaffordable level, rendering a potential AZT rollout for PMTCT financially infeasible.

The September 1999 agreement between the United States and South Africa regarding parallel importation of pharmaceuticals created hope for price reductions. While the legal battle with multinational pharmaceutical companies over parallel importation prevented South Africa from engaging in parallel importation, the agreement with the United States provided hope for a positive resolution.

The July 2000 announcement that the manufacturers of Nevirapine would make the drug available in the public health system free of charge for five years further eased concerns about the cost of antiretroviral medications. Despite the fact that the government failed to take advantage of the offer, the offer was significant in that the cost of Nevirapine could no longer be cited as a credible reason for the government's reluctance to provide the drug as part of a comprehensive PMTCT programme in the public health care system.

The resolution of the conflict over parallel importation between the South African government and multinational pharmaceutical companies eased concerns about the cost of antiretroviral medications. In March 2001, the South African government and the pharmaceutical companies went to court, and in April 2001, the pharmaceutical companies withdrew unconditionally from legal action following intense international pressure to do so. After the pharmaceutical companies withdrew from legal action, the South African government was free to purchase pharmaceuticals, including antiretroviral drugs, through parallel importation, a move that would lower costs of the medications.

In addition, policy decisions and impacts from other subsystems affected the use of antiretroviral medications for PMTCT. In January 2001, the World Health Organisation (WHO) issued a formal recommendation of Nevirapine for PMTCT. The WHO recommendation signalled an international acceptance and endorsement of the drug. The recommendation further legitimated calls for the medications to be a

cornerstone of a comprehensive PMTCT programme in the public health care system.

In April 2001, the South African Medicines Control Council (MCC) registered Nevirapine for PMTCT use. The registration of Nevirapine by the MCC signalled that the body had found the drug to be suitable for PMTCT, and that it was safe, of acceptable quality, and therapeutically efficacious.[153] Following the MCC registration, the South African government could no longer credibly question the safety and efficacy of the drug, although they would continue to do so with diminished credibility.

Additionally, policy decisions and impacts from other subsystems affected the court system's ability to enforce the provisions contained in the Bill of Rights. The Constitutional Court decision on the *Republic of South Africa v. Grootboom* case established that socio-economic rights are justiciable,[154] and that the court had a right to intervene in instances where the government was clearly acting in opposition to the provisions of the Bill of Rights. The Grootboom case provided a foundation for TAC's pursuit of legal action against the government.

TAC Changes Their Strategy

Ultimately, the changes in the dynamic system events converged with the relatively stable system parameters to create a new opportunity for the TAC-led coalition to pursue policy change in the PMTCT policy subsystem. Advances in technology made PMTCT possible. Changes in the governing coalition in the Western Cape opened up the doors for to a new PMTCT policy in the province. Barriers cited by the government as constraining the formulation and implementation of a comprehensive PMTCT programme in the public health care system, such as high pharmaceutical costs and the absence of formal approval of antiretroviral drugs for use in PMTCT, broke down as pharmaceutical prices fell and as Nevirapine was approved by domestic and international authorities. Informal barriers discouraging the pursuit of legal action by the TAC-led coalition were removed following the ruling in the Grootboom case.

New opportunities for influencing PMTCT policy had emerged that prompted

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[153] Constitutional Court of South Africa, *Minister of Health vs. Treatment Action Campaign* (2002) Case No. CCT 8/02, p. 14.

[154] Joan Fitzpatrick and Ron Slye, "Republic of South Africa v Grootboom. Case No. CCT 11/00. 2000 (11) BCLR 1169 and Minister of Health v Treatment Action Campaign. Case No CCT 8/02," *The American Journal of International Law,* 97:3 (July 2003), p. 670.

the TAC-led coalition to adopt a new strategy. The coalition would pursue a two-pronged strategy of legal action against the government, paired with public action campaigns. Legal action was a strategy of last resort, as it was acknowledged that it would be detrimental to partnerships between government and civil society; however, public action campaigns alone had failed to influence the government's PMTCT policy.

