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Research paper

Claims in vapour device (e-cigarette) regulation: A Narrative Policy Framework analysis

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ABSTRACT

Background: The electronic cigarette or e-cigarette (vapour device) is a consumer product undergoing rapid growth, and governments have been adopting regulations on the sale of the devices and their nicotine liquids. Competing claims about vapour devices have ignited a contentious debate in the public health community. What claims have been taken up in the state arena, and how have they possibly influenced regulatory outcomes?
Methods: This study utilized Narrative Policy Framework to analyze the claims made about vapour devices in legislation recommendation reports from Queensland Australia, Canada, and the European Union, and the 2016 deeming rule legislation from the United States, and examined the claims and the regulatory outcomes in these jurisdictions.
Results: The vast majority of claims in the policy documents represented vapour devices as a threat: an unsafe product harming the health of vapour device users, a gateway product promoting youth tobacco uptake, and a quasi-tobacco product impeding tobacco control. The opportunity for vapour devices to promote cessation or reduce exposure to toxins was very rarely presented, and these positive claims were not discussed at all in two of the four documents studied.
Conclusion: The dominant claims of vapour devices as a public health threat have supported regulations that have limited their potential as a harm reduction strategy. Future policy debates should evaluate the opportunities for vapour devices to decrease the health and social burdens of the tobacco epidemic.

Introduction

From its invention in 2003, the electronic cigarette and its evolving product designs (for example, tank systems) have become a US$ 7.99 billion worldwide market in 2015, with sales projected to more than double by 2020 (Euromonitor International, 2016). Governments have been faced with the policy problem of how to regulate these new consumer products which can (but do not necessarily) deliver nicotine. All these products are termed *vapour devices* in this study. As of 2016, vapour devices have been regulated as medicinal products (18 countries), as tobacco products (26 countries), or as a controlled substance (nicotine) (4 countries), while 26 countries have banned their sale (Institute for Global Tobacco Control, 2016).

In prior policy processes on tobacco, the public health community has presented a virtually united front, but when it comes to vapour devices, there is no agreement (Costa, Gilmore, Peeters, McKee, & Stuckler, 2014). A vitriolic debate rages (Sim & Mackie, 2014) as public health officials and researchers espouse radically divergent viewpoints on the health and population level effects of vapour devices. Claims have been dominating the debate. As Stimson, Thom, and Costall (2014) observed, "claims are made and contested by manufacturers, distributors, retailers, consumers, social movements, the state, and professional organisations. How this will play out with respect to electronic cigarettes is uncertain . . . " (p. 655).

In this study, we examined claims about vapour devices that have been taken up in the state arena. To date, no research has been conducted to examine what claims about vapour devices have been accepted in the legislative process. Understanding these claims reveals how the policy problem of vapour devices has been defined in government legislation. In our research questions we asked: What claims about vapour devices have been put forward in the documents recommending or justifying vapour device regulation? How have these claims potentially influenced the resulting legislation?

To identify these claims, we analyzed four government documents: three legislation recommendation reports and one

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regulatory ruling. These documents are from Queensland, Australia (2014) *Health Legislation Amendment Bill 2014, Report No. 59*; from Canada (2015) *Vaping: Towards a Regulatory Framework for E-Cigarettes*; from the European Union (2013) *Report A7-0276/2013, 24.7.2013*; and from the United States (2016) *Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act*. For Queensland, the European Union, and the United States, these documents are the recommendation reports on draft legislation written to inform the regulation of vapour devices and other tobacco products. The Canada report is a preliminary report initiated to prepare for drafting legislation for vapour devices. These four documents were selected, first and foremost, because they contained the claims about vapour devices that were not written in the regulations but provided the rationale for them. They also were chosen to provide examples of claims about vapour devices in the differing contexts of regional, national, and trans-national governments to observe the possible differences in their policy narratives. Finally, these documents were picked because they were written in the same language, facilitating the comparison between documents with their common English narrative text structures.

To examine these claims about vapour devices, we applied the Narrative Policy Framework (NPF), a methodology developed in 2004 (Shanahan, Jones, & McBeth, 2011) premised on the hypothesis that "narrative stories are the principal means for defining and contesting policy problems" (Stone, 2012, p. 158). NPF posits narratives as a key mechanism in the policy process because humans, by their very nature, are storytellers (McBeth, Jones, & Shanahan, 2014). Policy narratives are socially constructed stories produced within belief systems (Jones, McBeth, & Shanahan, 2014) that narrate the "reality" of the policy problem, and assign blame (McBeth et al., 2014). The purpose of policy narratives is persuasion (Weible & Schlager, 2014) to influence the framing of a policy problem and shape policy beliefs (Pierce, Smith-Walter, & Peterson, 2014).

