

Integrative review: identifying the evidence base for policymaking and analysis in health care.

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Evidence base for policy making and analysis in health care

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Conflict of interest

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Aim

To identify and synthesise the evidence underpinning the health policymaking process to inform the development of a health-related policy analysis framework.

Design

A mixed methods review using 'Best Fit' Framework synthesis.

Data sources

PUBMED and CINAHL+ databases for English language papers published between March 2013 - March 2017.

Review Methods

Titles were screened, data abstracted and analysed by two authors at each stage. Findings from included studies were coded against six *a priori* categories which had been constructed through a preliminary literature review, consultation and consensus.

Results

68 papers were included. There exists empirical support for six key domains which require to be addressed in the policymaking and analysis process: 1) Context 2) Process 3) Content 4) Stakeholder Consultation 5) Implementation 6) Evaluation. Failure to contextualise and integrate these six domains in problem identification, policy analysis, strategy and policy development, policy enactment and policy implementation is problematic.

Conclusion

There is a need to test and refine the constructs linked to the policymaking cycle taking cognisance of the context where these are developed, implemented and evaluated.

Impact

This review makes a novel contribution to the synthesis of evidence to inform the policymaking and analysis process. Findings illuminate the complexity of policymaking, the competing pressures involved and the importance of the local, national and international context. These findings have international relevance and provide empirical support for key criteria to guide those involved in context specific policymaking and/or the analysis of existing policy.

Keywords

literature review, nursing, policy, systematic review, nurses, health

INTRODUCTION

This literature review forms part of a substantial body of work conducted by the authors for the Nursing and Midwifery Board of Ireland. The primary output was the development of a framework for policy analysis and a user manual, which together constitute the Health-related Policy Analysis Framework (HrPAF) (Table 1) (Casey et al, 2017). The HrPAF is a framework that can be used by policy makers and healthcare professionals to prospectively guide policy development and to retrospectively analyse existing policy. Our purpose here is to synthesise the literature which helped shape and refine the emerging six *a priori* domains of the HrPAF for consideration in the policymaking and analysis process.

Background

Health policymaking is a local, national and/or international endeavor and a resource heavy activity. It is a broad term that includes government policies, regulatory guidelines, laws, strategies, strategic plans and action plans. To date, the content of policy documents rather than the process and context of policymaking has been the primary focus. This focus does not provide strategic direction for policy makers or provide them with information about the ‘hows’ and ‘whys’ of success or failure in policy implementation (Walt & Gilson, 2014). There is growing recognition of the need to account for the complexity of policymaking, the competing pressures involved and the context at a local, national and international level (Holland, 2007). Policy analysis determines not only “what governments do, why they do it and what difference it makes [but also] the processes of governance and policy advocacy” (Coveney, 2010, p.515).

A diverse range of stakeholders are increasingly involved in health policy development and can include patients, members of the public, politicians, public servants and interest groups (Walt et al, 2008). Therefore, a structured framework for analysis that speaks to stakeholders from this diversity of backgrounds is needed. Without one, policy makers may find it difficult to structure their data interpretation and may not be aware of all the variables they should be considering in their decision-making (Niessen, Grijseels, & Rutten, 2000). Additionally, theoretical models have been criticised for focusing solely on the policymaking process and not offering guidance on how policy already in existence can be examined (MacLachlan et al, 2012).

The HrPAF *a priori* framework was developed through consultation (four face-to-face cooperative inquiry meetings and 37 teleconferences) and a literature review to appraise how analytical frameworks inform agenda setting, policy formation and policy implementation in health. This resulted in six *a priori* domains and these shaped the HrPAF: 1) Context 2) Process 3) Content 4) Stakeholder Consultation 5) Implementation 6) Evaluation (Casey et al, 2017) (Table 1).

The need to underpin any framework for analysis with a literature review and face-to-face meetings is well recognised as an important first step in the process (Moher, Schulz, Simera, & Altman, 2010). However, development of an analysis framework is an iterative process and we noted recognition by the authors of the STROBE statement that a systematic review was not conducted for each of their checklist items (Casey et al., 2017; von Elm et al., 2007). Thereby this second review informed the iterative process of developing and refining the six *a priori* domains of the HrPAF to provide evidence as to its fitness for purpose.

THE REVIEW

Aim/s

To explore and synthesise the evidence underpinning the health policymaking process.

Design

The design was adapted from the 'Best Fit' Framework synthesis described by Carroll et al (2013). It also reflects that of a mixed methods review with evidence drawn from qualitative, descriptive quantitative and mixed methods studies rather than randomised controlled trials (RCTs) and meta-analysis. The 'Best Fit' Framework synthesis method involves coding data from the included studies framework against our *a priori* HrPAF domains. Teams of two reviewers were involved from the screening process through to the final decision making.

Arbitration when necessary was by a third member.

Search methods

A key word search strategy using the PI(C)O framework was used with PUBMED and CINAHL+ databases. Search terms were created using text terms and MeSH (Medical Subject Heading) nomenclature related to the process of policymaking (Table 2). The search was limited to English language papers published between March 2013 and March 2017 in order to gain a contemporary perspective on the topic. Studies that met the inclusion criteria were peer-reviewed empirical sources.

