The bit in the middle: a synthesis of global health literature on policy formulation and adoption

David Berlan,[1]* Kent Buse,[2] Jeremy Shiffman[3] and Sonja Tanaka[2]

[1]Askew School of Public Administration and Policy, Florida State University, 650 Bellamy, Tallahassee, FL 32306-2250, USA [2]The Joint United Nations Programme on HIV/AIDS, Geneva, Switzerland [3]American University, Washington, DC, USA

*Corresponding author. Askew School of Public Administration and Policy, Florida State University, 650 Bellamy, Tallahassee, FL 32306-2250, USA. E-mail: dberlan@fsu.edu

Policy formulation and adoption are poorly understood phases of the health policy process. We conducted a narrative synthesis of 28 articles on health policy in low- and middle-income countries to provide insight on what kinds of activities take place in these phases, the actors crafting policies and the institutions in which policy making occurs. The narrative synthesis involved an inductive process to identify relevant articles, extract relevant data from text and reach new understandings. We find that actors exercising decision-making power include not just various governmental entities, but also civil society, commissioners, nongovernmental organizations and even clergy. We also find that most articles identified two or more distinct institutions in which policy formulation and adoption occurred. Finally, we identify seven distinct activities inherent in policy formulation and adoption: generation of policy alternatives, deliberation and/or consultation, advocacy of specific policy alternatives, lobbying for specific alternatives, negotiation of policy decisions, drafting or enacting policy and guidance/influence on implementation development. Health policy researchers can draw on these categories to deepen their understanding of how policy formulation and adoption unfolds.

KEY MESSAGES

- Processes surrounding policy formulation and adoption in global health are poorly understood, under-theorized and under-researched.

- We identify seven distinct groups of activities that may occur during policy formulation and adoption, including drafting of alternatives, lobbying and providing guidance on implementation.

- These seven sets of activities provide a foundation for advancing research on this stage of the policy process.

Introduction

In this article, we synthesize literature focusing on health policy change in low- and middle-income countries (LMICs) to provide greater analytical clarity around the phase of the policy process bridging agenda setting and implementation.

This phase, which we term 'the bit in the middle', is commonly referred to as policy formulation, -adoption, -making or -diffusion. In addition, we use this synthesis to create a map of scholarly articles describing such processes and develop

questions for future research about this phase of the health policy process.

Part of a broader project to utilize synthesis methodologies to improve understanding of the policy process in global health and build the field of health policy analysis, this article is a companion to pieces on agenda setting (Walt and Gilson, 2014) and implementation (Erasmus, 2014; Erasmus, et al., 2014; Gilson, et al., 2014). The three 'mapping' articles in this series, Walt and Gilson, Erasmus *et al.*, and this article, draw upon a common body of health policy analysis literature, but consider only articles relevant to the specific policy stage in question. Each article uses a common group of analytic tools, synthesis methodologies, differing in the specific techniques used.

The area between agenda setting and policy implementation is relatively neglected in the literature, yet crucial to policy design and in determining whether the policy will achieve its intended purposes. Combining two of the more frequent names used for the phase, we refer to it as 'policy formulation and adoption'. The stage also raises unique questions and involves actors and processes that may differ substantially from the other stages in the policy cycle. For example, issue champions, civil society organizations and the media may be more centrally involved in setting agendas; technical experts and parliamentarians in policy formulation; while nurses, doctors and street level bureaucrats are more heavily involved in the implementation stage. The various processes leading to selection of specific policy alternatives appears to fall outside of both agenda setting and implementation, such as considering the pros and cons of different policy design options, consultation, negotiations and drafting of legislation. Poorly understood in theory and global health research, this 'bit in the middle' demands greater appreciation of the kinds of actors, institutions and processes encompassed in it.

We begin this article by examining theories of the policy process for existing definitions of policy formulation and adoption. Then, we discuss the methodology we selected for the analysis, narrative synthesis, detail the steps undertaken in this research project and introduce the body of articles we draw upon. We follow with the heart of this article, the synthesis of the literature, in which we identify cross-cutting themes, seek conceptual clarity on the bit in the middle and map the terrain covered by the literature. Through this synthesis, we identify seven distinct 'bits' rather than a single 'bit in the middle', providing future scholars with a more holistic and systematic approach for analysing policy formulation and adoption. These seven bits, groups of activities within policy formulation and adoption, can serve as a framework for future scholarship. We close by discussing the limitations of this article, conclusions we can draw and future steps that can build upon this research.

Drawing on policy process theory to delineate boundaries for examination

As a starting point for synthesizing articles, we needed boundaries for our analysis. Drawing on conceptualizations of this phase from policy process theories, we found the most useful boundaries to be policy activities that follow agenda setting (when issues come to receive policy-maker attention), and that precede implementation (when services are delivered).

Although Sabatier (1991) and others question the validity of a stages heuristic approach to policy analysis, viewing such a model as too linearly constricted, value remains in separating distinctive elements of the policy process. In particular, the stages model permits examination of a more limited group of related processes, establishes boundaries around an object of study and/or identifies related processes for improved comparability. The policy cycle variant of the stages heuristic, such as described in a review of policy process theories by Jann and Wegrich (2007), partially inspired the separation of this article from its two companion-mapping articles. The authors provide a clear definition of the formulation stage. 'During this stage of the policy cycle, expressed problems, proposals and demands are transformed into government programmes. Policy formulation and adoption includes the definition of objectives—what should be achieved with the policy—and the considerations of different action alternatives'. (Jann and Wegrich 2007, p. 48).

