A critical evaluation of the volume, relevance and quality of evidence submitted by the tobacco industry to oppose standardised packaging of tobacco products

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ARTICLE SUMMARY

Article Focus

- Better Regulation dictates that public policy ideas which may impact on businesses must be subject to public consultation and evidence-based impact assessment prior to policy progression.
- There is extensive evidence to support the case for standardised packaging of tobacco products as a contributor to the reduction in overall smoking prevalence.
- Transnational tobacco companies have been instrumental in promoting Better Regulation, and have a historical record of seeking to delay and prevent tobacco control regulations.

Key Messages

- Using Better Regulation processes, transnational tobacco corporations have legitimately sought to use evidence as a tool to influence the policy outcome on standardised packaging in the UK.
- The evidence tobacco manufacturers cited in their consultation submissions was not as relevant or as high quality as the evidence supporting packaging regulation.
- Improving the transparency of evidential management and interpretation strategies and thresholds may help address the potential conflict between Better Regulation and the Framework Convention on Tobacco Control.

Strengths and Limitations

- This study builds on the existing literature on corporate influence over public health policy and evidence.
- Further investigation of policy-makers perceptions of corporate evidence would be beneficial to corroborate the relevance of our findings.

ABSTRACT

BACKGROUND: Better Regulation is an overarching governance structure requiring early stakeholder consultation and evidence-based impact assessment (IA) of policies. In 2012, four transnational tobacco companies (TTCs) responded to a UK consultation on standardised packaging of tobacco products (SP), citing extensive evidence. Following the Government's evidence-based rationale to postpone any decision on SP, this paper aims to examine the volume, relevance and quality of TTCs' evidence that SP 'won't work'.

METHODS: Evidence cited in the TTC submissions and a systematic review (SR) of the potential impacts of SP was counted and coded for relevance (subject matter) and quality (independence and peer review). Fisher's Exact Test was used to assess differences in the quality of the evidence between the two sources and between TTC evidence on packaging compared to other topics.

RESULTS: 77/143 pieces of TTC-cited evidence were used to promote their claim that SP 'won't work'. 17/77 addressed SP: 82% tobacco industry connected; 0% published in a peer-reviewed journal. In comparison, 37/37 studies included in the SR addressed SP: 0% had tobacco industry connections; 57% published in a peer-reviewed journal ($p<0.0001$). TTCs' evidence on SP/packaging (26/77) was found to be of lower quality than their evidence on topics unconnected to tobacco packaging (51/77) ($p<0.0001$).

CONCLUSION: With few exceptions, evidence promoted by TTCs to promote their claim that SP 'won't work' lacks *either* policy relevance *or* key indicators of quality. Policymakers could use these three criteria – subject matter, independence and peer-review status – to critically assess evidence submitted to them by corporate interests via Better Regulation processes.

INTRODUCTION

Standardised packaging (SP) of tobacco products would further restrict the already limited opportunities of transnational tobacco companies (TTCs) to market their products. The policy's objective is to deter smoking initiation, particularly among young people, and promote cessation among existing smokers. Its introduction in Australia in December 2012 (1) sparked a wave of interest: Ireland and New Zealand gave strong indications of their intentions to introduce SP. In contrast, the UK government announced on July 12th 2013 that it had decided to wait for '*emerging evidence'* from Australia on impacts of SP before taking a policy decision. This announcement followed a lengthy debate which began in 2011 (2), included a four month public consultation ending in August 2012 (3), and was subject to nearly a year's deliberation within the Department of Health before the consultation report was published (4). The consultation aimed to inform policy development and gather additional evidence for an Impact Assessment (IA). The IA was rated amber (needing more work) by the Regulatory Policy Committee (RPC) in February 2012 (5).

Public consultations and IAs are processes within a global governance innovation known as *Better Regulation*. Public consultations effectively frontload problem-resolution in the policy process by offering affected businesses and other interested parties an early opportunity to comment on policy ideas and proposals, and to submit evidence supporting their views (6, 7). This evidence can then be taken into account in developing IAs, which entail quantitative evidence-based assessments of the potential effects of proposed regulations and consideration of alternative policy options (8). In the UK, these processes contribute to the attainment of five features of good governance: proportionality, accountability, consistency, transparency and targeting (7, 9).

Evidence plays a key role in the policy process, and, in practice, Better Regulation underpins a form of evidence-based policy making (EBP) which is deliberately open to stakeholder influence (10, 11). Under New Labour (10) and the Coalition Government (12), Better Regulation has formalised EBP, which is now subject to two stages of scrutiny: first, by the RPC (a body sponsored by the Department of Business Innovation and Skills); and, subsequently, by the Cabinet's Reducing Regulation Committee (RRC) . The upfront costs to government of this process are intended to be offset by an associated reduced impact on businesses post-implementation. A key impetus for Better Regulation has been pressure put on governments and inter-governmental organisations by TTCs and other transnational corporations to reduce regulatory business costs and prioritise business interests in the policy process (12, 13).

New tobacco control policies developed by the Department of Health are subject to Better Regulation. Thus, TTCs can make submissions to public consultations on tobacco control policies, citing evidence regarding impacts on their businesses, wider impacts, and in support of alternative policies. Yet, the Government is also required to meet an international commitment made under Article 5.3 of the Framework Convention on Tobacco Control (FCTC) to ensure that public health policies are protected from 'commercial and other vested interests of the tobacco industry' (14). A key rationale for this provision lies in the overwhelming evidence of the tobacco industry's efforts to bias the evidence base of health impacts of tobacco products and public health policies in its favour (15-18). Uniquely, in the case of tobacco, the co-existence of these two governance regimes raises the possibility of a regulatory conflict between commitments to include businesses in policy development and commitments to exclude them (19).

The UK's consultation (3) and IA (5) on SP provides an opportunity to consider how these two sets of commitments are reconciled by governments. The four largest TTCs in the UK market – Imperial Tobacco (IT), Japan Tobacco International (JTI), Philip Morris Ltd (PM) and British American Tobacco (BAT) – submitted lengthy consultation responses (1521 pages in total, of which 328 comprised their main responses and 1193 provided supplementary materials) (20-23). These were just 4 of 668,433 responses the Department of Health received (2,444 were 'detailed responses') (4). Associated time

and resource costs raise the question of how governments can effectively make a balanced, informed and transparent assessment of the policy relevance and quality of all evidence cited in submissions (24).

A Systematic Review (SR) of the evidence for SR, commissioned by the Department of Health, concluded that there is 'strong evidence' that SP would reduce the appeal of tobacco products and increase the prominence of health warnings (25). Yet, in their submissions, the TTCs rejected its findings and claimed that there is no evidence that SP would reduce smoking prevalence or initiation, citing extensive evidence to support their arguments (20-23): as SP was only implemented in Australia after the consultation closed there were no evaluations of its real-world impact available at the time. TTCs have maintained that advertising and promotional material – including packaging – only stimulate brand switching among current smokers (26). Yet, overwhelming evidence from the tobacco industry's own marketing documents suggests this claim is highly disingenuous (27-30).

In this paper, we aim to examine the volume, policy relevance and quality of the evidence TTCs cited in their submissions and compare it with that included in the SR. We use this analysis to explore the challenges public consultations and IAs on tobacco control policies present to governments and begin to unpack the conflict between the Better Regulation agenda and the FCTC. We suggest evidential management strategies for governments developing tobacco control policies in this multi-level governance context.

METHODS

Defining 'evidence'

The comparative analysis methodology employed in this research required that 'evidence' was interpreted narrowly as formal written research sources, such as reports or journal articles. Other forms of evidence (eg. opinion, political statements, legal rulings, press coverage) cited in the tobacco industry's submissions, were excluded.

Selecting and recording TTC evidence

Details [author, title, date, source] of each piece of evidence cited by the TTCs in their submissions were extracted into an Excel spreadsheet and categorised under three main arguments made by the TTCs: there is no evidence of the beneficial impact of SP on public health – SP 'won't work'; SP will have negative unintended consequences (including economic impacts on businesses, growth in illicit trade in tobacco products, reduction in the price of cigarettes, or contravention of existing trade and intellectual property rules); and the policy process was 'flawed'. Evidence was also categorised as to whether it was promoted by the TTCs as supporting their argument, or contested by them. Only evidence used by the TTCs to promote their argument that SP 'won't work' was obtained and examined further.

Evidence from the SR

The same process was followed for the evidence included in the SR. Details of the papers were recorded in Excel and obtained for further analysis.

Criteria for assessing evidence

Three criteria, identified via a review of similar studies of evidence used to oppose tobacco regulation (17, 31-35), were used to assess the policy relevance and quality of the evidence: subject matter, independence and peer-review (Table 1). These criteria represent a practical means for policymakers to assess the policy relevance and quality of large quantities of evidence cited in

submissions to public consultations. Although it was beyond the scope of this study to critically appraise the methodology, where required analysis of study design, data and methods (31-33) could be used by policymakers on an ad hoc basis to review key pieces of evidence in more detail.