Search outcomes

The search yields and exclusions are detailed in Figure 1 (PRISMA). A screening question, ‘Does this paper deal with an actual process of policy-making?’ guided decision-making on the inclusion and exclusion of full text documents.

Quality appraisal

Given the overall aim of this review was to extract key theories and/or concepts to confirm the six *a priori* domains of the HrPAF, an analysis of the risk of bias and quality appraisal of included papers was not undertaken (Ganann, Ciliska, & Thomas, 2010). The included papers used multiple approaches to reporting due to the range of disciplinary and philosophical approaches that underpin policy analysis (Walt & Gilson, 2014) (Table 3). We judged that the study design and methods, alongside the results or findings, were unlikely to have an impact on the development of our theoretical and conceptual understanding. Accordingly, a quality appraisal was not undertaken.

Data abstraction

Data were extracted from the 68 included articles. Some papers did not explicitly state their research approach (e.g. (Anderson, Yoder, Fogels, Krieger, & McLaughlin, 2013; Beland, Rocco, & Waddan, 2014)). Key messages relevant to the six *a priori* domains were extracted (Table 3).

Synthesis

Our approach to synthesis combined deductive and inductive approaches. This was to ensure evidence, not coded against the framework, was not missed. The first stage was to code evidence from the 68 included studies against the six *a priori* domains which confirmed their relevance (Carroll et al, 2013). During this process the influence of the context on understanding these six constructs became evident. To refine the HrPAF domains and indicative criteria for analysis (Table 1) data extracted were further scrutinised using the narrative approach described by Popay et al., (2006). Using this iterative process enabled us to explore; the role of theory in the findings that underpin each domain, the relationships in the data and the factors shaping the six *a priori* domains. Consequently, the six domains and indicative criteria of the HrPAF have contextual relevance across a range of settings.

RESULTS

Sixty-eight articles reporting 67 studies were included in this review. Two described different aspects of the same study (Nabyonga-Orem, Nanyunja, Marchal, Criel, & Ssengooba, 2014a; Nabyonga-Orem et al., 2014b).

Evidence to support the six *a priori* domains of the HrPAF emerged. Many of the papers addressed more than one of these domains with the process of policymaking and stakeholder consultation in 40 and 30 studies respectively. There was less evidence relating to evaluation (N=17 studies), implementation (N=17 studies), policy content (N=18 studies) and policy context (N=19 studies). The majority of studies were described as case studies (N=33). Others were described as using qualitative methods (N=13) or mixed methods (N=7) and five were described as surveys.

With regard to seven others, two used the Delphi method, one was an ethnographic study, one was a trial process evaluation, one used critical discourse analysis, one used expert workshops and one took a participatory approach. Of the remaining studies, one was a prospective health impact analysis using quantitative methods, one was described as a multi-phase study incorporating critical action research, realistic evaluation and program logic and another was a systems analysis of the policy-making process.

Thirteen studies were undertaken in North America (USA (N=7) Canada (N=6)). In addition, studies were conducted in Europe (N=16), Australia (N=6) and New Zealand (N=1). Low and middle-income countries (LMICs) also featured as in Asia (N= 8) and Africa (N= 15). Four studies took place in the Middle East and one in the Caribbean. The three other studies focused on more than one country with two in the United States and Mexico and one involved the United Nations.

Context

Eighteen papers dealt with this domain. Two studies undertook an analysis of national data sets containing quantitative data (Ádám, Molnár, Gulis, & Ádány, 2012; Crettenden et al., 2014), one study used quantitative data gathered employing a survey (Baggott & Jones, 2014) and the remainder were qualitative studies, often using a case study approach.

There exists limited evidence on how policy makers take account of contextual issues. At a national level, a stable political system has an positive impact on policy development (Basaza, O'Connell, & Chapcakova, 2013; Mbachu et al., 2016) where the converse was found to hinder policy development (El-Jardali, Bou-Karroum, Ataya, El-Ghali, &

Hammoud, 2014a). Health policymaking must sit comfortably within the wider national health strategic framework which can either act as a roadmap for policymaking or constrain attempts at policy reform (Mc Hugh, Perry, Bradley, & Brugha, 2014; Onwujekwe et al., 2015). Health policy-making cannot exist in a vacuum and policymaking in other sectors needs to be taken into consideration (Baum et al., 2014; Blaauw, Ditlopo, & Rispel, 2014; Corburn, Curl, Arredondo, & Malagon, 2014; Crettenden et al., 2014).

Drawing comparisons with other countries has encouraged national policy makers to reform health policy to reach or exceed international norms (Marzuki et al., 2015; Mc Hugh et al., 2014; Onwujekwe et al., 2015). Policy makers should acknowledge that what works in one context will not necessarily work in another (Albert & Porter, 2015). At a formal level, national governments may have signed up to international treaties that require policy changes. For example, the United Nation's Millennium Development Goals (MDGs) which aim to improve health and reduce mortality have had a bearing on health policy development especially in LMICs (Onwujekwe et al., 2015; Oronje, 2013). National health policymaking has also been influenced by World Health Organisation policies and recommendations (El-Jardali et al., 2014a; Odoch, Kabali, Ankunda, Zulu, & Tetui, 2015; Onwujekwe et al., 2015). European Union reports, standards, policies and regulations have provided an impetus for, or guidance on, policy reform (Ádám et al., 2012; Baggott & Jones, 2014; Mc Hugh et al., 2014).