On 19 August 2001, TAC officially announced that it would pursue legal action against the national Minister of Health and the provincial Members of the Executive Council (MECs) for Health. In a press release, TAC noted that lobbying efforts "to persuade the government to act urgently on [the matter of PMTCT had] been rebuffed." TAC proclaimed:

> In July, attorneys for the Treatment Action Campaign wrote to the Minister and MEC's for Health, requesting reasons why Nevirapine is not being made widely available to prevent mother-to-child-transmission of HIV, as well as a clear national policy on mother-to-child transmission prevention (MTCTP). The Minister's response was unsatisfactory.[155]

TAC saw themselves as the protectors of poor and vulnerable people whose constitutional rights were being violated by the government's failure to take action on the issue.[156]

On 21 August 2001, TAC served the Minister of Health and the nine Provincial Health Ministers with legal papers, seeking relief from the High Court for two demands:

> 1.) ...the medicine Nevirapine, which is of undisputed safety and efficacy in reducing the risk of HIV transmission during delivery and for a period afterwards, be made available for prescription by doctors and other medical professionals who work in the public health sector to pregnant women with HIV... [and]
>
> 2.) that the government provide, or be ordered to provide, a comprehensive national plan that aims to prevent mother-to-child infections, including provision of necessary services such as voluntary counselling and testing and formula as a substitute for breastfeeding.[157]

On 24 August 2001, TAC called for public mobilisation in support of the legal action. TAC urged the public to take action through a public action campaign, aimed at:

> 1. Getting more people involved in support of this social and political campaign to make essential medicines to pregnant mothers and their babies.

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[155] Treatment Action Campaign, "Press Alert, 19 August 2001: TAC to Announce Details of Court Action to Save Lives," (2001) [Online]. Available at www.tac.org.za. [14 December 2004].
[156] Ibid.
[157] Mark Heywood, "Memorandum on the Mother-to-Child Case for TAC Activists and International Supporters," (2001) [Online]. Available at www.tac.org.za. [14 December 2004].

> 2. Convincing the MECs in all nine provinces not to oppose the court case and to start implementing the MTCT programme as widely as possible.[158]

TAC hoped that legal action could be avoided should the Department of Health meet their specific requests.

On 18 October 2001, TAC issued an open letter to the Minster of Health, calling on the Minister to take action to resolve the dispute before the case went to court the following month. The letter reiterated the demands that doctors in the public health system be allowed to prescribe Nevirapine for PMTCT, and that the government formulate a comprehensive PMTCT plan.

TAC appealed to the Minister to resolve the matter, stating:

> Legal proceedings were our last resort – they give people who have lost faith in the government a legitimate and legal avenue to defend their constitutional rights to healthcare access, life, dignity and equality. We appeal to you to abandon your opposition to the court case and to once again give people hope in the government. The world was heartened by the unity we displayed earlier this year against the pharmaceutical industry – we are willing to work with you in doing the right thing.[159]

TAC was intent on pursuing their goals and defending constitutional rights of HIV-positive people, but was by no means intent on pursuing court action if it could be avoided. The Minister of Health showed no signs of submitting to TAC's requests.

On 22 October 2001, the government officially opposed TAC's application, filing over 1,000 pages of replying papers. "The state opposed the TAC case on the grounds that the relief was unaffordable, that the efficacy and safety of Nevirapine was not fully proven and that its widespread use risked a public health catastrophe."[160]

On 5 November 2001, TAC lodged its replying affidavits to the legal papers submitted by the Department of Health.[161] On 22 November, TAC announced the details of a national and international mobilisation campaign to support the court action.[162] On 25 and 26 November 2001, the mass mobilisation campaign culminated with rallies, marches and an all-night vigil of 600 TAC members outside of the court

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[158] Treatment Action Campaign, "Press Alert, 24 August 2001: TAC to Picket Provincial Health Departments and National Parliament," (2001) [Online]. Available at www.tac.org.za. [14 December 2004].

[159] Treatment Action Campaign, "Open Letter to Minister Tshabalala-Msimang and all MECs for Health," 18 October 2001 [Online]. Available at www.tac.org.za. [14 December 2004].

[160] Mark Heywood, "Preventing Mother-to-Child HIV Transmission in South Africa: Background, Strategies and Outcome of the Treatment Action Campaign Against the Minister of Health," *South African Journal of Human Rights*, 19 (2003), 296.

[161] Treatment Action Campaign, "TAC Replies in MTCT Court Case," 6 November 2001. [Online]. Available at www.tac.org.za. [14 December 2004].