The *subject matter* of the evidence speaks to its relevance to the policy issue (24). Similar work has coded policy position, argument, topic and conclusion (33-35). On *independence*, research indicates that connection of research with a financially vested interest group can produce results which favour the sponsor, casting doubt on the independence, and therefore quality, of the evidence (33, 36, 37). The tobacco industry's efforts to discredit the science on environmental tobacco smoke and bias evidence on the impacts of smokefree legislation provide historical examples of this (15-18, 38). On *peer-review status*, articles which appear in peer-reviewed journals have been shown to be of superior quality to other research outputs in terms of study design, reporting and interpretation (33). Some alternative publication routes also include external peer-review (eg. government-commissioned research, academic press volumes and conference papers); others rely on internal peer-review (eg. charity and university research reports); research funded and published by the tobacco industry tends not to be subject to external peer-review: '[T]he tobacco industry has had a long-standing strategy of funding research and disseminating it through their sponsored, non-peer-reviewed publications.' (39)

Table 1 Coding framework for classifying evidence

	Evidential Criteria	*Use in previous studies*	Data coding framework	Coding categories
Relevance	**Subject matter**	*What is the topic, argument, position or conclusion of the evidence? [Montini et al. 2002; Bero et al. 2001; Barnes and Bero 1997]*	What issue does the research address?	• Standardised Packaging (SP) of tobacco • Tobacco Packaging, eg. graphic health warnings • Tobacco, not packaging • Unrelated to tobacco
Quality	**Independence**	*Who funded the evidence? Are authors affiliated to the tobacco industry? [Montini et al. 2002, Scollo et al. 2003, Bero et al. 2001, Barnes and Bero 1996]*	Who funded the research? Has the author of the research any connection with the tobacco industry?	• Tobacco industry-funded (Statement included that the research was funded by the tobacco industry) • Tobacco industry-linked (No statement that the research was funded by the tobacco industry, but evidence of other connection: for example, author or funder have prior links to the tobacco industry) • Independent of the tobacco industry (Statement included that the research was funded by a source independent of the tobacco industry) • No apparent tobacco industry connection (No information provided about funding source and no evidence of prior connection with the tobacco industry)

	Peer-review status	*Has the evidence been peer-reviewed? What is the impact factor of the journal and date of publication? [Montini et al. 2002, Scollo et al. 2003, Bero et al. 2001, Barnes and Bero 1997]*	Was the research published in peer-reviewed journal? If not, where was the research published?	• Peer-reviewed journal • Academic press volume • Conference paper • Government-commissioned research • University research report • Government internal research • Charity research report • Private company research report • Unpublished

Evidential coding

Each piece of evidence was obtained via online searches, (general search engines and the research database Scopus), with non-digital documents obtained from library sources. Researchers read abstracts, introductions, conclusions, funding statements and cover pages of all evidence documents, and searched documents for key terms ('plain', 'pack*', 'standard*', 'tobacco', 'smok*'). Additional web searches were conducted (eg. the Legacy Library of tobacco industry documents and Scopus) to clarify independence and peer-review status of evidence.

Analytical process

The researchers used a content analysis methodology to code and analyse the data. Each piece of evidence was accessed and coded by one researcher (JH) using the criteria outlined in Table 1. A second researcher (GF) blind coded a random sample of 20% of the data (n=21). This process achieved a 97% level of inter-coder reliability. Once all the data had been analysed, a third researcher [KER] blind coded 100% of the data. This process achieved a 94.7% level of inter-coder reliability. All disagreements were fully resolved between the coders.

Having quantified and coded the evidence, we compared the policy relevance (subject matter) and quality (independence and peer review) of the industry evidence with that of the evidence supporting SP in the SR (25). We also examined the relationship between policy relevance and quality by comparing the quality of the industry's evidence on tobacco packaging with its evidence on other topics. Differences were compared using a two-tailed Fisher's Exact Test. The results were used to develop relevance-quality typologies of TTC evidence. Evidence was classified as relevant if it focused on SP/tobacco packaging, and parallel if it focused on other tobacco issues/was unrelated to tobacco. Evidence was classified as featuring 'quality indicators' if it was either independent, published in a peer-reviewed journal or both.

RESULTS

Overview of evidence cited by TTCs in their submissions

143 unique pieces of formal written research evidence were referred to or included in the four TTCs' submissions (22 referenced by more than one company) (Table 2): 88 cited to support arguments that SP would not have beneficial impacts on public health; 36 cited to argue that SP will have negative unintended consequences, half of which related to the illicit trade in tobacco; 19 cited to argue that the policy process – particularly the IA – was 'flawed'. TTCs did not cite any research showing that the tobacco industry has extensively studied and holds considerable evidence attesting to the impact of packaging on smoking behaviour (27-30).

Of the 143 documents, TTCs promoted 131 as supporting their arguments and contested the methods, findings or accessibility of the remaining 12, all of which were included in the SR. 77 pieces of evidence were used to promote the TTC argument that SP 'won't work' and were therefore the subject of further analysis in this paper.

Table 2 Overview of formal written evidence cited by TTCs in their submissions to the UK SP consultation 2012

Theme of evidence / How cited by TTCs	SP 'won't work': No evidence of impacts on smoking behaviour	SP 'will have negative unintended consequences'				The policy process was 'flawed'	Total
		Economic	*Illicit*	*IP/ Trade*	*Price*		
Promoted	77*	3	18	5	9	19	**131**
Contested	11	1	0	0	0	0	**12**
Total	**88**	4	18	5	9	**19**	**143**
		36					

*the evidence examined further in this paper

Comparison of TTC and SR evidence on the impact of SP on smoking behaviour

There are marked differences between the relevance and quality of the TTC and SR evidence (Figures 1a/b). Only 17/77(22%) pieces of evidence promoted by the TTCs addressed SP directly: the majority of which were industry-funded/linked (14/17, 82%), none were published in a peer-reviewed journal (0/17, 0%). The remaining 60 pieces of evidence (78% of the total, comprising the majority of the evidence the industry cites) did not address SP. In contrast, 37/37 (100%) pieces of evidence included in the SR focused on SP, none (0/37, 0%) had a connection with the tobacco industry, and 21/37 (57%) were published in a peer reviewed journal. The results of a comparison of the TTCs' SP subset of evidence (n=17) with the SR evidence on SP (n=37), using Fisher's Exact Test, illustrate the statistical significance of the different distribution of relevance and quality indicators: $p<0.0001$ on subject, independence and peer-review status.

Relationships between subject matter, independence and peer-review within the TTC evidence

A low proportion of TTCs' evidence relating to SP was independent or peer-reviewed (Figures 1a/b). When evidence on tobacco packaging was added to the SP evidence, the same pattern was found : 9/26 (35%) were independent (independent/no apparent tobacco industry connection); 1/26 (4%) was published in a peer reviewed journal (Tables 3a/b). However, a greater proportion of the 51 pieces of evidence the TTCs cited on parallel topics (including non-packaging drivers of youth and adult smoking behaviour, and drivers of youth behaviour in general) were independent (47/51, 92% independent/no apparent connection) and peer-reviewed (30/51, 59% published in peer reviewed journal). These differences are statistically significant ($p<0.0001$, Table 3a). We also found a clear relationship between the two indicators of quality – independence and peer-review – in the TTCs' evidence: industry-funded/linked studies cited by TTCs were significantly less likely to be published in a peer-reviewed journal (3/21, 14%) than independent/no apparent connection studies they cited (28/56, 50%) ($p=0.0045$, Table 3b).

Table 3a Relationship between policy relevance and two measures of quality in the TTC evidence, number and per cent in parenthesis			
	Policy relevance: Subject matter		
Quality	*Relevant: Standardised packaging/Tobacco packaging (n=26)*	*Parallel: Tobacco not packaging/Unrelated to tobacco (n=51)*	*Fisher's p-value*
Independent of/no apparent tobacco industry connection	9/26 (35%)	47/51 (92%)	p<0.0001
Published in a peer-reviewed journal	1/26 (4%)	30/51 (59%)	p<0.0001

Table 3b Relationship between two measures of quality in the TTC evidence, number and per cent in parenthesis			
Peer review status	*Independent of/no apparent tobacco industry connection (n=56)*	*Connected with the tobacco industry (n=21)*	*Fisher's p-value*
Published in a peer-reviewed journal	28/56 (50%)	3/21 (14%)	p0.0045

TTCs' evidence was classified into four typologies (Figure 2): relevant/quality indicators, relevant/no quality indicators, parallel/quality indicators, parallel/no quality indicators. While 100% of the SR evidence was both relevant and featured at least one of the two quality indicators, only 12% of evidence cited by TTCs in their submissions qualified for this category.

DISCUSSION

Four main findings are apparent. TTCs cited a large volume of evidence in their submissions to the UK SP consultation. They commissioned 15 studies to support their case that SP 'won't work'. The quality of TTC evidence on SP is significantly lower, as judged by independence and peer-review, than that included in the SR. Finally, the evidence cited by TTCs is shown, with few exceptions, to fit one of two typologies – *either* relevant/no quality indicators *or* parallel/quality indicators (Figure 2).