Grindle and Thomas's (1989) 'decision making' provides a conceptualization of the 'bit in the middle' that places primary emphasis on adoption and a lesser focus on formulation. Influenced by whether the context of the issue in question is a 'perceived crisis' or 'politics-as-usual' (p. 235), the authors treat decision making as clearly subsequent to agenda setting in their model of the policy process, much like Jann and Wegrich. In turn, the characteristics of the policy created through the decision-making process influence the succeeding stages of implementation and sustainability. By placing these processes into a linear progression, Grindle and Thomas devise a stages model of policy making with a distinct stage, decision making, which despite the new label fits within conceptions of policy adoption and formulation.

Kingdon's (1984) streams model of agenda setting covers both agenda setting and policy formulation and adoption. For Kingdon, policy is made, or changed, when three independent streams of activity intersect—problems, policies and politics. The 'problem' stream fits cleanly within agenda setting, but both the 'policy' and 'politics' streams can be perceived as fitting within both agenda setting and some conceptualization of policy formulation and adoption. The policy stream, perhaps most relevant to this stage, is the development of competing proposals by experts. In this stream, ideas are tested, altered and winnowed down, both consciously and by chance events, to a narrower set of choices which may or may not come to the attention of a relevant set of policy makers at some point in time. The political stream, which includes elements such as change in government, interacts with the policy stream, closing off some policy proposals and supporting others. A model of policy formulation and adoption drawing upon Kingdon would then include two separate processes he identifies as part of a simplified model of policy making, 'specification of alternatives' and 'authoritative choice among those specified alternatives' (p. 3).

Drawing from scholarship on agenda setting, particularly Kingdon (1984), we emerge with agenda setting at its core being the attention paid to competing issues in society. For our most restrictive definition, then, we view agenda setting as the attention and discussion paid to an issue, not the specific decisions, budgetary allocations or policies enacted to address these issues, even though Kingdon and others would attribute

all or some of these latter acts as either part of the agenda-setting process or evidence of an agenda having been set.

On the other side of policy formulation and adoption, to identify the most relaxed boundary with implementation, we needed a core definition that satisfies both top-down and bottom-up views of the implementation stage. For top-down scholars, 'policy implementation encompasses those actions by public and private individuals (or groups) that are directed at the achievement of objectives set forth in prior policy decisions' (Van Meter and Van Horn 1975, p. 447). Scholars viewing implementation as emerging from the bottom-up would disagree, and see this stage beginning with citizens/consumers influencing service providers and eventually policy makers (Matland 1995). Work unifying the two perspectives, such as Elmore's (1979) on 'forward' and 'backward mapping', considers the necessary connections between individual behavioural choices, implementation choices by street-level bureaucrats and the crafting of policy. The act of service provision, whether spurred by demand or policy fiat, would be considered by either school of thought to fit fully into the implementation stage. Thus, we can take service provision, defined broadly, either directly to citizens or indirectly between layers of government or providers, to be the most restrictive definition of implementation, permitting us to consider the discussion and decisions concerning different possibilities of policy details guiding the provision of such services to lie within policy formulation and adoption.

Methodology and characteristics of articles selected

In this article, we sought to achieve two purposes: mapping the literature on health policy in LMICs related to formulation and adoption and synthesizing this literature to gain greater conceptual clarity on the form this stage of the policy process takes. To achieve these purposes, we needed an approach and methodology that would allow us to set aside our pre-existing views and synthesize a diverse set of studies. Electing for an inductive approach and narrative synthesis methodology enabled us to do both.

Narrative synthesis, also dubbed 'textual narrative synthesis', is characterized by the use of text, rather than data, to draw together prior research and devise new inferences (Arai *et al.* 2007; Lucas *et al.* 2007; Rodgers *et al.* 2009). Particularly suited for handling diverse groups of studies (Arai *et al.* 2007), this approach draws on findings, context and characteristics of studies to reach new conclusions (Lucas *et al.* 2007). By performing this synthesis inductively, we could allow empirical findings to guide our understanding of policy formulation and adoption and later identify potential alignment with theory. To gain the necessary distance from our pre-existing views for approaching this research inductively, we drew on theory to establish the broadest possible room for the stage between agenda setting and implementation, even refusing to name this stage anything other than 'the bit in the middle' until completion of the synthesis.

Synthesis methodologies use a relatively standard set of steps that can be performed iteratively. Such steps include forming a research question, identifying possible literature, deciding whether to include particular studies, assessing the quality of included studies, extracting data (which can take the form of raw data, findings, cited text, summarized text, arguments and/or context), summarizing evidence and interpreting or synthesizing the evidence (de Savigny and Adam 2009). After iterations of testing our methodology, we included quality assessment in the article inclusion/exclusion decision. In addition, we split the inclusion/exclusion decision into two stages, an initial screen and more extensive assessment of the article's relevance and merit. For narrative synthesis, the final step of performing the synthesis is itself composed of four sub-stages that identify constructs, initial findings, relationships and limits to the synthesis (Rodgers *et al.* 2009).

To identify potential articles for inclusion, we used a body of articles from 1994 to 2007 identified by Gilson and Raphaely (2008), a comprehensive survey of scholarship on health policy in LMICs. We updated this search to include articles from 2007 to 2009, using the same searches and databases they did, including *PubMed* and the *International Bibliography of Social Sciences*. Like Gilson and Raphaely and the two companion mapping articles, we included only English language academic journal articles.