Crises caused by an epidemic or pandemic have influenced policy decision making particularly where immediate government action is expected (Uddin, Sarma, Bari, & Koehlmoos, 2013). A push for policy reform has also come from within health care

professions (Archer, Regan de Bere, Nunn, Clark, & Corrigan, 2015). This includes the need to implement standards from regulation agencies (Blaauw et al, 2014) or because of health system restructuring and reform (Basaza et al., 2013; Mc Hugh et al., 2014).

The economic context has influenced policymaking. For example, the broader economic context in LMICs means that the focus of policymaking is often different. LMICs may focus on issues such as child mortality and geographical and financial access to health facilities. If policy changes are expected to be cost neutral, this can make the policymaking process difficult, if not impossible (Mc Hugh et al, 2014). Thus the economic feasibility of implementing new or revised health policy must be accounted for in any policymaking process (Odoch et al, 2015).

Process

Forty papers dealt with the process of policymaking and comprised mainly case studies (N=19) with the remainder qualitative or mixed methods studies. Consensus on priorities and activities must be identified to facilitate the policymaking process and avoid tension (Archer et al., 2015; Khayatzadeh-Mahani et al., 2012; Vandenbroeck et al., 2014; Zida et al., 2017) and stakeholders must be accountable during the policymaking process (Spitters et al., 2017). International best practice recommends setting an agenda driven by practitioners rather than by political agendas (Vos, Lagasse, & Levêque, 2014). During the process of making policy, engagement with policy holders in other countries provides valuable information to avoid challenges other countries may have encountered previously (Basaza et al., 2013). Where there is a lack of communication, consultation and planning, delays may be experienced (Tumwesigye et al., 2013; Valaitis et al., 2016).

Depending on the cultural context, moral and ethical opinions can influence the process of policymaking rather than the production of empirical evidence (Carey, Crammond, & Keast, 2014; Chanturidze, Adams, Tokezhanov, Naylor, & Richardson, 2015; Engel, 2013). While it is best practice to formulate policy based on the evidence from research (Harris, Sainsbury, & Kemp, 2014), it has been acknowledged that it is costly and time consuming (Imani-Nasab et al., 2014).

Content

Eighteen papers reviewed the policy content. Most were case studies and the remaining papers were an outline of the development of a system dynamics model to guide policy (N=1) (Guariguata et al., 2016) and a cross-sectional descriptive study (N=1) (Nabyonga-Orem et al., 2016). The policy analysis framework by Walt and Gilson (1994) was used in two papers (Blaauw et al., 2014; Gagnon & Labonte, 2013). Ellen, Lavis and Shemer (2016) sought to explore health systems and policy researcher's views and the barriers and facilitators to the use of evidence in policy-making. Valaitis et al. (2016) explored implementation of policy in relation to two public health programmes. In Walt and Gilson's framework, the analysis of content focuses on the nature and details of the policy proposals. Gagnon and Labonte (2013) also used Fidler's (2005) health and foreign policy conceptualizations and Kingdon and Thurber's (1984) multiples streams model of the policymaking process.

Priority setting and policy content may reflect a political agenda driven by public or media concerns or international trends. Various key stakeholders set priorities for policy content with funding often a key priority where there is a scarcity of resources (Khayatzaadeh-Mahani et al., 2012). Where there are resource implications the public or regulating body must

consider this in relation to recommendations. This can steer the policy content in certain directions rather than ensuring that public interests are central to the policy content (Khayat-zadeh-Mahani et al., 2012; Oronje, 2013). In determining policy content societies' needs should be prioritised rather than political agendas (El-Jardali et al., 2014b; Engel, 2013; Gagnon & Labonte, 2013; Onwujekwe et al., 2015; Oronje, 2013). Political drivers may be more influential than evidence in driving the policy content (Gagnon & Labonte, 2013).

The contribution of evidence to inform policy is varied. Policy makers may lack skills in translating research evidence into policy decisions (Aro et al., 2016; Catallo & Sidani, 2014; Crettenden et al., 2014; Ellen et al., 2016; Nabyonga-Orem et al., 2014a). Policies are more acceptable where the evidence base is robust and there is an appreciation for the role of research in supporting the policy development process (Crettenden et al., 2014). The explicit use of research evidence was noted to be rare in a review of 21 health related physical activity policies from six European countries (Aro et al., 2016). Policy content should include a plan for dissemination, implementation and evaluation and effective communication strategies required to reach target audiences (El-Jardali et al., 2014a; Walugembe et al., 2015).

Stakeholder Consultation

Of the 68 papers included in the review, 30 engaged with the topic of stakeholder consultation. The majority of the studies (N=13) were case studies or employed a qualitative research approach (N=9). Many of the studies used existing policy analysis frameworks in data analysis. Two studies used frameworks related specifically to stakeholder consultation (Cleemput et al., 2015; Li, Li, Huang, & Zhang, 2015).