These findings raise a number of concerns about the impact of Better Regulation on tobacco control policy. First, our findings highlight how Better Regulation with its requirement for public consultations and IAs imposes costs on government departments in the earliest stage of policy development. Just as TTCs habitually launch legal challenges in the post-decision phase of policy-making (40), so too can they use their resource advantage to exploit Better Regulation processes by both commissioning new research and submitting extensive and complex responses in the pre-decision phase of the policy process, effectively frontloading their opposition. The combination of a requirement for due diligence and the volume and nature of responses may have contributed to the eleven month delay in publication of the Department of Health's consultation report.

Second, Better Regulation's requirement that policymakers consider alternative policy options, with its underlying intention of preventing unnecessary regulation, imposes additional upfront costs on governments. In the case of SP, this requirement was explicitly addressed via the consultation questions and effectively encouraged extensive citation of evidence beyond the focus of the policy proposal. This may partly explain why nearly two thirds of the evidence the TTCs cited to claim that SP 'won't work' addressed non-packaging drivers of youth and adult smoking: studies which do not consider SP in their methodology or analysis. A second possible explanation is that the level of independence and peer-review of this parallel evidence is significantly higher than that of the evidence they cite on tobacco packaging and its inclusion may therefore have been intended to add legitimacy to TTC arguments.

Third, the absence of guidelines regarding the declaration of any connection between TTCs and the evidence they cite enable tobacco industry-funded/linked work to be cited by TTCs in such a way that any link is undeclared, implying independence. For example, BAT, IT and PM all cited tobacco industry-funded/linked evidence in their submissions without explicitly acknowledging their connection to it (20, 22, 23). This speaks to a lack of transparency in the policy process regarding the provenance of evidence submitted by corporate interests.

Fourth, the lack of clarity regarding whether or how civil servants assess the policy relevance and quality of evidence is reflected by an equivalent lack of clarity regarding how governments handle the absence of evidence. We have identified a clear omission in the TTCs' submissions of evidence regarding the importance TTCs place on tobacco packaging in the marketing of their products.

Taken collectively, evidence present in and absent from the TTCs' submissions highlights the lack of provision in Better Regulation processes for policymakers to take transparent account of the judicious selection and exclusion of evidence in consultation submissions from corporate actors with vested interests in policy outcomes. Considering the statutory requirement imposed by Article 5.3 of the FCTC to protect tobacco control policy from tobacco industry influence, it would be advisable for governments to implement and publish clear guidelines on how TTC submissions to public consultations, and evidence cited within, should be managed by policymakers. One way of achieving this would be for policymakers to adopt a similar methodology to that used in this research. Adopting a process of classifying evidence for subject matter, independence and peer-review status may help policymakers to systematically prioritise good quality, policy-focused evidence; and to flag evidence about which they need to be more sceptical, such as that which is not policy-focused, not independent or not peer-reviewed. This recommendation has relevance across government departments in all states which are signatories to the FCTC. It may be appropriate to explore whether this critical perspective ought also to be applied to non-tobacco public health regulation – for example, of the alcohol and food industries – where corporate interests also seek to influence policy being developed for the public good.

What has been learned from the UK Government's 2013 decision to postpone any decision on SP until further evidence is available is that evidence occupies a critical instrumental role in policymaking. Thus, how government departments handle and interpret evidence in the development of public health policy, and what evidential relevance and quality thresholds are set for policy progression in the context of Better Regulation, are of vital importance.

CONTRIBUTORSHIP STATEMENT

JH, GF and AG conceived the idea for this study. JH was responsible for data gathering, coding, analysis and writeup. GF and KER were responsible for secondary coding. JH, GF, KER, ZT and AG were involved in discussion of findings and commented on drafts.

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COMPETING INTERESTS

ABG is a member [unpaid] of the Council of Action on Smoking and Health, and was a member of the WHO Expert Committee convened to

develop recommendations on how to address tobacco industry interference with tobacco control policy.

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DATA SHARING STATEMENT

Extra data is available by emailing j.hatchard@bath.ac.uk

FIGURE LEGENDS

Figure 1a: A comparison of the subject matter and independence of evidence cited in TTCs' submissions (n=77) and the SR (n=37)

Figure 1b: A comparison of the subject matter and peer-review status of evidence cited in TTCs' submissions (n=77) and the SR (n=37)

Figure 2: Four Typologies of TTC evidence (n=77)

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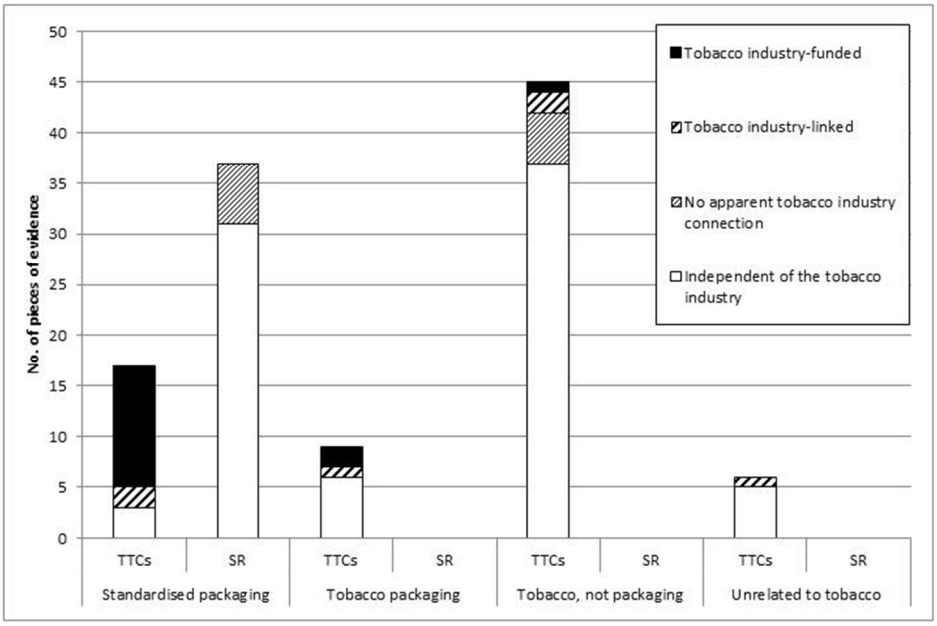

Figure 1a: A comparison of the subject matter and independence of evidence cited in TTCs' submissions (n=77) and the SR (n=37)
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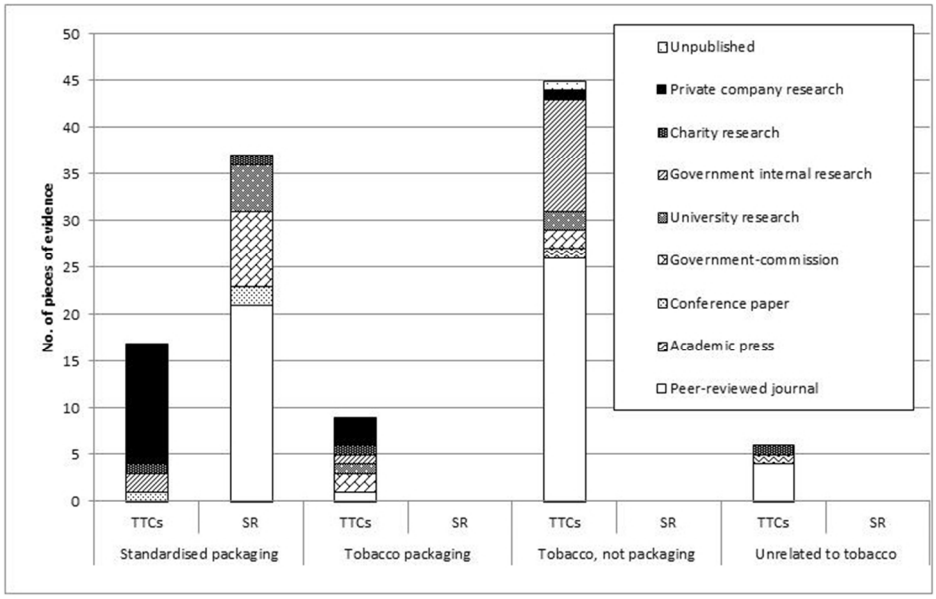

Figure 1b: A comparison of the subject matter and peer-review status of evidence cited in TTCs' submissions (n=77) and the SR (n=37)
214x143mm (96 x 96 DPI)

Figure 2: Four Typologies of TTC evidence (n=77)
108x102mm (120 x 120 DPI)

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A critical evaluation of the volume, relevance and quality of evidence submitted by the tobacco industry to oppose standardised packaging of tobacco products

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A critical evaluation of the volume, relevance and quality of evidence submitted by the tobacco industry to oppose standardised packaging of tobacco products

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ABSTRACT

BACKGROUND: Better Regulation is an overarching governance structure requiring early stakeholder consultation and evidence-based impact assessment of policies. In 2012, four transnational tobacco companies (TTCs) responded to a UK consultation on standardised packaging of tobacco products, citing extensive evidence. Following the Government's evidence-based rationale to postpone any decision on standardised packaging, this paper aims to examine the volume, relevance and quality of TTCs' evidence that the policy 'won't work'.

METHODS: Evidence cited in the TTC submissions and a Systematic Review of the potential impacts of standardised packaging was counted and coded for relevance (subject matter) and quality (independence and peer review). Fisher's Exact Test was used to assess differences in the quality of the evidence between the TTC and Systematic Review evidence and between TTC evidence on packaging compared with their evidence on other topics.