We devised five yes and no questions; a negative answer on any of the five resulted in the exclusion of the article. Hence, all articles selected: (1) analysed events in a low- or middle-income country; (2) occurred at a national or sub-national level; (3) focused on a health issue; and spoke to some processes that lay outside both the (4) agenda setting and (5) implementation stages, using the strictest definition we established in the previous section (see Table 1). Through an initial screen of abstracts, we excluded articles that clearly failed to fulfil these criteria. Any articles that fit these criteria moved to a more in-depth review that also took into account four questions about the article's relevance and quality (Table 1). By relevance, we mean that articles devote a substantial portion of their content to the 'bit in the middle' and by quality that those portions have a high degree of scholarly rigour. At least two of the four authors evaluated each article to ensure uniform standards for inclusion.

From an initial pool of 146 articles, we excluded 72 studies for failing to meet the basic inclusion criteria. We examined the remaining 74 articles by the quality criteria. Lack of theory or analytic framework did not lead to article exclusion, but we considered the presence of theory or framework to mitigate a limitation in one of the other three criteria. After this in-depth review, we excluded another 46 articles, leaving 28 for synthesis.

We used a standardized table (Table 2) to extract data in the form of summaries of text from each of the 28 included articles. To perform the synthesis, we identified themes emerging from clusters of articles within the 17 individual questions shown in Table 2. By keeping the article information together, we maintained the ability to synthesize the articles without stripping them of context. By grouping articles with like elements, we were able to identify the actors and institutions involved in this stage of the policy process and understand them in LMIC health context as a set of seven distinct potential groups of activities or 'bits' in this policy phase. An important caveat to this form of mapping exercise is

Table 1 Inclusion/exclusion criteria

Basic inclusion criteria—answer with a yes or no				
National or sub-national rather than global?	In the health sector?	In a low- or middle-income country?	Continues beyond agenda setting?	Begins before implementation?
Assessment of article quality—answer with a sentence of description				Decision
Relevance to 'bit in the middle'?	Rich empirical data?	Grounded in theory or analytic framework?	Overall article quality supports relevance?	Include, exclude or undecided? Why?

Table 2 Data extraction questions for individual articles

Name of article

Name of country or region

Health issue

Academic discipline (can include two)
    Anthropology, economics, political science, public administration/policy, sociology, other

Insider/outsider status of author(s)

Research question(s)

Central argument

Policy stage(s) covered by article

How do author(s) define and describe the bit in the middle?

What is the decision being made? –or—what change is being considered? –or—what outcome is being sought?

Who decides?

Who seeks to influence decision makers?

What processes are described?
    Developing policy alternative, drafting technical guidance, drafting legislation, deliberations, advocacy, lobbying, negotiations, voting

Where do these processes occur?

What was the outcome of the processes?

Theoretical approach or analytical framework, if any

Research methodology

Source of data (primary/secondary)

Assessment of quality of relevant material

Any other comments

that elements unaddressed in the relevant research cannot, by their very exclusion, be discovered through the process of synthesis.

The 28 articles included in the synthesis (see References) cover a wide range of geography and health issues (see Figure 1). Brazil, South Africa and Thailand are the only countries with more than two articles, while HIV, health systems, family planning and health finance/insurance are the only issues covered in more than two articles.

Methodologically, most of the articles (15 of 28) are single case studies, suggesting the value of syntheses of scholarship on health policy in LMICs to enhance the ability to generalize findings (Table 3). Theoretically, 16 of the 29 articles draw on three policy models: Walt and Gilson's policy triangle (6 in total), Grindle and Thomas' policy space (5) and Kingdon's policy streams (5). The other articles include a range of political science, public administration/policy and sociology theories, or none at all.