Stakeholder consultation was conceptualised as a continuum of approaches. On one end of the continuum is passive provision of information to stakeholders with the aim of informing or educating them. In the middle sits a two-way communication between policy makers and stakeholders to seek input and feedback from stakeholders. On the other end of the spectrum is deliberate, active and iterative involvement of stakeholders in policy decision-making.

If key stakeholders are not consulted, a policy decision may receive low support and have a decreased likelihood of successful implementation (Basaza et al., 2013; Nabyonga-Orem et al., 2016). Inclusion of a range of stakeholders in policymaking can build support through several different mechanisms. Firstly, it can help address tensions and achieve consensus across sectors and between those with different interests (Gagnon & Labonte, 2013; Mulvale, Chodos, Bartram, MacKinnon, & Abud, 2014). Secondly, by providing a forum for concerns to be aired and a range of perspectives to be presented, stakeholder consultation facilitates policy development that is appropriately contextualised (Basaza et al., 2013; El-Jardali et al., 2014a) and aligned with real stakeholder needs (Boivin et al., 2014). Thirdly, stakeholder consultation can provide an opportunity for stakeholder education, which can support the legitimisation of policy decisions (Boivin et al., 2014; Kreis & Schmidt, 2013). Fourthly, stakeholder engagement can result in more innovative policy than might otherwise be achieved (Boivin et al., 2014). Lastly, stakeholder consultation can result in better uptake of evidence in the policy development process (Nabyonga-Orem et al., 2014a).

Stakeholders can be a diverse group with different backgrounds and frames of reference (Baum et al., 2014). The time and resource requirement and financial cost of participating in policymaking can also create difficulties for stakeholders as it can mean redirecting resources away from other activities (Baggott & Jones, 2014; Cleemput et al., 2015; Mulvale et al., 2014).

Managing stakeholders is a key factor in achieving policy change and low stakeholder involvement can impede the process and the sustainability of change (Ade et al., 2016; Basaza et al., 2013; Mc Hugh et al., 2014).

Public and patient participation is important because it presents empowerment opportunities for these stakeholder groups (Boivin et al., 2014; Li et al., 2015; Mier et al., 2013; Park, Kim, You, Lee, & Park, 2014), or a means to build public support for policy decisions (Mulvale et al., 2014). However, concerns have been raised that often there is no real attempt to provide patients and members of the public with an active voice in policy making, even though policy makers may use the notions of ‘the patient’ or ‘the public’ to justify their own agendas (Archer et al., 2015). It can be difficult for these groups to engage in policymaking because they do not have a background in the field or they may be marginalised due to poverty, lack of education or health problems (Mulvale et al., 2014; Nabyonga Orem et al., 2013). A formal preparation process can provide patients or members of the public with training allowing them to establish their legitimacy as representatives (Boivin et al., 2014).

Implementation

Seventeen papers referred to the implementation process. The included papers were descriptive in nature; case studies (N=6); mixed methods studies using, for example, pre-and post-questionnaires with follow up focus group interviews with documentary analysis or individual interviews with follow questionnaires (N=7). The remaining papers (N=4) were referred to as qualitative studies. Factors such as planning, clear authentic leadership, stakeholder involvement, clarity of documentation, resources, awareness of the political environment, were identified as key elements of the policy implementation process and for

quality assurance (Damani et al., 2016). Such factors were identified at organisational, local, national and federal levels (Valaitis et al., 2016). The lack of planning was noted by Blaauw et al. (2014) as leading to poor implementation. A traditional top-down approach was noted to restrict policy implementation (Nabyonga-Orem et al., 2016). Similarly, Ditlopo, Blaauw, Rispel, Thomas and Bidwell (2013) argued that better planning with clear guidelines and improved communication were necessary prerequisites for implementation (Ditlopo et al., 2013).

Clear leadership is important in moving policy forward. Mc Hugh et al. (2014) noted that when the Health Service Executive (HSE) set up an Expert Advisory Group as the main source of policy and strategic advice on diabetes management, one of the problems encountered was the lack of authority in the group. Leadership by an authoritative and credible policy entrepreneur is also a critical factor for successful implementation (Gagnon & Labonte, 2013). Strong authentic leadership and contextual factors including stakeholder involvement (Ditlopo et al., 2013) through community participation are necessary when seeking to introduce and implement policy (Garcia et al., 2013; Hardy, Wertheim, Bohan, Quezada, & Henley, 2013; Shearer, Abelson, Kouyaté, Lavis, & Walt, 2016). A top down governmental approach may not lead to a positive implementation plan (Albert & Porter, 2015).

Finance and resources often outweigh evidence based policy application (Evans, Snooks, Howson, & Davies, 2013). For policy to succeed it was important to have political backing and support (Gagnon & Labonte, 2013). Decisions on priority setting are as much a political process as they are technical (Khayatzaideh-Mahani et al., 2012). Kelly, Garvey and Palcic

(2016) examined the implementation of the primary care policy in Ireland and identified three risk factors that inhibited the achievement of the policy objectives. Power included the political support and empowerment of those involved in implementation; and capability referred to the operational capacity to implement the strategy. In addition, a destabilising effect was observed when there was a lack of clarity around the resources required to implement the strategy.