RESULTS: 77/143 pieces of TTC-cited evidence were used to promote their claim that standardised packaging 'won't work'. 17/77 addressed standardised packaging: 82% tobacco industry connected; 0% published in a peer-reviewed journal. In comparison, 37/37 studies included in the Systematic Review addressed standardised packaging: 0% had tobacco industry connections; 57% published in a peer-reviewed journal. The difference in quality of the Systematic Review and TTC evidence on standardised packaging was found to be statistically significant ($p<0.0001$). TTCs' evidence on standardised packaging/packaging (26/77) was found to be of lower quality than their evidence on topics unconnected to tobacco packaging (51/77) ($p<0.0001$).

CONCLUSION: With few exceptions, evidence promoted by TTCs to promote their claim that standardised packaging 'won't work' lacks *either* policy relevance *or* key indicators of quality. Policymakers could use these three criteria – subject matter, independence and peer-review status – to critically assess evidence submitted to them by corporate interests via Better Regulation processes.

A critical evaluation of the volume, relevance and quality of evidence submitted by the tobacco industry to oppose standardised packaging of tobacco products

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ARTICLE SUMMARY

Article Focus

- Better Regulation dictates that public policy ideas which may impact on businesses must be subject to public consultation and evidence-based impact assessment prior to policy progression.
- There is extensive evidence to support the case for standardised packaging of tobacco products as a contributor to the reduction in overall smoking prevalence.
- Transnational tobacco companies have been instrumental in promoting Better Regulation, and have a historical record of seeking to delay and prevent tobacco control regulations.

Key Messages

- Using Better Regulation processes, transnational tobacco corporations have legitimately sought to use evidence as a tool to influence the policy outcome on standardised packaging in the UK.
- The evidence tobacco manufacturers cited in their consultation submissions was not as relevant or as high quality as the evidence supporting packaging regulation.
- Improving the transparency of evidential management and interpretation strategies and thresholds may help address the potential conflict between Better Regulation and the Framework Convention on Tobacco Control.

Strengths and Limitations

- This study builds on the existing literature on corporate influence over public health policy and evidence.
- Further investigation of policymakers' perceptions of corporate evidence would be beneficial to corroborate the relevance of our findings.

INTRODUCTION

Standardised packaging of tobacco products entails the prohibition of logos, brand imagery, symbols, other images, colours and promotional text from tobacco products and tobacco product packaging. Despite the common use of the term 'plain packaging' in media coverage of this issue, graphic and textual health warning labels would still feature prominently on packs and key anti-counterfeiting marks would be retained.

Standardised packaging would further restrict the already limited opportunities of transnational tobacco companies (TTCs) to market their products. The policy's objective is to deter smoking initiation, particularly among young people, and promote cessation among existing smokers. Its introduction in Australia in December 2012 (1) sparked a wave of interest: Ireland and New Zealand gave strong indications of their intentions to introduce standardised packaging. In contrast, the UK government announced on July 12th 2013 that it had decided to wait for '*emerging evidence'* from Australia on impacts of standardised packaging before taking a policy decision. This announcement followed a lengthy debate which began in 2011 (2), included a four month public consultation ending in August 2012 (3), and was subject to nearly a year's deliberation within the Department of Health before the consultation report was published (4). The consultation aimed to inform policy development and gather additional evidence for an impact assessment. The impact assessment was rated amber (needing more work) by the Regulatory Policy Committee (RPC) in February 2012 (5).

Public consultations and impact assessments are processes within a global governance innovation termed *Better Regulation* (also known as *Smart Regulation* or *Better Lawmaking*). Drawing heavily on American Administrative Law and the cost-benefit approach to regulatory review in the US (6, 7), versions of Better Regulation are in place, for example, in multiple EU states (UK, Netherlands, Czech Republic, Sweden and Germany) (8), in the EU itself (9), and in Canada (10) and Australia (11). A key impetus for Better Regulation has been pressure put on governments and inter-governmental organisations by TTCs and other transnational corporations to reduce regulatory business costs and prioritise business interests in the policy process (8, 12).

Public consultations effectively frontload problem-resolution in the policy process by offering affected businesses and other interested parties an early opportunity to comment on policy ideas and proposals, and to submit evidence supporting their views (13, 14). Examples of consultation systems elsewhere include 'notice and comment' in the US (15) and the European Commission's 'Your voice in Europe' (16). Evidence gathered from consultations can then be taken into account in developing impact assessments, which entail quantitative evidence-based assessments of the potential effects of proposed regulations and consideration of alternative policy options (17). Evidence plays a key role in the policy process, and, in practice, Better Regulation underpins a form of evidence-based policy making which is deliberately open to stakeholder, and particularly business, influence (18, 19).

In the UK, these processes contribute to the attainment of five features of good governance: proportionality, accountability, consistency, transparency and targeting (14, 20). Under New Labour (18) and the Coalition Government (8), Better Regulation has formalised evidence-based policy making, which is now subject to two stages of scrutiny: first, by the RPC (a body sponsored by the Department of Business Innovation and Skills); and, subsequently, by the Cabinet's Reducing Regulation Committee (RRC) . The upfront costs to government of this process are intended to be offset by an associated reduced impact on businesses post-implementation.

New tobacco control policies developed by the Department of Health are subject to Better Regulation. Thus, TTCs can make submissions to public consultations on tobacco control policies, citing evidence regarding impacts on their businesses, wider impacts, and in support of alternative policies. Yet, the Government is also required to meet an international commitment made under

Article 5.3 of the Framework Convention on Tobacco Control (FCTC) to take steps to ensure that: '…in setting and implementing their public health policies with respect to tobacco control, Parties shall act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law' (21). A key rationale for this provision lies in the overwhelming evidence of the tobacco industry's efforts to bias the evidence base of health impacts of tobacco products and public health policies in its favour (22-25). Uniquely in the case of tobacco, the co-existence of these two governance regimes raises the possibility of a regulatory conflict between commitments to include businesses in policy development and commitments to exclude them (26).

The UK's consultation (3) and impact assessment (5) on standardised packaging provides an opportunity to consider how these two sets of commitments are reconciled by governments. The four largest TTCs in the UK market – Imperial Tobacco (IT), Japan Tobacco International (JTI), Philip Morris Ltd (PM) and British American Tobacco (BAT) – submitted lengthy consultation responses (1521 pages in total, of which 328 comprised their main responses and 1193 provided supplementary materials) (27-30). These were just 4 of 668,433 responses the Department of Health received (2,444 were 'detailed responses') (4). Associated time and resource costs raise the question of how governments can effectively make a balanced, informed and transparent assessment of the policy relevance and quality of all evidence cited in submissions (31).

A Systematic Review of the evidence for standardised packaging, commissioned by the Department of Health, concluded that there is 'strong evidence' that standardised packaging would reduce the appeal of tobacco products and increase the prominence of health warnings (32). However, in their submissions, the TTCs rejected the findings of the Systematic Review on the grounds that there is no evidence that standardised packaging would reduce smoking prevalence or initiation. (27-30). They cited extensive evidence to support their arguments, claimed that key evidence on smoking behaviour had not been considered in the Systematic Review, and pointed to the absence of real-world evidence as problematic: the UK consultation preceded implementation of standardised packaging in Australia in December 2012. TTCs have maintained that advertising and promotional material – including packaging – only stimulate brand switching among current smokers (27-30, 33). Yet, overwhelming evidence from the tobacco industry's own marketing documents suggests this claim is highly disingenuous (34-37).

In this paper, we aim to examine the volume, policy relevance and quality of the evidence TTCs cited in their submissions and compare it with that included in the Systematic Review (further work is underway to investigate the TTCs' interpretation of the evidence itself). We use this analysis to explore the challenges public consultations and impact assessments for tobacco control policies present to governments and begin to unpack the conflict between the Better Regulation agenda and the FCTC. We suggest evidential management strategies for governments developing tobacco control policies in this multi-level governance context.

METHODS

Defining 'evidence'

The comparative analysis methodology employed in this research required that 'evidence' was interpreted narrowly as formal written research sources, such as reports or journal articles. This restriction enabled a comparison of similar evidence in the two data sets: TTC citations and Systematic Review evidence. Other forms of evidence (eg. opinion, political statements, legal rulings, press coverage) cited in the 4 TTCs' submissions, were excluded.

Selecting and recording TTC evidence

Details [author, title, date, source] of each piece of evidence cited by the TTCs in their submissions were extracted into an Excel spreadsheet and categorised under three main arguments made by the TTCs: there is no evidence of the beneficial impact of standardised packaging on public health – standardised packaging 'won't work'; standardised packaging will have negative unintended consequences (including economic impacts on businesses, growth in illicit trade in tobacco products, reduction in the price of cigarettes, or contravention of existing trade and intellectual property rules); and the policy process was 'flawed'. Evidence was also categorised as to whether it was promoted by the TTCs as supporting their argument, or contested by them. Only evidence used by the TTCs to promote their argument that standardised packaging 'won't work' was obtained and examined further.

Evidence from the Systematic Review

Details of the papers cited in the Systematic Review were recorded in Excel and obtained for further analysis of their relevance and quality.