Findings

By synthesizing the sections of these articles falling within the loosest boundaries of the policy formulation and adoption stage, some cross-cutting understandings of this stage emerge. Comparison between how each article describes the stage and theoretical definitions provides a rough understanding of how health policy analysts conceive of policy formulation and adoption. The descriptions and details of individual policy processes and contexts provide further explanation of this stage by identifying the institutions, actors and intermediary steps involved. This last finding builds on existing understanding of policy formulation and adoption by identifying seven distinct 'bits' that comprise it. As this synthesis only includes conceptions, institutions, actors and activities identified from the included articles, this article's findings are not exhaustive and may have reduced applicability outside the context of health policy analysis in LMICs.
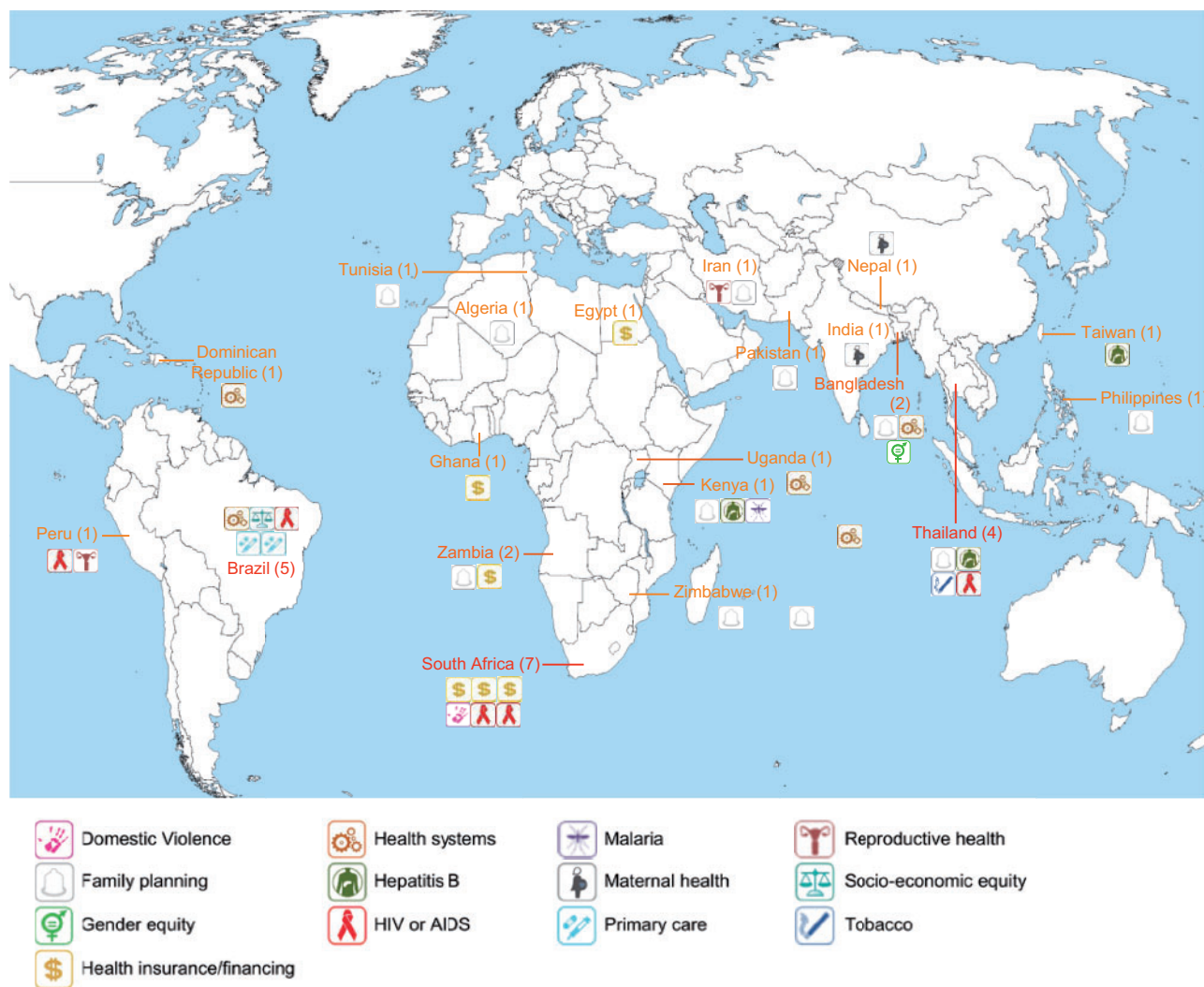
Figure 1 Range of geographic and health issues addressed in synthesis articles.
Note: Counts do not total with included articles due to some articles covering multiple countries and/or issues

Table 3 Article methodology counts

Research design		Data sources	
Single case study	15	Primary	4
Paired case studies	4	Secondary	5
Multiple case studies	2	Both	17
Statistical analysis	2	Unclear	2
Historical narrative	1		
Self-reflective	1		
Ethnography	1		
Unspecified	2		

Definitions and conceptions

Recognizing that the purposes of the authors of the studies included in the synthesis differed significantly from our own, with none of them explicitly seeking to map out the policy process under examination, we nonetheless saw merit in using their descriptions and definitions of the process they examine to gain greater conceptual clarity on policy formulation and adoption. To synthesize these descriptions of this stage, we drew upon both explicit definitions or theory-driven terminology (as per the theory section of this article) and descriptions of the processes studied to capture implicit definitions. We found a substantial group of articles aligned with theoretical descriptions of policy formulation and adoption as defined by Jann and Wegrich (2007), with a few articles that diverge significantly.

Just fewer than half of the synthesis articles (13 of 28) describe the stage in a manner that conforms with theories on policy formulation or adoption. Five articles (Usdin *et al.* 2000; Nandakumar *et al.* 2000; Kapiriri *et al.* 2003; Mehryar *et al.* 2007; Lairumbi *et al.* 2008) make little or no attempt to define or describe the policy process studied in them, while the remaining 10 articles take a wide variety of approaches (see Table 4).

Table 4 How the authors describe the piece of the policy process they are investigating

Policy formulation/adoption	Other conceptions/definitions	
Formulation	*Actor-centred*	*Little or no attempt to define*
Lee *et al.* 1998	Weyland 1995	Kapiriri *et al.* 2003
MacKenzie *et al.* 2004		Lairumbi *et al.* 2008
Macrae *et al.* 1996	*Influence government*	Mehryar *et al.* 2007
Tantivess and Walt 2008	Cornwall and Shankland 2008	Nandakumar *et al.* 2000
Thomas and Gilson 2004	Robins 2004	Usdin *et al.* 2000
Adoption	*Issue-centred*	
Ensor *et al.* 2009	Agypeong and Adjei 2008	
Gilson and McIntyre 2008	Cáceres *et al.* 2008	
Glassman *et al.* 1999	Crichton 2008	
Lieberman 2007	Gauri and Lieberman 2006	
Munira and Fritzen 2007	Steytler 2003	
Sugiyama 2008a		
Sugiyama 2008b	*Part of agenda setting*	
	Shiffman and Ved (2007)	
Both		
Gilson *et al.* 2003		
Jahan 2003		

The articles outlining some variation of policy formulation discuss efforts to craft the details of policy, aligning with the stages heuristic definition of policy formulation (Jann and Wegrich 2007). Descriptions similar to policy formulation range from explicit reference to the stages model (Macrae *et al.* 1996; Tantivess and Walt 2008), to the development and consideration of proposals (Thomas and Gilson 2004), to the creation of a piece of legislation (MacKenzie *et al.* 2004). Other articles focus more upon taking a substantive decision, rather than the details of policy proposals, similar to theory on both policy adoption (Jann and Wegrich 2007) and decision making (Grindle and Thomas 1989). The decision-making/policy adoption articles focus upon selection of a specific policy or reform proposal (Glassman *et al.* 1999; Munira and Fritzen 2007; Gilson and McIntyre 2008; Ensor *et al.* 2009), consider the diffusion of specific programmes between municipal governments (Sugiyama 2008a; 2008b) or focus more broadly on national policies and resource allocation (Lieberman 2007). Two articles combine the concepts of policy formulation and adoption, considering both the process and content for health systems reforms (Jahan 2003) and focusing on both design and approval of detailed policies (Gilson *et al.* 2003).