NPF has been described as both a research platform (Weible & Schlager, 2014) and as a rubric (Shanahan et al., 2011). As a research platform, NPF provides a "structuralist interpretation of narrative" (McBeth et al., 2014, p. 228) which asserts that policy narratives can be empirically studied across different policy contexts by examining their strategies and policy beliefs, as opposed to the post-positivist view that every narrative is unique and therefore not generalizable (narrative relativism). As a rubric, NPF offers generalizable content structures (or structural elements) for analyzing policy narratives. These content structures are based on the construct of the *story*, and NPF approaches policy narratives as stories constructed through the elements of the setting, characters, plot, and moral of the story (Jones & McBeth, 2010; Jones et al., 2014). These variables can be applied across different contexts, and at micro (individual), meso (group), and macro (culture) levels (Jones et al., 2014). This study applies NPF at the meso-level of policy making and policy outputs, which is symbolized in NPF by the *agora narrans*, the ancient Greek public space where citizens made their speeches (McBeth et al., 2014).

The broad goal of NPF is to understand "to what extent do policy narratives influence policy outputs?" (Jones et al., 2014, p. 18). The primary goal of this study is to identify claims about vapour devices that may have had traction in the regulatory process, and to show how these claims may have, in turn, influenced policy outcomes. A secondary purpose of this research is to inform interested parties on how vapour device regulation has been crafted in four jurisdictions, including the major markets of the European Union and the United States. In addition, this study contributes to the further development of the relatively new NPF methodology through the transparent reporting of this study's techniques for the identification of characters and the classification of plots. Finally, it enriches the scope of NPF by utilizing the framework with a public health policy issue, as NPF research has to date focused almost exclusively on environmental policy (Pierce et al., 2014).

Methods: Narrative Policy Framework analysis

The unit of analysis for this study is the claim, which for this research is a statement of fact about the potential or actual effects of vapour devices made in the documents of Queensland, Canada, the European Union (EU), and the United States (US). Claims act as a form of evidence, a truth claim. Claims about vapour devices purport to be a true evaluation of the product or a trustworthy prediction of its impacts on health.

This study is based on three sets of textual data: (1) contextual information about vapour device prevalence, prior regulations, and the processes that produced the policy document; (2) the claims presented in the document; and (3) the regulatory outcome. These data sets facilitate an understanding of the contexts of the policy processes, identify the claims for NPF analysis, and provide details of the regulations to examine how specific claims in the documents may have influenced the resulting policy outputs.

The datasets were constructed from multiple sources. For the context data, vapour device prevalence was located in national health surveys, and prior regulations were found in scholarly journals and reports from non-profit organizations. The policy processes that produced the documents were identified through reviewing the respective governments' websites with additional historical details provided by journal articles and grey literature. This contextual information acts as the NPF's setting of the story, and it has been presented as a narrative summary for each jurisdiction in the Results section. The selected policy documents were downloaded from the governments' websites, and the process of identifying the claims is described in the Methods section below. The final legislation is, in effect, the moral of the story, and the legislation was summarized from the final published regulations.

The identification of claims was carried out through multiple close readings of the documents. Semantic content analysis was conducted to retrieved declarative sentences and phrases about vapour devices which constitute the claims, and all further analysis was performed with the NPF content structures described below. The documents reported the testimony and claims of numerous witnesses, but not all of their claims were accepted in the recommendations. For example, the US document reported but dismissed a research study demonstrating that bans on vapour device sales to youth resulted in *higher* smoking rates compared to states without a ban, and instead the US report endorsed bans on sales to youth. Therefore, only the claims about vapour devices that were endorsed in the Queensland, Canada, and EU recommendation reports and only the claims validated in the US regulatory document were included in the analysis.

Once identified, the full claim text was then extracted, and listed in a table for each document. Some texts, particularly those in the Queensland report, contained multiple claims in one sentence, so for purposes of analysis, these were segmented into single claims. These segmented texts are indicated by shading in the claims text tables. Each claim text was assigned an identification number (ID). The tables of the claim texts were edited into a truncated text to support our readers in following the analysis. (The full texts of the claims are available as a supplemental file, Tables S1-S4.)

For the analysis of the claims, the first author defined each claim's content with the NPF content structures of characters and plots. In this framework, the *characters* are classified as the heroes who purport to solve the policy problem, the villains who cause the