Evaluation

Seventeen papers addressed issues linked to the evaluation of policy. All papers were descriptive using case study (N=5), survey design (N=2), secondary data analysis (N=1), systems-analysis (N=1), qualitative methods (N=3) or mixed methods (normally survey and interviews) (N=5). Five papers specifically addressed the use/development of approaches to evaluation mainly at the planning and implementation stages rather than an overall evaluation of the policy impact. One study detailed a protocol for process evaluation.

Evaluation should be a continuous, ongoing and independent process throughout the policymaking cycle (Baum et al., 2014; Corburn et al., 2014; Ditlopo et al., 2013; Gagnon & Labonte, 2013; Nanney et al., 2014) although little evidence of this is reported. Evaluation should be participatory, cooperative (Hämäläinen et al., 2016) and informed by key actors. In health this includes health consumer and patient organisations (Baggott & Jones, 2014). The need to identify clear outcomes for measurement at the outset was identified with challenges noted in relation to anticipating and predicting health impacts/outcomes (Ádám et al., 2012; Anderson et al., 2013; Archer et al., 2015; Baum et al., 2014). The use of Health Impact

Assessment was reported in the initial stages of policy development rather than continuously throughout the policymaking cycle (Ádám et al., 2012; Anderson et al., 2013).

The evaluation framework should cover policy formulation, implementation and evaluation and include key indicators which may or may not be available (Davies & Sherriff, 2014). Evaluation should include key actors and requires negotiation and a theoretical base (de Leeuw, Clavier, & Breton, 2014; Haynes et al., 2014). Resource issues including time and finances, were identified as potential barriers to robust evaluation.

DISCUSSION

The synthesis of findings presented here support the constructs underpinning the six domains of the HrPAF and make a novel contribution to our understanding of the complex process of health policymaking (Casey et al., 2017). Our findings allowed us to refine the HrPAF to reflect the importance of context across all six domains and the corresponding indicative criteria. As such, the HrPAF has utility across contexts and can inform the development, implementation and analysis of policy.

Specifically, our findings demonstrate that what works in one context will not necessarily work in another. We refined the context domain to reflect a need to identify the drivers for change from healthcare professionals, regulating agencies and the national context. The context domain also recognises the influence of national and international policy as a driver for change. Policy developers and evaluators can therefore benefit from seeking out context specific evidence, stakeholder input or historical evidence (Walt et al., 2014). The political context at both national and international level as well as policymaking in different sectors

such as education and regional planning can have an impact on policymaking so identifying key contextual drivers is both important and time consuming.

Policies expected to be resource neutral are particularly difficult to implement and those that are culturally controversial may need an education campaign. Aligning any new policy with national strategy and emulating previous successful policymaking attempts can help gain acceptability for policy changes.

Key to success is recognition that the process of policymaking depends on clear identification of the issue and the potential value or purpose of the policy for key stakeholders. Our findings support the need for policy makers to set an agenda driven by key stakeholders (especially patients/public) rather than political agendas (Imani-Nasab et al., 2014). Balancing the influence of local and personal agendas, national and international policy that inform the context with key stakeholder and political views emphasises the complexity of this process.

Resource implications need to be considered throughout alongside stakeholder consultation, best research evidence and an exploration of best practice nationally and internationally. Our findings reveal that the process of gathering, analysing and synthesising evidence to underpin the policymaking process is variable so policy development may not be evidence based. There are challenges in establishing an evidence base so reviewing the outcomes of policies or practices in other countries can mitigate some of these.

The acceptability and feasibility of the implementation plan involves risk assessment, realistic timeframes and availability of appropriate infrastructure (such as IT) and recognition of the needs of diverse and vulnerable groups. Good communication is essential and technical support may be required.

Our findings demonstrate the various drivers requiring consideration in relation to policy content. The intended scope, stakeholder contributions, sources of data used and assumptions influence the process of developing the content. State actors, driven by a political agenda that can be influenced by public concerns, media pressure, resource implications or international trends (El-Jardali et al., 2014a; Walugembe et al., 2015), usually make final decisions on policy content. Yet the literature emphasises the importance of prioritising societal needs rather than political agendas in policy content development which highlights the need for a systematic and transparent approach in identifying priorities, decision making and identifying implementation implications.

The requirement for stakeholder consultation in policy development emerged as critical to the whole process. Stakeholder groups can be individuals, organisations and other groups both inside and outside of regulatory bodies including governments. Stakeholder involvement uses different modes of consultation from passive, where information is simply shared by policy makers, to active, where stakeholders are heavily involved in decision-making in the policy process. Their roles include advocacy, information dissemination, representation, opinion provision, community mobilisation and decision making. Stakeholders are increasingly included in the policymaking process to provide legitimisation, to ensure that policy is appropriately contextualised and innovative, to ensure that implementation barriers are

considered and ultimately because their exclusion can result in lower support for policy decisions. However, there are barriers to stakeholder consultation.

Firstly, if stakeholders are consulted or are actively involved in decision-making, the process takes longer and there are resource implications. Including a range of stakeholders in policymaking can create tensions and make consensus difficult to achieve. This can lead to questions about their legitimacy to represent others and create difficulties for them in their own organisations if policy decisions do not align with organisational objectives (Boivin et al., 2014; Li et al., 2015; Mier et al., 2013; Park et al., 2014).