The remaining 10 articles fell into four groups of descriptions: incorporating policy formulation and adoption into agenda setting; centring attention on a particular actor; attempting to influence government decision makers and issue-centred processes. One article explicitly wrapped the details and decisions of policy within agenda setting (Shiffman and Ved 2008) and would either exclude the possibility of the formulation and adoption stage or consider it further along toward implementation, where adjustments are made to policies after governments decide on a specific policy. Two other articles focus on the dialogue around policy making, with actors seeking to influence government decision makers, including through citizen deliberation (Cornwall and Shankland 2008) and expert involvement (Robins 2004).

A final group of six articles focused primarily upon an issue and/or movement, with a topical rather than procedural definition. A movement-oriented study (Weyland 1995) discussed health reforms broadly, concerned with the extent to which large-scale national reforms could be deemed 'progressive' and the power of actors rather than specific policy details or processes. Similarly, Cáceres *et al.* (2008) focus on a single issue and, while identifying some specific policy measures as being of interest, also consider the tone of policy and its implications for specific interest groups. These articles covered policy formulation and adoption indirectly, as a consequence of examining its relationship to the actors primarily being studied. One issue-centred article (Crichton 2008) focused on the availability of 'policy space' (the agency held by policy makers on a specific issue in light of competing interests, ideas and the nature of the issue under consideration), describing the concept in a manner leaving significant overlap with agenda setting, where context, decision-making setting and policy characteristics influences the room for policy space on family planning. Another article centred heavily on a single decision, the switch in policy from fee-based to health insurance-based financing (Agyepong and Adjei 2008), also blurs the lines between the two activities, with garnering attention and support for a specific policy shift occurring, both conceptually and in practice, close together. Gauri and Lieberman (2006) consider the 'aggressiveness' of government response to HIV, which includes both broad reforms (such as establishing a bureaucracy) and specific policy indicators (such as treatment protocols). The final issue-centred article (Steytler 2003) demonstrates some similarity to a description of policy formulation and adoption, with concern over specific policy choices, but predominantly focuses upon the interactions between different layers of government in crafting policy.

The institutions and actors involved

As one might expect, the institutions where policy formulation and adoption take place are quite varied—although in many cases the authors were imprecise or silent on the matter. Those authors who were clear specified that these processes take place most frequently in the arena of organs of the state—and reveal

the complex, expansive and multiple bureaucracies within the modern state that have a hand in crafting policy. Fifteen of the articles indicate that decision making takes place within ministerial bureaucracies—in both health and finance—including through closed committees, task forces and working groups. Eleven articles described processes established by government to consult with experts and interest groups on policy details including through a variety of mechanisms. The parliament, legislature or locally elected government officials were identified as sites of policy formulation in eight of the articles. The judiciary, gatherings of religious leaders and political party conventions were further sites identified in the articles. Most of the articles described activities in at least two of these venues.

From the above, the kinds of actors that the articles identified as decision makers and decision-making bodies become apparent. As shown in Table 5, and perhaps unsurprisingly, parliaments were most commonly identified as making authoritative decisions concerning health policy (10), followed by bureaucrats, planners and other government officials (7), ministers including of health and finance (6), executives such as heads of state (5) and locally elected officials (3). Other articles focused on the role of donors (where policy content was largely decided by the availability of external funding to implement the policy) (2), civil society (2), commissioners (1) and the clergy (dealing with the origins of a fatwa) (1) in decision making. Three of the articles did not identify any specific decision makers. Thirteen of the articles focused on one of these actors/bodies as decision makers while 11 identified two decision-making entities. For example, Gilson *et al.* (2003) identified the Ministers of Health as the key actors in health care financing reform in South Africa and Zambia, deriving their political influence and capacity to undertake 'personalized' decision making from their formal and pre-eminent role in the process of health policy development during a moment of major political change. Another comparative study examined four decision-making entities across eight countries—including heads of state, legislatures, donors and civil society organizations (Lee *et al.* 1998). Of course, the predominance of government actors in formulating policy could be either empirical evidence of their role or an artefact of researcher decisions on what actors, issues, and processes to study. As a result, the identified roles for non-state actors in policy formulation and adoption may just be limited in prior research, and not in practice.

Given the range of policy issues studied in significantly different contexts, a wide variety of stakeholders were found to seek to influence the outcomes of policy formulation and adoption. The nature of decision-making bodies, while often fluid, reveals much about a country's health governance, political processes and political legitimacy, as well as the origins of specific policy content. For example, the clergy's powerful role in shaping Iran's family planning policies (Mehryar *et al.* 2007) combines policy formulation and adoption roles held in other contexts by both government officials and civil society. An examination of the people, in addition to the institutions that influence and ultimately decide policy content often reveals the personal nature of policy making and the impact of individuals or small circles of policy elites to determine policy content.