Criteria for assessing evidence

Three criteria, identified via a review of similar studies of the quality of evidence used to oppose tobacco regulation (24, 38-42), were used to assess the policy relevance and quality of the evidence: subject matter, independence and peer-review (Table 1). These criteria represent an objective and practical means for policymakers to assess the policy relevance and quality of large quantities of evidence cited in submissions to public consultations prior to considering their content. It was beyond the scope of this study to critically appraise the methodology used in evidence cited by TTCs. However where required, analysis of study design, data and methods (38-40) could be used by policymakers on an ad hoc basis to review key pieces of evidence in more detail.

The *subject matter* of the evidence speaks to its relevance to the policy issue (31). Similar work has coded policy position, argument, topic and conclusion (40-42). On *independence*, research indicates that connection of research with a financially vested interest group can produce results which favour the sponsor, casting doubt on the independence, and therefore quality, of the evidence (40, 43, 44). The tobacco industry's efforts to discredit the science on environmental tobacco smoke and bias evidence on the impacts of smokefree legislation provide historical examples of this (22-25, 45). On *peer-review status*, articles which appear in peer-reviewed journals have been shown to be of superior quality to other research outputs in terms of study design, reporting and interpretation (40). Some alternative publication routes also include external peer-review (eg. government-commissioned research, academic press volumes and conference papers); others rely on internal peer-review (eg. charity and university research reports); research funded and published by the tobacco industry tends not to be subject to external peer-review: '[T]he tobacco industry has had a long-standing strategy of funding research and disseminating it through their sponsored, non-peer-reviewed publications.' (46, 47)

Table 1 - Coding framework for classifying evidence

	Evidential Criteria	*Use in previous studies*	Data coding framework	Coding categories

Relevance	**Subject matter**	*What is the topic, argument, position or conclusion of the evidence? [Montini et al. 2002; Bero et al. 2001; Barnes and Bero 1997]*	What issue does the research address?	• Standardised Packaging of tobacco • Tobacco Packaging, eg. graphic health warnings • Tobacco, not packaging • Unrelated to tobacco
Quality	**Independence**	*Who funded the evidence? Are authors affiliated to the tobacco industry? [Montini et al. 2002, Scollo et al. 2003, Bero et al. 2001, Barnes and Bero 1996]*	Who funded the research? Has the author of the research any connection with the tobacco industry?	• Tobacco industry-funded (Statement included that the research was funded by the tobacco industry) • Tobacco industry-linked (No statement that the research was funded by the tobacco industry, but evidence of other connection: for example, author or funder have prior links to the tobacco industry) • Independent of the tobacco industry (Statement included that the research was funded by a source independent of the tobacco industry) • No apparent tobacco industry connection (No information provided about funding source and no evidence of prior connection with the tobacco industry)
	Peer-review status	*Has the evidence been peer-reviewed? What is the impact factor of the journal and date of publication? [Montini et al. 2002, Scollo et al. 2003, Bero et al. 2001, Barnes and Bero 1997]*	Was the research published in peer-reviewed journal? If not, where was the research published?	• Peer-reviewed journal • Academic press volume • Conference paper • Government-commissioned research • University research report • Government internal research • Charity research report • Private company research report • Unpublished

Evidential coding

Each piece of evidence was obtained via online searches, (general search engines and the research database Scopus), with non-digital documents obtained from library sources. Researchers read abstracts, introductions, conclusions, funding statements and cover pages of all evidence documents, and searched documents for key terms ('plain', 'pack*', 'standard*', 'tobacco', 'smok*'). Additional web searches were conducted (eg. the Legacy Library of tobacco industry documents and Scopus) to clarify independence and peer-review status of evidence.

Analytical process

The researchers used a content analysis methodology to code and analyse the data. Each piece of evidence was accessed and coded by one researcher (JH) using the criteria outlined in Table 1. A second researcher (GF) blind coded a random sample of 20% of the data (n=21). This process achieved a 97% level of inter-coder reliability. Once all the data had been analysed, a third researcher [KER] blind coded 100% of the data. This process achieved a 94.7% level of inter-coder reliability. All disagreements were fully resolved between the coders.

Having quantified and coded the evidence, we compared the policy relevance (subject matter) and quality (independence and peer review) of the industry evidence with that of the evidence supporting standardised packaging in the Systematic Review (32). We also examined the relationship between policy relevance and quality by comparing the quality of the industry's evidence on tobacco packaging with its evidence on other topics. Differences were compared using a two-tailed Fisher's Exact Test. The results were used to develop relevance-quality typologies of TTC evidence. Evidence was classified as *relevant* if it focused on standardised packaging/tobacco packaging, and *parallel* if it focused on other tobacco issues/was unrelated to tobacco. Evidence was classified as featuring '*quality indicators*' if it was either independent, published in a peer-reviewed journal or both.

RESULTS

Overview of evidence cited by TTCs in their submissions

143 unique pieces of formal written research evidence were referred to or included in the four TTCs' submissions (22 referenced by more than one company) (Table 2). Of the 143 documents, TTCs promoted 131 as supporting their arguments and contested the methods, findings or accessibility of the remaining 12, all of which were included in the SR. 88 were cited to support arguments that standardised packaging would not have beneficial impacts on public health; 36 cited to argue that standardised packaging will have negative unintended consequences, half of which related to the illicit trade in tobacco; 19 cited to argue that the policy process – particularly the impact assessment – was 'flawed'. 77 pieces of evidence were used to promote the TTC argument that standardised packaging 'won't work' and were therefore the subject of further analysis in this paper.

Among these 77 documents, TTCs did not cite any research showing that the tobacco industry has extensively studied and holds considerable evidence attesting to the impact of packaging on smoking behaviour (34-37). Instead, they cited industry-funded research which critiqued the SR papers, the impact assessment and the consultation document. And they cited a body of independent research into the drivers of youth smoking which, while published in peer-reviewed health and psychology journals with no apparent connection to the tobacco industry, did not explicitly address the role of packaging in youth uptake or prevalence.

Table 2 - Overview of formal written evidence cited by TTCs in their submissions to the UK SPstandardised packaging consultation 2012

Theme of evidence / How cited by TTCs	Standardised packaging 'won't work': No evidence of impacts on smoking behaviour	Standardised packaging 'will have negative unintended consequences'				The policy process was 'flawed'	Total
		Economic	*Illicit*	*IP/ Trade*	*Price*		
Promoted	77*	3	18	5	9	19	**131**
Contested	11	1	0	0	0	0	**12**
Total	**88**	4	18	5	9	**19**	**143**
		36					

*the evidence examined further in this paper

Comparison of TTC and Systematic Review evidence on the impact of standardised packaging on smoking behaviour

There are marked differences between the relevance and quality of the TTC and Systematic Review evidence (Table 3, Figure 1). Only 17/77(22%) pieces of evidence promoted by the TTCs addressed standardised packaging directly: the majority of which were industry-funded/linked (14/17, 82%); none were published in a peer-reviewed journal (0/17, 0%). The remaining 60 pieces of evidence

(78% of the total, comprising the majority of the evidence the industry cites) did not address standardised packaging. In contrast, 37/37 (100%) pieces of evidence included in the Systematic Review focused on standardised packaging, none (0/37, 0%) had a connection with the tobacco industry, and 21/37 (57%) were published in a peer reviewed journal. The results of a comparison of the TTCs' standardised packaging subset of evidence (n=17) with the Systematic Review evidence on standardised packaging (n=37), using Fisher's Exact Test, illustrate the statistical significance of the different distribution of relevance and quality indicators: $p<0.0001$ on subject, independence and peer-review status.

Table 3 - Quality and relevance of Transnational Tobacco Corporation (TTC) and Systematic Review evidence

	Relevance – *Subject matter*				
	Standardised packaging		Other (TTC evidence only)		
Quality	**Systematic Review evidence (n=37)**	**TTC evidence (n=17)**	Tobacco packaging (n=9)	Tobacco, not packaging (n=45)	Unrelated to tobacco (n=6)
Independence					
Industry-funded	**0**	**12**	2	1	0
Industry-linked	**0**	**2**	1	2	1
Independent	**31**	**3**	6	37	5
No apparent connection to the tobacco industry	**6**	**0**	0	5	0
Publication route					
Peer-reviewed journal	**21**	**0**	1	26	4
Academic press	**0**	**0**	0	1	1
Conference paper	**2**	**1**	0	0	0
Government-commission	**8**	**0**	2	2	0
University research	**5**	**0**	1	2	0
Government internal research	**0**	**2**	1	12	0
Charity research	**1**	**1**	1	0	1
Private company research	**0**	**13**	3	1	0
Unpublished	**0**	**0**	0	1	0