The implementation process is acknowledged as being a salient component of policy development and should be considered at the outset. Careful planning with meaningful stakeholder participation supports the successful implementation of policy. In particular community participation can help overcome resistance to policy changes in the planning stages and therefore increase the chance of successful implementation. Sufficient finances and resources to support policy implementation are also required (Odoch et al., 2015). Additionally, authentic leadership with political acumen is essential in driving policy change forward.

Finally, evaluation should be continuous, reflexive, evidence-based and independent and should occur throughout the policymaking process. An in-built evaluation plan with the identification of clear robust outcomes for measurement which fits with a policy-making agency's overall evaluation plan is a necessary base (de Leeuw et al., 2014; Haynes et al., 2014). However, there is limited evidence of this happening in reality making it difficult to

assess how outcomes from ongoing evaluation feedback into the policymaking cycle. Additionally, as the stages of policy implementation and policy evaluation intersect, community based participatory research approaches which includes key actors are strongly advocated.

Limitations and strengths

The lack of rigorous study designs and heterogeneity limits the robustness of current evidence. We did not include the Grey literature given a large number of papers and only studies published in English were included. Strengths of this review lie in a rigorous approach which involved at least two members of the research team at each stage and several cycles of refinement and consultation.

CONCLUSION

This review confirms that the six domains and underpinning criteria included in the HrPAF are fit for purpose at this point. Generally, there is failure to contextualise and integrate policy context, process, content, stakeholder inclusion, implementation and impact evaluation in the overall policy-making process and to relate it to all phases: problem identification, policy analysis, strategy and policy development, policy enactment and policy implementation. Identification of an evaluation strategy at the outset is essential.

We acknowledge the need to further identify, test and refine the constructs linked to the policymaking cycle taking cognisance of the context where these are developed, implemented and evaluated. Additionally, more methodologically robust research on health policymaking is needed that goes beyond describing policymaking processes. Nevertheless, findings from

this review contextualise and inform the policymaking process. The breadth of included studies strengthen the utility of this framework to an international policymaking context.

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Table 1: Overview of key domains included in the Health related Policy Analysis Tool (HrPAT).

Key domains	Indicative criteria
1: Context	<ul style="list-style-type: none"> • Drivers for change are clearly articulated • Policy is situated within relevant national, EU and International health and social strategic networks • Sufficient account is taken of the national context.
2: Process	<ul style="list-style-type: none"> • There is a clear methodology including adaptation (if appropriate), risk assessment and timeframe • Leadership and governance is evident • Personnel with technical and methodological capacity are involved • Evidence of rigour in the gathering, review, use and presentation of evidence • Evidence of benchmarking against sectoral and international policies.
3: Content	<ul style="list-style-type: none"> • Core concepts and principles are identified and defined • There is clarity of presentation/structure/language • Content is relevant to the overall purpose of the policy • The evidence base reviewed is comprehensive.
4. Stakeholder Consultation	<ul style="list-style-type: none"> • Evidence of consideration of the needs of stakeholders • Evidence of stakeholder consultation • Stakeholders views are represented.
5. Implementation	<ul style="list-style-type: none"> • Accessibility and feasibility of implementation plan is considered. • Leadership and governance of an implementation plan is identified.
6. Evaluation	<ul style="list-style-type: none"> • In-built Monitoring and evaluation plan, including timeframe, is included • Governance of the evaluation is identified • Outcome measures are identified • Account taken of immediate and longer term impact.

Table 2 Search terms utilised

P	Nursing or nurse or midwife or midwifery or health or “social care” AND
I	Process or processes or steps AND
O	Policy or "Policy Studies" or "Policy Making" or "policy origins" or "policy process" or "policy provision" or "policy processes" or "policy principles" or "policy prioritization" "policy prioritisation" or "policy outcomes" or "policy paper" or "policy papers" or "policy performance" or "policy perspective" or "policy perspectives" or "policy planning" or "policy planning monitoring" or “policy evaluation” or "policy planning process" or "policy planning purposes" or "policy plans" or "policy position" or "policy practice implications" or "policy predictors" or “policy analysis” or “policy development” or “policy creation” or “regulation” or “policy regulation”