Table 5 Various actors identified in the articles involved in decision making

Actors involved in decision making	Number of articles
Parliaments and legislatures	10
Bureaucrats, planners and other government officials	7
Ministers including of health and finance	6
Executives such as heads of state	5
Locally elected officials	3
Donors	2
Civil society	2
Commissioners	1
Clergy	1
None	3

The processes of policy formulation and adoption: seven bits in the middle

The articles reviewed describe, in different levels of detail, a variety of political, procedural and technical processes through which the design and content of health policy is elaborated and either enacted or challenged and rejected. These processes range in the extent to which participation and input from outside government is sought, but tend to suggest that the government is the ultimate policy formulator (or at least that is the focus of health policy analyst's attention). Yet, as the articles revealed, a government's ability to take certain decisions are conditioned on the support it has from interest groups. It is apparent that policy formulation and adoption will vary from policy to policy and that analysts rarely capture it in its complexity and entirety. From the literature, one gets the distinct impression that one is simply scratching the surface.

The activities and processes described by authors in relation to the space where agenda setting ends and implementation begins can be roughly placed into seven distinct and layered categories (see Figure 2). These categories can themselves be viewed as a series of steps or stages from agenda setting to implementation—not all of which take place in every policy formulation process.

Generation of policy alternatives

Fourteen articles (see Table 6) focused on generating policy alternatives and/or recommendations—which included specification of principles and programmatic activities. In some articles, these activities involved research processes, developing technical guidance, assessing policy alternatives as well as involving decision makers in research processes and producing white articles for consultation. In their article, for example, Munira and Fritzen (2007), propose a framework for examining the process by which governments' consideration and adoption of new vaccines takes place, finding that central to the process in the countries studies was the proactive role that medical associations played in generating policy alternatives and using emerging scientific evidence to influence the adoption of the new vaccine in policy and political circles. Four articles (Gilson *et al.* 2003; Gilson and MacIntyre 2008; Lairumbi *et al.* 2008;
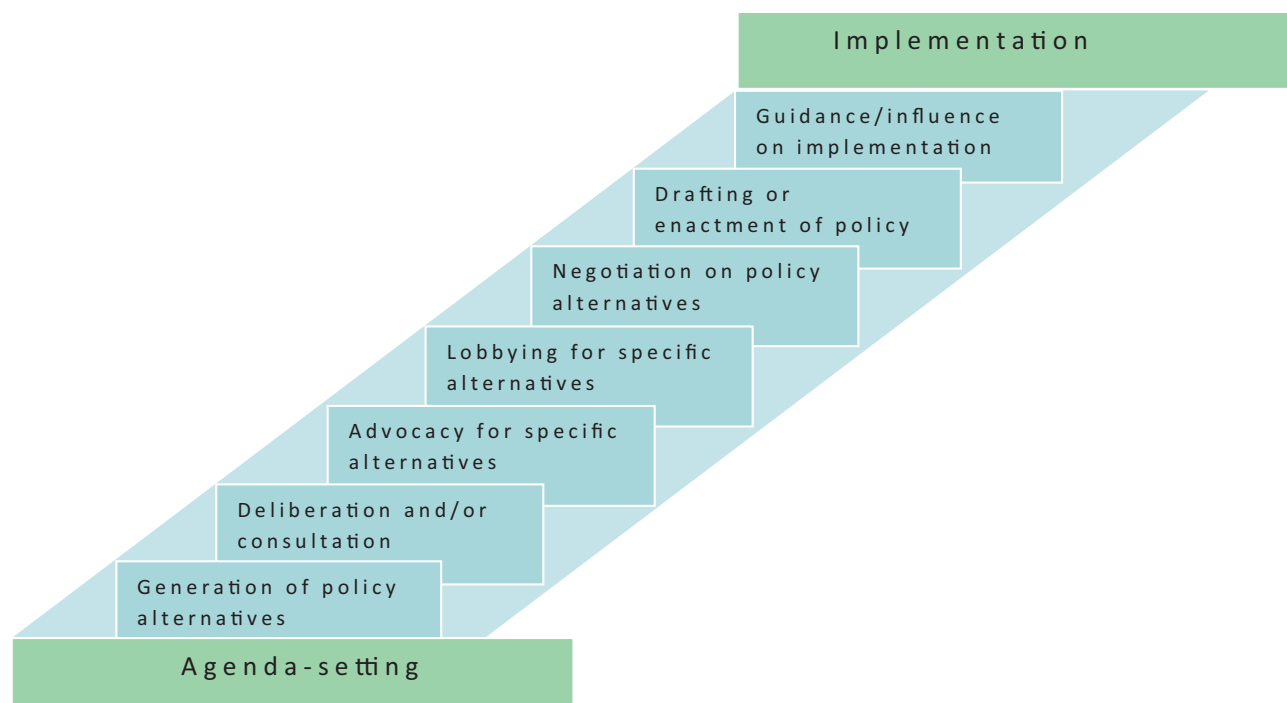
Figure 2 The 'bit in the middle': seven bits

Ensor *et al.* 2009) described the role of scholars and their research in improving the quality of policy alternatives.