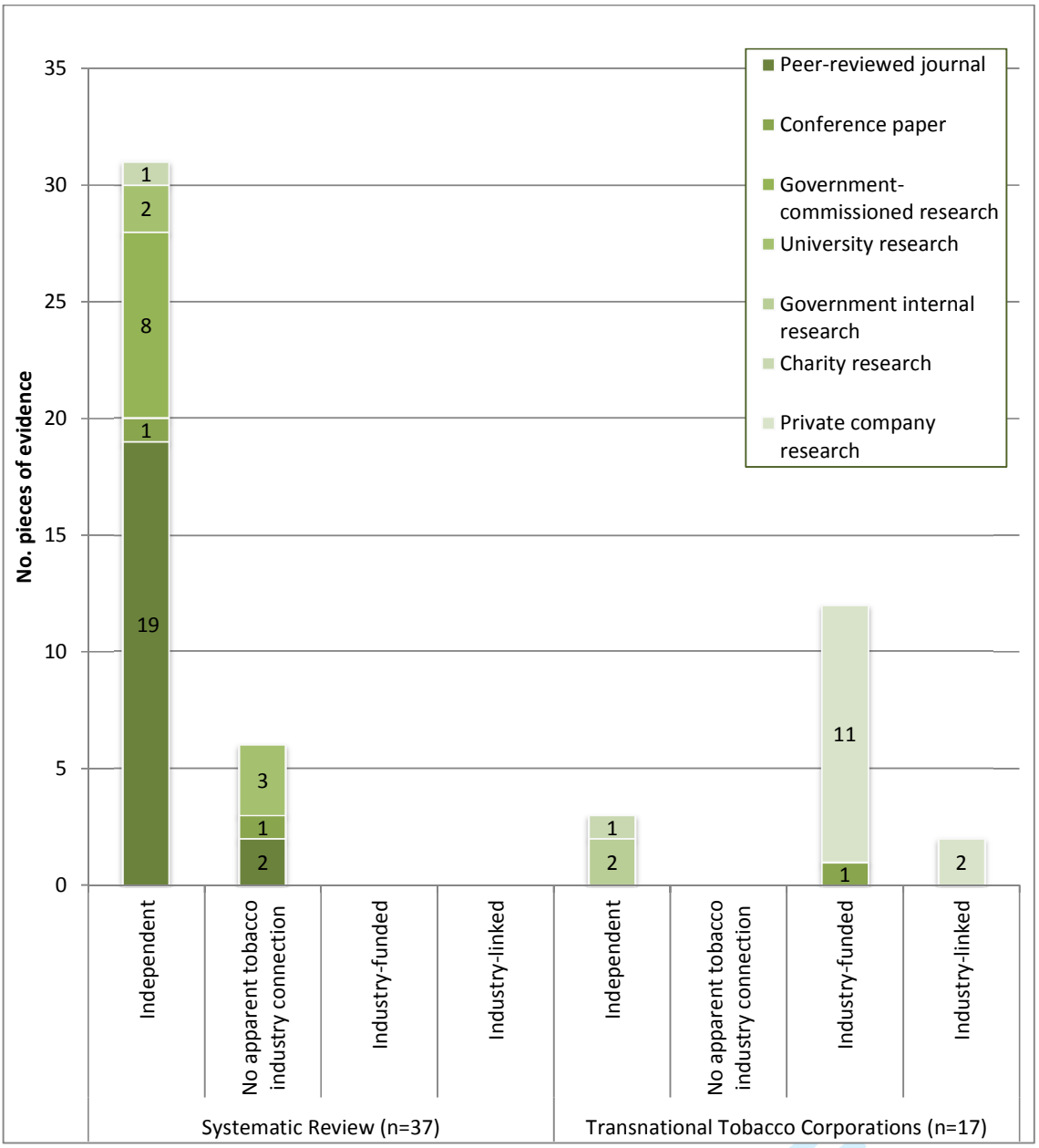

Figure 1 - Comparison of quality (independence and publication route) of Systematic Review and TTC evidence directly addressing standardised packaging of tobacco products

Relationships between subject matter, independence and peer-review within the TTC evidence

A low proportion of TTCs' evidence relating to standardised packaging was independent or peer-reviewed (Figure 1). When evidence on tobacco packaging was added to the standardised packaging evidence, the same pattern was found: 9/26 (35%) were independent (independent/no apparent tobacco industry connection); 1/26 (4%) was published in a peer reviewed journal (Tables 4a/b). However, a greater proportion of the 51 pieces of evidence the TTCs cited on parallel topics (including non-packaging drivers of youth and adult smoking behaviour, and drivers of youth behaviour in general) were independent (47/51, 92% independent/no apparent connection) and peer-reviewed (30/51, 59% published in peer reviewed journal). These differences are statistically significant ($p<0.0001$, Table 4a). We also found a clear relationship between the two indicators of

quality – independence and peer-review – in the TTCs' evidence: industry-funded/linked studies cited by TTCs were significantly less likely to be published in a peer-reviewed journal (3/21, 14%) than independent/no apparent connection studies they cited (28/56, 50%) (p=0.0045, Table 4b).

Table 4a - Relationship between policy relevance and two indicators of quality in the TTC evidence, number and per cent in parenthesis

	Policy relevance: Subject matter		
Qualityindicators	*Relevant: Standardised packaging/Tobacco packaging (n=26)*	*Parallel: Tobacco not packaging/Unrelated to tobacco (n=51)*	*Fisher's p-value*
Independent of/no apparent tobacco industry connection	9/26 (35%)	47/51 (92%)	p<0.0001
Published in a peer-reviewed journal	1/26 (4%)	30/51 (59%)	p<0.0001

Table 4b - Relationship between two indicators of quality in the TTC evidence, number and per cent in parenthesis

Peer review status	*Independent of/no apparent tobacco industry connection (n=56)*	*Connected with the tobacco industry (n=21)*	*Fisher's p-value*
Published in a peer-reviewed journal	28/56 (50%)	3/21 (14%)	p0.0045

TTCs' evidence was classified into four typologies (Table 5): relevant/quality indicators, relevant/no quality indicators, parallel/quality indicators, parallel/no quality indicators. While 100% of the Systematic Review evidence was both relevant and featured at least one of the two quality indicators, only 12% of evidence cited by TTCs in their submissions qualified for this category.

Table 5 - Distribution of TTC evidence across typologies

		Quality	**Quality indicators**	**No quality indicators**
Relevance			*Either independent, peer-reviewed or both*	*Neither independent nor peer-reviewed*
Relevant	*Standardised packaging and other tobacco packaging*		**12%** (100% Systematic Review evidence)	**22%**
Parallel	*Tobacco, not packaging and unrelated to tobacco*		**65%**	**1%**

DISCUSSION

Four main findings are apparent. TTCs cited a large volume of evidence in their submissions to the UK standardised packaging consultation. They commissioned 15 studies to support their case that standardised packaging 'won't work'. The quality of TTC evidence on standardised packaging is significantly lower, as judged by independence and peer-review, than that included in the Systematic Review. Finally, the evidence cited by TTCs is shown, with few exceptions, to fit one of two typologies – *either* relevant/no quality indicators *or* parallel/quality indicators (Figure 1).

These findings raise a number of concerns regarding the potential impact of Better Regulation on tobacco control policymaking in jurisdictions around the world. First, our findings highlight how Better Regulation, with its requirement for public consultations and impact assessments, imposes costs on government departments in the earliest stage of policy development. Just as TTCs habitually launch legal challenges in the post-decision phase of policy-making (48), so too can they use their resource advantage to exploit Better Regulation processes by both commissioning new research and submitting extensive and complex responses in the pre-decision phase of the policy process, effectively frontloading their opposition. The combination of a requirement for due diligence and the volume and nature of responses may have contributed to the eleven month delay in publication of the Department of Health's consultation report.

Second, Better Regulation's requirement that policymakers consider alternative policy options, with its underlying intention of preventing unnecessary regulation, imposes additional upfront costs on governments. In the case of standardised packaging, this requirement encouraged extensive citation of evidence beyond the focus of the policy proposal. This may partly explain why nearly two thirds of the evidence the TTCs cited to claim that standardised packaging 'won't work' addressed non-packaging drivers of youth and adult smoking: studies which do not consider standardised packaging in their methodology or analysis. A second possible explanation is that the level of independence and peer-review of this parallel evidence is significantly higher than that of the evidence they cite on tobacco packaging and its inclusion may therefore have been intended to add legitimacy to TTC arguments.

Third, the absence of guidelines requiring a declaration of any conflict of interest between corporations and the evidence they cite enable tobacco industry-funded/linked work to be cited by TTCs in such a way that any link is undeclared, implying independence. For example, BAT, IT and PM all cited tobacco industry-funded/linked evidence in their submissions without explicitly acknowledging their connection to it (27, 29, 30). This speaks to a lack of transparency in the policy process regarding the provenance of evidence submitted by corporate interests.

Fourth, the lack of clarity regarding whether or how civil servants assess the policy relevance and quality of evidence is reflected by an equivalent lack of clarity regarding how governments handle the absence of evidence. We have identified a clear omission in the TTCs' submissions of evidence regarding the importance TTCs place on tobacco packaging in the marketing of their products.

Taken collectively, evidence present in and absent from the TTCs' submissions highlights an important transparency deficit within Better Regulation processes. This deficit obscures the view of policymakers, potentially preventing them from identifying and taking account of the judicious selection and exclusion of evidence by corporate actors with vested interests in policy outcomes. Because Better Regulation requires evidence-based impact assessments and invites evidence-based submissions to public consultations, the potential exists for corporations to exert undue and unnoticed influence on the policy process.