Author	Year	Country	Aim/Purpose of the Study	Type of study
Adam <i>et al.</i> ,	2012	Hungary	Introduction of smoke-free policy legislation – impact on health	Quantitative-Health impact analysis
Ade <i>et al.</i> ,	2016	France	Exploration of the perceptions of the Guinean stakeholders who participated in the policy dialogue process	Qualitative case study
Albert and Porter	2015	India	To explore, in one province in India where traditional tribal medicine and biomedicine dominate, the roll out of a policy to mainstream other approaches to medicine	Qualitative study
Anderson <i>et al.</i> ,	2013	USA	This paper describes a programme – Alaska's HIA programme to ensure that development projects are designed to maximise positive health benefits and minimise negative health impacts.	Case study
Archer <i>et al.</i> ,	2015	India	To analyse prevailing definitions of revalidation (i.e. a recently instituted system of ongoing review for all physicians in the United Kingdom), the circumstances of their origin, and proposed applications	Qualitative – critical discourse analysis
Aro et al	2016	Finland, Netherlands, Denmark, Romania, Italy, UK and Canada	To explore the use of evidence in health enhancing physical activity (HEPA) policies	Case study
Baggott and Jones	2014	UK	To explore the policy role of voluntary health organisations in the UK over the past two decades.	Quantitative
Basaza <i>et al.</i> ,	2013	Uganda	Contextual and stakeholder analysis of setting policies for a proposed National Health Insurance Scheme in Uganda	Case study
Baum <i>et al.</i> ,	2014	Australia	Determining the extent to which Health in All Policies is effective as a method of developing and delivering public policy	Multi-phase study incorporates critical action research, realistic evaluation and program logic
Beland <i>et al.</i> ,	2014	USA	To explore the challenges of inter-governmental policy design related to health insurance.	Case study
Blaauw <i>et al.</i> ,	2014	South Africa	A policy analysis of the development of a new Nursing Qualifications Framework in South Africa	Qualitative Case Study
Boivin <i>et al.</i> ,	2014	Canada	To compare policy priority setting with and without public involvement	Trial process evaluation
Brolan <i>et al.</i> ,	2014	United Nations	Evaluate the outcome of using the Millennium Development Goals (MDG)	Qualitative
Carey et al	2014	Australia	To understand the nature of government and policymaking as it pertains to action on the social determinants of health	Qualitative
Catallo & Sidani	2014	Canada	To assess the psychometric properties of the instrument <i>Self-assessment of Organisational Capacity to Support the use of Research Evidence to Inform Decisions</i>	Cross Sectional design
Chanturidze <i>et al.</i> ,	2015	Kazakhstan	A programme of capacity building focused on strengthening strategic planning and policy making in health	Case study
Chimhutu <i>et al.</i> ,	2015	Tanzania	The policy process behind the introduction of a payment for performance scheme of the health sector of Tanzania	Qualitative
Cleemput <i>et</i>	2015	Belgium	To evaluate the acceptability and perceived benefits and risks of public and patient	Delphi Survey

<i>al.</i>			involvement in coverage decision making to Belgian stakeholders	
Corburn <i>et al.</i> ,	2014	USA	To describe and analyse the emergence and development of HiAP (Health in all Policies) in Richmond California	Case Study
Crettenden <i>et al.</i> ,	2014	Australia	How evidence based workforce planning is being used in Australia to inform effective policy development	Case Study using quantitative methods
Damani <i>et al.</i> ,	2016	Canada	Using guiding principles of public participation processes, to engage stakeholders and use their input to refine the policy directions.	Mixed methods
Davies & Sheriff	2014	European Union	To introduce and analyse the development of the Gradient Evaluation Framework (GEF)	Qualitative
De Leeuw <i>et al.</i> ,	2014	Australia	To review the nature of policy and the definition and directions of health policy.	Case Study
Ditlopo <i>et al.</i> ,	2013	South Africa	To examine the impact of occupation-specific dispensation policy for nurses	Descriptive case study design
Dovlo <i>et al.</i> ,	2016	Cabo Verde, Chad and Mali.	To review the policy dialogue processes involved in developing major policies in three African countries	Exploratory qualitative
El-Jardali <i>et al.</i> ,	2014a	Lebanon	A retrospective policy analysis on the Lebanese Voluntary Health Insurance policy	Qualitative case study design
El_Jardali <i>et al.</i> ,	2014b	Lebanon	A policy analysis of nursing practice law in Lebanon to generate in-depth insights on the public policymaking process.	Qualitative
Ellen <i>et al.</i> ,	2016	Israel	Explore Israeli health systems and policy researchers' views and perceptions regarding the role of health systems and policy research (HSPR) in health policymaking	Quantitative
Engel	2013	India	To examine the construction of multi drug resistant tuberculosis as a public problem in the making	Ethnography
Evans <i>et al.</i> ,	2013	Wales	The role of research evidence through implementation of a national chronic conditions management policy	Mixed methods
Field <i>et al.</i> ,	2016	New Zealand	A theory-informed framework for enhancing the use of evidence in government public health nutrition policymaking	Case study
Gagnon & Labonte	2013	UK	In-depth investigation and analysis of the UK global health policy	Case Study
Garcia <i>et al.</i> ,	2013	US and Mexico	To explore the potential of an intergenerational photovoice approach as a health-promoting strategy for participants and their communities	Mixed methods
Guariguata <i>et al.</i> ,	2016	Caribbean	A system dynamics model to guide policy on the prevention and control of diabetes, using a process designed to fully engage with policymakers	Mixed methods
Hamalainen <i>et al.</i> ,	2016	Finland, Denmark & UK	To describe the governance structures and processes of cross-sector cooperation in health-enhancing physical activity policies	Mixed methods
Hardy <i>et al.</i> ,	2013	USA	The Policy Coalition Evaluation Tool (PCET) - a model to guide and measure efforts and outcomes of a local community-based policy coalition in the prevention of childhood obesity	Mixed methods
Harris <i>et al.</i> ,	2014	Australia	Public policy theory used to explain Health Improvement Assessment (HIA) - practitioners' experiences'	Qualitative exploratory