Deliberation and consultation

Equally frequent were articles that described activities that involved some form of deliberation and/or consultation on policy alternatives. Some authors focused on external consultation with the public, communities and other stakeholders, others on less broad-based consultations with and among experts including the role of networks, coalitions and norm entrepreneurs in policy diffusion, and others on both 'internal' and 'external' consultation. For example, Cornwall and Shankland (2008) explore the innovative mechanisms for popular involvement and accountability that are part of the architecture for governance of Brazil's universal health system as an institutionalized structure for wide and inclusive deliberation. In examining the process of health sector reform in Bangladesh, Jahan (2003) explores the Ministry of Health's consultations strategies including the establishment of 17 task forces to define various elements of the reform strategy, with members drawn from government, donors, and civil society which met for a period of 2 years. In Thailand, consultation took the form of policy formulation panels that included advocates and other potential partners, who provided input on antiretroviral policy (Tantivess and Walt 2008).

Advocacy of specific policy alternatives

Fourteen of the articles dealt with activities that were described as advocacy of specific policy alternatives. Again, some were more focused on advocacy within the bureaucracy and/or parliament, whereas others involved advocacy to the broader public and advocacy undertaken by civil society and interest groups to advance their particular policy options through press releases, grass roots mobilization and campaigns, position

articles, publicity stunts and focusing events—targeting both the public and decision makers. We included deliberative framing of policy problems and solutions (agenda setting within policy formulation) within this category of advocacy. In her article, Crichton (2008) analyses shifts in family planning policy space in Kenya, demonstrating how champions of family planning, particularly within the government, took advantage of shifts in the political context and widened policy space through both public and 'hidden'—wherein bureaucrats in one department quietly influenced those in another—advocacy activities. Agyepong and Adjei (2008) described a process of advocacy in which organized labour submitted a formal resolution challenging some elements of a proposed health insurance bill. Glassman *et al.* (1999) examine negative reactions by members of the health bureaucracy and medical associations to a 'white paper' supporting reorganization of the Dominican Republic's health systems. Such analysis provides useful insights into the dynamics of routine policy evolution and the challenge of sustaining support for specific policy alternatives after they have reached the policy agenda.

Lobbying for specific alternatives

Only five of the articles involved what the authors described as lobbying for specific alternatives, although it might be that the distinction between advocacy and lobbying was not observed by other authors. Lobbying is defined, at least in the Anglo-American context, more narrowly than advocacy as efforts to directly or indirectly influence legislators (Vernick 1999); articles that distinguish between advocacy and lobbying, then, would define advocacy as efforts to influence policy processes other than legislation. In a classic example, MacKenzie *et al.* (2004) reveal the intensive, often covert, lobbying campaign targeted at senior officials undertaken by transnational tobacco companies to prevent legislation on tobacco control in

Table 6 Presence of the seven categories of 'bits in the middle' in the articles

Article	Generation of policy alternatives	Deliberation and/or consultation	Advocacy of specific policy alternatives	Lobbying for specific alternatives	Negotiation of policy decisions	Drafting the enactment of policy	Guidance/influence on implementation
Agyepong and Adjei 2008	X	X	X			X	
Cáceres *et al.* 2008			X	X		X	
Cornwall and Shankland 2008	X	X	X				
Crichton 2008		X	X				X
Ensor *et al.* 2009	X	X				X	
Gauri and Lieberman 2006			X			X	
Gilson *et al.* 2003	X	X				X	
Gilson and McIntyre 2008	X	X				X	
Glassman *et al.* 1999	X		X			X	
Jahan 2003		X	X				
Kapiriri *et al.* 2003		X					
Lairumbi *et al.* 2008			X				
Lee *et al.* 1998	X	X				X	
Lieberman 2007							
MacKenzie *et al.* 2004				X		X	X
Macrae *et al.* 1996	X						
Mehryar *et al.* 2007		X				X	
Munira and Fritzen 2007	X	X	X	X	X		
Nandakumar *et al.* 2000	X					X	
Robins 2004	X		X				X
Shiffman and Ved 2007	X					X	
Steytler 2003		X				X	X
Sugiyama 2008a						X	
Sugiyama 2008b						X	
Tantivess and Walt 2008	X	X	X				
Thomas and Gilson 2004	X	X	X			X	
Usdin *et al.* 2000			X	X			X
Weyland 1995			X	X		X	
Total number of articles with bit present	14	14	14	5	1	17	5

Thailand—despite an official ban on lobbying while legislation was being considered. Cáceres *et al.* (2008) do not directly use the term lobbying, but mention the use of language by church leaders to 'attack' individual legislators and sway them against passing a bill permitting some abortions.

Negotiation over policy content
A single article described efforts to negotiate over policy content. In this example, both Taiwan and Thailand incorporated Hepatitis-B vaccines into their immunization campaigns only after negotiations between government ministries and manufacturers led to lower prices (Munira and Fritzen 2007).

Drafting or enacting legislation
Seventeen of the articles described activities relating to drafting, passing, enacting, or adopting legislation (including fatwas and policy) and constructing budgets (and agreeing upon

allocations/formulas). This category can be understood in two parts: (1) activities related to drafting of legislation and (2) activities related to enactment. It was these activities that most authors associate with the bit in the middle. Weyland (1995) provides an example of 'clientelist' politicians stalling or blocking proposed legislation intended to make health care in Brazil more equitable and the eventual drafting of a law following a new constitution through compromises between reformers and their opponents. Shiffman and Ved (2007) describe both the creation of new government programmes for maternal health and the related allocation of government funding. For Sugiyama (2008a; 2008b), this occurs through policy diffusion, whereby local governments enact specific legislation modelled by other municipalities. In Iran, national family planning policy first appeared in general development policy rather than specific legislation, though such legislation followed five years later (Mehryar *et al.* 2007). Failures to draft legislation, enact policies, or dedicate funding also appear in studies, such as Gauri and Lieberman (2006) finding deep divisions in South Africa preventing as much progress on HIV as in Brazil.