Considering the statutory requirement imposed by Article 5.3 of the FCTC to 'protect' tobacco control policies 'from commercial and other vested interests of the tobacco industry' (21), it would

be advisable for the 177 states which are party to the Convention to implement and publish clear guidelines on how TTC submissions to public consultations, and evidence cited within, should be managed by policymakers. Two steps could be taken by governments to achieve this. First, conflict of interest declarations regarding evidence cited could be made a mandatory element of public consultations. Second, policymakers could adopt a similar methodology to that used in this research. Adopting a process of classifying evidence for subject matter, independence and peer-review status may help policymakers to systematically prioritise good quality, policy-focused evidence; and to flag evidence about which they need to be more sceptical, such as that which is not policy-focused, not independent or not peer-reviewed.

These recommendations have relevance across government departments in all states which are signatories to the FCTC. It would also be appropriate to explore applying this critical perspective to the development of non-tobacco public health regulation – for example, of the alcohol and food industries – where corporate interests also seek to influence policy being developed for the public good (49, 50).

What has been learned from the UK Government's 2013 decision to postpone any decision on standardised packaging until further evidence is available is that Better Regulation ensures that evidence occupies a critical instrumental role in policymaking. Thus, how government departments handle and interpret evidence in the development of public health policy, and what evidential relevance and quality thresholds are set for policy progression in the context of Better Regulation, are of vital importance.

CONTRIBUTORSHIP STATEMENT

JH, GF and AG conceived the idea for this study. JH was responsible for data gathering, coding, analysis and write-up. GF and KER were responsible for secondary coding. JH, GF, KER, ZT and AG were involved in discussion of findings and commented on and edited drafts of the paper.

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COMPETING INTERESTS

ABG is a member [unpaid] of the Council of Action on Smoking and Health, and was a member of the WHO Expert Committee convened to develop recommendations on how to address tobacco industry interference with tobacco control policy.

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DATA SHARING STATEMENT

Extra data is available by emailing j.hatchard@bath.ac.uk

REFERENCE LIST

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ARTICLE TITLE:
A critical evaluation of the volume, relevance and quality of evidence submitted by the tobacco industry to oppose standardised packaging of tobacco products

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A critical evaluation of the volume, relevance and quality of evidence submitted by the tobacco industry to oppose standardised packaging of tobacco products

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ARTICLE SUMMARY

Article Focus

- Better Regulation dictates that public policy ideas which may impact on businesses must be subject to public consultation and evidence-based impact assessment prior to policy progression.
- There is extensive evidence to support the case for standardised packaging of tobacco products as a contributor to the reduction in overall smoking prevalence.
- Transnational tobacco companies have been instrumental in promoting Better Regulation, and have a historical record of seeking to delay and prevent tobacco control regulations.

Key Messages

- Using Better Regulation processes, transnational tobacco corporations have legitimately sought to use evidence as a tool to influence the policy outcome on standardised packaging in the UK.
- The evidence tobacco manufacturers cited in their consultation submissions was not as relevant or as high quality as the evidence supporting packaging regulation.
- Improving the transparency of evidential management and interpretation strategies and thresholds may help address the potential conflict between Better Regulation and the Framework Convention on Tobacco Control.

Strengths and Limitations

- This study builds on the existing literature on corporate influence over public health policy and evidence.
- Further investigation of policy-makers' perceptions of corporate evidence would be beneficial to corroborate the relevance of our findings.

ABSTRACT

BACKGROUND: Better Regulation is an overarching governance structure requiring early stakeholder consultation and evidence-based impact assessment ~~(IA)~~ of policies. In 2012, four transnational tobacco companies (TTCs) responded to a UK consultation on standardised packaging of tobacco products ~~(SP)~~, citing extensive evidence. Following the Government's evidence-based rationale to postpone any decision on standardised packaging~~SP~~, this paper aims to examine the volume, relevance and quality of TTCs' evidence that the policy~~SP~~ 'won't work'.

METHODS: Evidence cited in the TTC submissions and a S~~s~~ystematic R~~r~~eview ~~(SR)~~ of the potential impacts of standardised packaging~~SP~~ was counted and coded for relevance (subject matter) and quality (independence and peer review). Fisher's Exact Test was used to assess differences in the quality of the evidence between the ~~two sources~~TTC and Systematic Review evidence and between TTC evidence on packaging compared ~~to~~with their evidence on other topics.

RESULTS: 77/143 pieces of TTC-cited evidence were used to promote their claim that standardised packaging~~SP~~ 'won't work'. 17/77 addressed standardised packaging~~SP~~: 82% tobacco industry connected; 0% published in a peer-reviewed journal. In comparison, 37/37 studies included in the ~~SR~~ Systematic Review addressed standardised packaging~~SP~~: 0% had tobacco industry connections; 57% published in a peer-reviewed journal. The difference in quality of the Systematic Review and TTC evidence on standardised packaging was found to be statistically significant ($p<0.0001$). TTCs' evidence on standardised packaging~~SP~~/packaging (26/77) was found to be of lower quality than their evidence on topics unconnected to tobacco packaging (51/77) ($p<0.0001$).

CONCLUSION: With few exceptions, evidence promoted by TTCs to promote their claim that standardised packaging~~SP~~ 'won't work' lacks *either* policy relevance *or* key indicators of quality. Policymakers could use these three criteria – subject matter, independence and peer-review status – to critically assess evidence submitted to them by corporate interests via Better Regulation processes.

INTRODUCTION

Standardised packaging ~~(SP)~~ of tobacco products entails the prohibition of logos, brand imagery, symbols, other images, colours and promotional text from tobacco products and tobacco product packaging. Despite the common use of the term 'plain packaging' in media coverage of this issue, graphic and textual health warning labels would still feature prominently on packs and key anti-counterfeiting marks would be retained.

Standardised packaging would further restrict the already limited opportunities of transnational tobacco companies (TTCs) to market their products. The policy's objective is to deter smoking initiation, particularly among young people, and promote cessation among existing smokers. Its introduction in Australia in December 2012 (1) sparked a wave of interest: Ireland and New Zealand gave strong indications of their intentions to introduce standardised packaging~~SP~~. In contrast, the UK government announced on July 12th 2013 that it had decided to wait for '*emerging evidence*' from Australia on impacts of standardised packaging~~SP~~ before taking a policy decision. This announcement followed a lengthy debate which began in 2011 (2), included a four month public consultation ending in August 2012 (3), and was subject to nearly a year's deliberation within the Department of Health before the consultation report was published (4). The consultation aimed to inform policy development and gather additional evidence for an i~~I~~mpact a~~A~~ssessment ~~(IA)~~. The i~~I~~mpact assessment~~A~~ was rated amber (needing more work) by the Regulatory Policy Committee (RPC) in February 2012 (5).

Public consultations and impact ~~IAs~~assessments are processes within a global governance innovation termed~~known as~~ *Better Regulation* (also known as *Smart Regulation* or *Better Lawmaking*). Drawing heavily on American Administrative Law and the cost-benefit approach to regulatory review in the US (6, 7), versions of Better Regulation are in place, for example, in multiple EU states (UK, Netherlands, Czech Republic, Sweden and Germany) (8), in the EU itself (9), and in Canada (10) and Australia (11). ~~.~~ A key impetus for Better Regulation has been pressure put on governments and inter-governmental organisations by TTCs and other transnational corporations to reduce regulatory business costs and prioritise business interests in the policy process (8, 12).

Public consultations effectively frontload problem-resolution in the policy process by offering affected businesses and other interested parties an early opportunity to comment on policy ideas and proposals, and to submit evidence supporting their views (13, 14). Examples of consultation systems elsewhere include 'notice and comment' in the US (15) and the European Commission's 'Your voice in Europe' (16). ~~This evidence~~Evidence gathered from consultations can then be taken into account in developing impact assessments~~IAs~~, which entail quantitative evidence-based assessments of the potential effects of proposed regulations and consideration of alternative policy options (17). Evidence plays a key role in the policy process, and, in practice, Better Regulation underpins a form of evidence-based policy making which is deliberately open to stakeholder, and particularly business, influence (18, 19).

In the UK, these processes contribute to the attainment of five features of good governance: proportionality, accountability, consistency, transparency and targeting (14, 20).

~~Evidence plays a key role in the policy process, and, in practice, Better Regulation underpins a form of evidence-based policy making (EBP) which is deliberately open to stakeholder influence (18, 19).~~ Under New Labour (18) and the Coalition Government (8), Better Regulation has formalised evidence-based policy making ~~EBP~~, which is now subject to two stages of scrutiny: first, by the RPC (a body sponsored by the Department of Business Innovation and Skills); and, subsequently, by the Cabinet's Reducing Regulation Committee (RRC) . The upfront costs to government of this process are intended to be offset by an associated reduced impact on businesses post-implementation. ~~A key impetus for Better Regulation has been pressure put on governments and inter-governmental~~

~~organisations by TTCs and other transnational corporations to reduce regulatory business costs and prioritise business interests in the policy process~~ (8, 12)~~.~~

New tobacco control policies developed by the Department of Health are subject to Better Regulation. Thus, TTCs can make submissions to public consultations on tobacco control policies, citing evidence regarding impacts on their businesses, wider impacts, and in support of alternative policies. Yet, the Government is also required to meet an international commitment made under Article 5.3 of the Framework Convention on Tobacco Control (FCTC) to take steps to ensure that: '…in setting and implementing their public health policies with respect to tobacco control, Parties shall act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law' ~~ensure that public health policies are protected from 'commercial and other vested interests of the tobacco industry'~~ (21). A key rationale for this provision lies in the overwhelming evidence of the tobacco industry's efforts to bias the evidence base of health impacts of tobacco products and public health policies in its favour (22-25). Uniquely~~,~~ in the case of tobacco, the co-existence of these two governance regimes raises the possibility of a regulatory conflict between commitments to include businesses in policy development and commitments to exclude them (26).