Hunter <i>et al.</i> ,	2014	USA	Exploring national policy-makers' interpretation and use of indicators from country profiles and reports developed by Countdown to 2015	Qualitative
Imani-Nasab <i>et al.</i> ,	2014	Iran	The barriers and facilitators in developing evidence-based health policy documents from the perspective of their producers in a developing country	Qualitative study with framework analysis approach
Kelly <i>et al</i>	2016	Ireland	The formation and implementation of a primary care policy in identifying risk categories within the policy making process	Case study
Khayatzaadeh-Mahani <i>et al.</i> ,	2012	Iran	To investigate how a national priority setting programme works in the centralized health system of Iran	Case study
Kreis & Schmidt	2013	France, Germany & the United Kingdom	Public engagement processes and underlying rationales at NICE, HAS, and G-BA	Case study
Marzuki <i>et al.</i> ,	2015	Malaysia	To explore the factors that underpin the development of Telehealth policy and its implementation	Case study
Mbachu <i>et al.</i> ,	2016	Nigeria	The role of evidence in policymaking and in 'the policy triangle' using the case of the Nigerian Integrated Maternal Newborn and Child Health (IMNCH) strategy	A retrospective case-study using mixed methods
Mc Hugh <i>et al.</i> ,	2014	Ireland	To examine the development of recommendations by the Expert Advisory Group (looking at Diabetes policy) as an instrumental case study of the policy formulation process	Case study
Mier <i>et al.</i> ,	2013	USA-Mexico border	A knowledge transfer process that engaged researchers and stakeholders in addressing the physical activity needs and environmental barriers among low-income, Mexican-American	Exploratory study employed a qualitative research design
Mulvale <i>et al.</i> ,	2014	Canada	Review of the essential role that engagement of civil society played in the creation of the Mental Health Strategy	Case study
Nabyonga Orem <i>et al.</i> ,	2013	Uganda	To develop a better understanding of the perceived roles of the key stakeholders in knowledge translation and partnerships in Uganda	Qualitative study including documentary review
Nabyonga-Orem <i>et al.</i> ,	2014 a	Uganda	Examines the uptake of evidence in policy development, specifically in reference to changes in the malaria treatment policy in Uganda	Case study
Nabyonga-Orem <i>et al.</i> ,	2014 b	Uganda	To explore how different stakeholders shaped the evidence uptake in relation to malaria treatment policy change,	Case study
Nabyonga-Orem <i>et al.</i> ,	2016	Lusophone Cabo Verde, Francophone Chad, Guinea and Togo, and Anglophone Liberia	To assess stakeholders' understanding and perceived importance of health policy dialogue and of policy dialogue coordination	Cross-sectional descriptive study using qualitative methods
Nanney <i>et al.</i> ,	2014	US - Minnesota	School Obesity-Related Policy Evaluation study to demonstrate the use of surveillance data to address identified gaps in school policy evaluation literature	Cross-sectional study
Odoch <i>et al.</i> ,	2015	Uganda	To explore the policy process of the introduction of male circumcision for HIV prevention	Conceptual framework
Onwujekwe <i>et al.</i> ,	2015	Nigeria	To explore the role and use of evidence in policymaking	Cross-sectional qualitative study
Oronje	2013	Kenya	To deconstruct three Sexual and Reproductive Health policy development processes in order to identify the political interests and power dynamics that have determined the resultant policies	Case study
Park <i>et al.</i> ,	2014	South Korea Seoul	To assess public participation in-local health policy and its implication through the	Survey

Shearer, et al	2016	Burkina Faso	analysis of policy networks in health centre programs To explore drivers for policy change using the theoretical integration of networks framework with policy theories in Burkina Faso	Comparative case study
Spitters <i>et al.</i> ,	2017	Netherlands, Denmark & Romania	To unravel the stakeholder network in the policy process by conducting three systems analyses, and to increase insight into the similarities and differences in the policy processes of three European countries	A systems analysis of policymaking process
Tabak <i>et al.</i> ,	2015	USA	To describe ways that advocates seek information for health policy advocacy	Telephone survey
Tumwesigye <i>et al.</i> ,	2013	Uganda	To explore the policy development and revision processes to identify strengths and weaknesses to inform adjustments	Case study
Uddin <i>et al.</i> ,	2013	Bangladesh	To map and analyze the formal decision-making process in relation to the introduction of new vaccines within the context of health policy and health systems	Qualitative
Valaitis et al	2016	Canada	Exploration of policy implementation in two exemplar Public Health programmes – chronic disease prevention and sexually transmitted infection prevention	Qualitative
Vandenbroeck <i>et al.</i> ,	2014	Belgium	To set up a participatory process to lay down the contours of a future Belgian community mental health service system	Soft Systems Methodology including a participatory process
Vos, <i>et al.</i> ,	2014	Belgium	To document the political agenda-setting process which led to the introduction of a new-born hearing screening programme	Qualitative study
Walugembe, et al	2015	Bangladesh	To explore how research findings were utilized in the policymaking and strategic planning processes in Bangladesh	Case study
Zida <i>et al.</i> ,	2017	Burkina Faso	To analyse the policymaking processes associated with the establishment of two national health system support units in Burkina Faso,	Mixed methods

Table 3: Included Studies

Figure 1 PRISMA Searching and screening process