Guiding implementation

This final category, included in five articles, seeks to address those activities that continue to shape the content of policy after legislation—recognizing that significant opportunities to influence policy or legislative design or impact arise as policy makers move towards implementation. Such activities include developing detailed regulations, orders or guidelines for implementation, advocating or lobbying for policy 'interpretation' alternatives, and post-legislation judicial ruling. Usdin *et al.* (2000) and MacKenzie *et al.* (2004), in their articles on legislation related to domestic violence in South Africa and tobacco control in Thailand, respectively, illustrate how successful advocacy and lobbying campaigns after a policy's enactment continued to significantly shape its content before implementation. Two other articles (Stetlyer 2003; Robins 2004) in the sample described the process of a legal challenge and the subsequent reversal of a policy decision.

Although it is likely that activities in most of the aforementioned categories take place in all cases of real-world policy formulation in democratic regimes (with the exception perhaps of judicial challenges), the articles tended to focus on a subset of the range of activities. The bulk of articles discussed activities related to only two or three of the seven categories and only two articles engaged with four or more. There was also considerable variation between articles as to the level of detail provided.

Conclusion

In this article we have sought to bring greater analytical clarity to the phase of the policy process that bridges agenda setting and implementation, as it pertains to scholarship on health policy change in LMICs. We conclude with several observations about the state of and directions for research. The seven bits introduced in this article provide an alternative to vague definitions of policy formulation and adoption as an intermediate stage between agenda setting and implementation and serve

as a starting point for future researchers to better unpack the activities and processes in this stage.

High-quality research on this phase appears to be scant, mirroring the situation for the field of health policy analysis in LMIC as a whole, although it is arguably even more limited for this phase. Although we found 146 articles that touched in some way on policy formulation and adoption, only 28 articles passed our inclusion criteria, a number insufficient to provide firm answers to any specific analytical question—such as the determinants of policy adoption—that we may have hoped to address via a synthesis methodology. Part of the problem may lie with our search criteria: a focus on English language academic journal articles; possibly, inclusion of books, grey literature and foreign language articles could have expanded the pool considerably. Also, the cut-off date for included articles, 2009, precluded synthesis of more recent policy formulation and adoption scholarship. As research on this subject continues to accumulate, enough evidence may emerge to begin addressing firmer analytical questions.

This paucity of research notwithstanding, these 28 articles reveal much about policy formulation and adoption. Most notably, they show that this phase of the policy process, rather than being characterized by a single decision point, is better understood as a set of seven layered steps, each in some way connected to the development and selection among policy alternatives: alternative generation, deliberation, advocacy, lobbying, negotiation, drafting and guidance for implementation. These seven span the set of activities that parliamentarians, donors, ministers, researchers, civil society activists and other actors engage in as they move beyond agenda setting—the attention generating phase of the policy process—toward implementation – the act of providing services. Though our synthesis cannot shed light on the frequency of these bits in practice, the order in which they may occur, or significant guidance on conducting them, the separation of policy formulation and adoption into constituent pieces serves helpful purposes for scholarship and practice alike.

One advantage of the seven bit framework is that it helps to identify specific questions to guide future research on health policy formulation and adoption. We lay out several in three groups.

On alternative generation and deliberation (bits 1 and 2):

- To what extent do medical professionals and civil servants dominate policy alternative generation? Under what circumstances are other actors—for instance social activists, policy advisors and legislators—also the source of policy ideas?
- What role do international forces play in generating policy alternatives? How frequently and under what circumstances are policy ideas imported from abroad, without or with minimal modification for the domestic context?
- What role does scientific evidence play in policy alternative generation?
- How does the framing of a policy alternative shape the likelihood of its uptake?
- What prompts governments to consult with non-state actors for feedback on policy proposals? What forces (for instance, political contentiousness) compel them to limit consultation?

- How does the degree of consultation shape the likelihood that a policy will be adopted? The likelihood that it will be implemented?

On advocacy, lobbying, negotiation and drafting (bits 3, 4, 5 and 6):

- What social mobilization strategies increase the likelihood that civil society activists will successfully shape policy content?
- What strategies do commercial interests (for instance, transnational tobacco and food industries) and religious institutions (for instance, the Catholic Church) use to sway legislation? Under what circumstances are legislatures insulated from these and other external pressures?
- How often and under what conditions are legislative bodies the primary site for authoritative policy decisions? When are such decisions made by ministries, higher levels of the executive branch of government, or other entities?
- Who actually drafts legislation and how does this vary by circumstance? What role do legislators play? Medical professionals? Technical agencies? Officials from donor or international agencies? Civil society institutions?

On guidance for implementation (bit 7):

- Once legislation is passed, how do agencies use regulations to facilitate or thwart policy implementation?
- What factors increase the likelihood the judiciary will be involved in challenging enacted legislation?

We expect that future research surrounding these and other questions concerning health policy formulation and adoption will help to sharpen this framework and our understanding of this phase of the policy process. Such research may identify additional bits missed in this article, suggest combinations of bits with similar characteristics, or specify relationships between the bits including nonlinear or iterative processes. To do so, researchers should consider using less restrictive search criteria, longer time frames, more recent publications and alternative synthesis methodologies.

Ultimately we want to build on definitional and mapping exercises to identify and answer analytical questions about health policy processes in LMICs. These questions are not easily answered, given the paucity of research on the bit in the middle and the inadequate use of theory to drive empirical work. We hope, though, that this synthesis of existent literature helps to offer greater analytical clarity and a scoping of the field that may encourage research leading toward clearer answers.

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