[162] Treatment Action Campaign, "TAC to Announce Plans for National and International Mobilisation Supporting Court Case," 21 November 2001. [Online]. Available at www.tac.org.za. [14 December 2004].

building where the case was to be heard.[163]

[163] Mark Heywood, "Preventing Mother-to-Child HIV Transmission in South Africa: Background, Strategies and Outcome of the Treatment Action Campaign Against the Minister of Health," *South African Journal of Human Rights,* 19 (2003), p. 300.

Chapter 5: The Involvement of a Policy Broker

Chapter 4 examined the changes in the prevention of mother to child HIV transmission (PMTCT) policy subsystem that created an opportunity for the Treatment Action Campaign (TAC)-led coalition to involve the courts in the conflict. Paul Sabatier's advocacy coalition framework acknowledges the key role of "policy brokers" in mediating conflict between competing coalitions, with the aim of reducing conflict between coalitions and finding a reasonable compromise between coalitions.

This chapter will examine the involvement of the courts as a policy broker, mediating the conflict between the TAC-led coalition and the government-led coalition. The chapter will look at the initial case in the High Court and the reaction to the High Court ruling. The chapter will consider the subsequent Constitutional Court hearing, resulting from the government's appeal of the High Court's ruling. The chapter will highlight the Constitutional Court ruling and the implications of the ruling for PMTCT policy. In the end, the involvement of the courts as a policy broker in the conflict produced a favourable outcome for the TAC-led coalition – the government was legally mandated to alter its PMTCT policy.

Initiation of Legal Proceedings

The TAC-led coalition, composed of lobby groups, public health officials, academics and individuals affected by and infected with HIV/AIDS, had engaged in extensive lobbying efforts to compel the government to implement a comprehensive PMTCT programme in the public health system. When it came time to initiate legal proceedings against the government, supporters of the TAC-led coalition united in a formal legal alliance to oppose the government in court. TAC joined with Dr. Haroon Saloojee and the Children's Rights Centre as the three applicants in the case.

The TAC-led coalition was supported by a variety of individuals and organisations associated with the coalition, including:

> The AIDS Law Project – one of the leading human rights projects for people with HIV/AIDS internationally;
> The AIDS Consortium – an affiliation of more than 500 community-based AIDS organisations and [nongovernmental organisations];
> The Congress of South African Trade Unions – the leading trade union federation with nearly two million members;
> The New Women's Movement – a grassroots women's organisation; and

The Southern African Catholic Bishops Conference.[164]

In addition, the coalition was supported, to varying degrees, by allies of Dr. Saloojee and the Children's Rights Centre. Dr. Saloojee was backed by over 250 health care professionals, the South African Paediatricians Association (SAPA), and Dr. Max Price, Dean of Health Sciences at the University of Witwatersrand.[165] The Children's Rights Centre worked closely with the Coalition for Children's Rights in an HIV-Positive World, a coalition consisting of over 70 organisations in KwaZulu-Natal, concerned with health, development and legal services for children and families living with and affected by HIV/AIDS.[166]

A number of individuals provided invaluable support to the coalition through testimony in the applicants' favour. While many of the witnesses were not actively involved outside of the court in the fight over government policy, the testimony that they provided spoke to the core beliefs of the TAC-led coalition and convinced previously immobilised actors of the truth and validity of the coalition's claims.

The role played by members and partners of the Western Cape Department of Health was also of note. As was previously discussed, the Western Cape was planning and implementing a comprehensive PMTCT programme in the province's public health care system. While most representatives of the Western Cape were not openly aligned with the TAC-led coalition, the example set by the province's PMTCT programme provided compelling evidence, noted in the court case, supporting the arguments of the TAC-led coalition.

As was previously discussed, the inner workings of TAC-led advocacy coalition were undoubtedly more complex than this basic list of coalition partners can convey. Current information provides a superficial picture of the TAC-led coalition, but does not delve into the deeper complexities. Given the available information, the basic description of the TAC-led coalition provided above will have to suffice.

The High Court Hearing

In November 2001, the Pretoria High Court began to hear the case led by the TAC-led coalition against the government. In the court case, the applicants argued:

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[164] Treatment Action Campaign, *The Treatment Action Campaign and Others v. The Minister of Health and Others* (n.d.).
[165] Ibid.
[166] Ibid.

1. The state must make Nevirapine available to women who are HIV-positive and give birth in the public health sector. The state must allow doctors clinical independence to prescribe this drug in the public health service.
2. The state is obliged to implement and set out clear time frames for a national programme to prevent mother-to-child transmission of HIV. This includes voluntary testing and counselling, anti-retroviral therapy and the option to use formula milk for feeding purposes.[167]

The applicants based their demands on key provisions found in the Bill of Rights. These provisions, found in Sections 27 and 28, discuss access health care and the right of children to basic health care.[168] The applicants contended that the restrictions of Nevirapine to two test sites per province violated the constitutional right to access to health care, as well as the right of every child to basic health care. Additionally, the applicants argued that the provision of the Bill of Rights, calling the progressive realisation of the right to have access to health care, required the government to formulate and implement a comprehensive PMTCT programme throughout the country.[169]

The applicants' testimony addressed the issues at stake from a variety of perspectives. Witnesses from the fields of paediatrics, pharmacology, epidemiology, public health, economics and statistics provided specialised testimony on PMTCT. Doctors, nurses and other health professionals discussed the daily challenges of HIV/AIDS and PMTCT. HIV-positive individuals called for access to Nevirapine outside the designated pilot facilities.[170]

Bu contrast, the government's testimony expressed concerns about factors inhibiting the implementation of a comprehensive PMTCT programme. Government officials and health professionals testified to the challenges impeding the implementation of a comprehensive, nation-wide PMTCT programme in the public health care system.

The High Court Ruling

On the 14 December 2001, the High Court handed down a decision on the case. The ruling, written by Judge Chris Botha, found in favour of the TAC-led coalition. In the decision, Botha noted:

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[167] Mark Heywood, "Preventing Mother-to-Child HIV Transmission in South Africa: Background, Strategies and Outcome of the Treatment Action Campaign Against the Minister of Health," *South African Journal of Human Rights,* 19 (2003), p. 294-295.
[168] Constitution of the Republic of South Africa, 1996, Chapter 2, Section 27 and 28.
[169] Constitutional Court of South Africa, *Minister of Health vs. Treatment Action Campaign* (2002) Case No. CCT 8/02, pp. 4-5.
[170] Ibid, pp. 5-6.

> ...the real issue is whether the steps taken by the first to ninth respondents with regard to the prevention of MTCT of HIV by establishing 18 pilot sties and confining the dispensing of Nevirapine to those sites, can be considered to be a compliance with the obligation of the State in terms of section 27(2).[171]

Reasonable measures to achieve the progressive realisation of the right to access to health care were dictated by available resources.[172]

Botha asserted that there was incontrovertible evidence suggesting that capacity existed outside the designated pilot sites, concluding that the respondents' policy limiting the use of Nevirapine to the pilot sites was "not reasonable and... [was] an unjustifiable barrier to the progressive realisation of the right to health care."[173]

Botha held that the evidence led him to conclude that the state did not have a "comprehensive and coordinated plan for a roll out of the MTCT prevention programme." He added:

> About one thing there must be no misunderstanding: a countrywide MTCT prevention programme is an ineluctable obligation of the State. ... To the extent that the impression was created in the affidavits filed on behalf of some of the respondents that the further roll out of the programme will depend on the availability of resources, it must be dispelled. The resources will have to be found progressively. The availability of resources can only have an influence on the pace of the extension of the programme. But there must be a plan for a further roll out.[174]

Botha issued nine orders in the judgment on the case, ruling that the first through ninth respondents were obliged and consequently ordered:

> To make Nevirapine available to pregnant women with HIV who give birth in the public sector, and to their babies, in public health facilities to which the respondents' present programme for the prevention of mother-to-child transmission of HIV has not yet been extended, where in the opinion of the attending medical practitioner, acting in consultation with the medical superintendent of the facility concerned, this is medically indicated, which shall at least include that the woman concerned has been appropriately tested and counselled.[175]

Additionally, Botha ruled that the first through ninth respondents were under a duty and consequently ordered:

> To plan an effective comprehensive national programme to prevent or reduce the mother-to-child transmission of HIV, including the provision of voluntary counselling and testing, and where appropriate, Nevirapine or other appropriate medicine, and formula milk for feeding, which programme must provide for its progressive implementation to the whole of the Republic, and to implement it in a reasonable manner.[176]

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[171] High Court of South Africa, Transvaal Provincial Division, *Minister of Health vs. Treatment Action Campaign* (2001) Case No. 21182/2001.
[172] Ibid.
[173] Ibid.
[174] Ibid.
[175] Ibid.
[176] Ibid.