The UK's consultation (3) and impact assessment~~IA~~ (5) on ~~SP~~ standardised packaging provides an opportunity to consider how these two sets of commitments are reconciled by governments. The four largest TTCs in the UK market – Imperial Tobacco (IT), Japan Tobacco International (JTI), Philip Morris Ltd (PM) and British American Tobacco (BAT) – submitted lengthy consultation responses (1521 pages in total, of which 328 comprised their main responses and 1193 provided supplementary materials) (27-30). These were just 4 of 668,433 responses the Department of Health received (2,444 were 'detailed responses') (4). Associated time and resource costs raise the question of how governments can effectively make a balanced, informed and transparent assessment of the policy relevance and quality of all evidence cited in submissions (31).

A Systematic Review ~~(SR)~~ of the evidence for standardised packaging~~SR~~, commissioned by the Department of Health, concluded that there is 'strong evidence' that ~~SP~~standardised packaging would reduce the appeal of tobacco products and increase the prominence of health warnings (32). ~~Yet~~However, in their submissions, the TTCs rejected ~~its~~ the ~~findings~~ findings of the Systematic Review on the grounds~~and claimed~~ that~~-~~ there is no evidence that ~~SP~~standardised packaging would reduce smoking prevalence or initiation. ~~, citing extensive evidence to support their arguments~~ (27-30). They cited extensive evidence to support their arguments, claimed that key evidence on smoking behaviour had not been considered in the Systematic Review, and pointed to the absence of real-world evidence as problematic: the UK consultation preceded implementation of standardised packaging in Australia in December 2012. ~~: as SP was only implemented in Australia after the consultation closed there were no evaluations of its real-world impact available at the time.~~ TTCs have maintained that advertising and promotional material – including packaging – only stimulate brand switching among current smokers (27-30, 33). Yet, overwhelming evidence from the tobacco industry's own marketing documents suggests this claim is highly disingenuous (34-37).

In this paper, we aim to examine the volume, policy relevance and quality of the evidence TTCs cited in their submissions and compare it with that included in the Systematic Review~~SR~~ (~~.~~ ~~f~~urther work is underway to investigate the TTCs' interpretation of the evidence itself). We use this analysis to explore the challenges public consultations and impact assessment~~IA~~s for~~on~~ tobacco control policies present to governments and begin to unpack the conflict between the Better Regulation agenda and the FCTC. We suggest evidential management strategies for governments developing tobacco control policies in this multi-level governance context.

METHODS

Defining 'evidence'

The comparative analysis methodology employed in this research required that 'evidence' was interpreted narrowly as formal written research sources, such as reports or journal articles. This restriction enabled a comparison of similar evidence in the two data sets: TTC citations and Systematic Review evidence. Other forms of evidence (eg. opinion, political statements, legal rulings, press coverage) cited in the 4 TTCs' submissions, were excluded.

Selecting and recording TTC evidence

Details [author, title, date, source] of each piece of evidence cited by the TTCs in their submissions were extracted into an Excel spreadsheet and categorised under three main arguments made by the TTCs: there is no evidence of the beneficial impact of ~~SP~~standardised packaging on public health – ~~SP~~standardised packaging 'won't work'; ~~SP~~standardised packaging will have negative unintended consequences (including economic impacts on businesses, growth in illicit trade in tobacco products, reduction in the price of cigarettes, or contravention of existing trade and intellectual property rules); and the policy process was 'flawed'. Evidence was also categorised as to whether it was promoted by the TTCs as supporting their argument, or contested by them. Only evidence used by the TTCs to promote their argument that ~~SP~~standardised packaging 'won't work' was obtained and examined further.

Evidence from the Systematic Review~~SR~~

~~The same process was followed for the evidence included in the SR.~~ Details of the papers cited in the Systematic Review were ~~-~~recorded in Excel and obtained for further analysis of their relevance and quality.

Criteria for assessing evidence

Three criteria, identified via a review of similar studies of the quality of ~~?~~evidence used to oppose tobacco regulation (24, 38-42), were used to assess the policy relevance and quality of the evidence: subject matter, independence and peer-review (Table 1). These criteria represent an objective and practical means for policymakers to assess the policy relevance and quality of large quantities of evidence cited in submissions to public consultations prior to considering their content. ~~Although i~~It was beyond the scope of this study to critically appraise the ~~methodolog~~methodology used in evidence cited by TTCs. However~~y,~~ where required, analysis of study design, data and methods (38-40) could be used by policymakers on an ad hoc basis to review key pieces of evidence in more detail.

The *subject matter* of the evidence speaks to its relevance to the policy issue (31). Similar work has coded policy position, argument, topic and conclusion (40-42). On *independence*, research indicates that connection of research with a financially vested interest group can produce results which favour the sponsor, casting doubt on the independence, and therefore quality, of the evidence (40, 43, 44). The tobacco industry's efforts to discredit the science on environmental tobacco smoke and bias evidence on the impacts of smokefree legislation provide historical examples of this (22-25, 45). On *peer-review status*, articles which appear in peer-reviewed journals have been shown to be of superior quality to other research outputs in terms of study design, reporting and interpretation (40). Some alternative publication routes also include external peer-review (eg. government-commissioned research, academic press volumes and conference papers); others rely on internal peer-review (eg. charity and university research reports); research funded and published by the tobacco industry tends not to be subject to external peer-review: '[T]he tobacco industry has had a

long-standing strategy of funding research and disseminating it through their sponsored, non-peer-reviewed publications.' (46, 47)

Table 1 - Coding framework for classifying evidence

	Evidential Criteria	*Use in previous studies*	Data coding framework	Coding categories
Relevance	**Subject matter**	*What is the topic, argument, position or conclusion of the evidence? [Montini et al. 2002; Bero et al. 2001; Barnes and Bero 1997]*	What issue does the research address?	• Standardised Packaging ~~(SP)~~ of tobacco • Tobacco Packaging, eg. graphic health warnings • Tobacco, not packaging • Unrelated to tobacco
Quality	**Independence**	*Who funded the evidence? Are authors affiliated to the tobacco industry? [Montini et al. 2002, Scollo et al. 2003, Bero et al. 2001, Barnes and Bero 1996]*	Who funded the research? Has the author of the research any connection with the tobacco industry?	• Tobacco industry-funded (Statement included that the research was funded by the tobacco industry) • Tobacco industry-linked (No statement that the research was funded by the tobacco industry, but evidence of other connection: for example, author or funder have prior links to the tobacco industry) • Independent of the tobacco industry (Statement included that the research was funded by a source independent of the tobacco industry) • No apparent tobacco industry connection (No information provided about funding source and no evidence of prior connection with the tobacco industry)
	Peer-review status	*Has the evidence been peer-reviewed? What is the impact factor of the journal and date of publication? [Montini et al. 2002, Scollo et al. 2003, Bero et al. 2001, Barnes and Bero 1997]*	Was the research published in peer-reviewed journal? If not, where was the research published?	• Peer-reviewed journal • Academic press volume • Conference paper • Government-commissioned research • University research report • Government internal research • Charity research report • Private company research report • Unpublished

Evidential coding

Each piece of evidence was obtained via online searches, (general search engines and the research database Scopus), with non-digital documents obtained from library sources. Researchers read abstracts, introductions, conclusions, funding statements and cover pages of all evidence documents, and searched documents for key terms ('plain', 'pack*', 'standard*', 'tobacco', 'smok*'). Additional web searches were conducted (eg. the Legacy Library of tobacco industry documents and Scopus) to clarify independence and peer-review status of evidence.

Analytical process

The researchers used a content analysis methodology to code and analyse the data. Each piece of evidence was accessed and coded by one researcher (JH) using the criteria outlined in Table 1. A second researcher (GF) blind coded a random sample of 20% of the data (n=21). This process achieved a 97% level of inter-coder reliability. Once all the data had been analysed, a third researcher [KER] blind coded 100% of the data. This process achieved a 94.7% level of inter-coder reliability. All disagreements were fully resolved between the coders.

Having quantified and coded the evidence, we compared the policy relevance (subject matter) and quality (independence and peer review) of the industry evidence with that of the evidence supporting ~~SP~~standardised packaging in the Systematic Review~~SR~~ (32). We also examined the relationship between policy relevance and quality by comparing the quality of the industry's evidence on tobacco packaging with its evidence on other topics. Differences were compared using a two-tailed Fisher's Exact Test. The results were used to develop relevance-quality typologies of TTC evidence. Evidence was classified as *relevant* if it focused on ~~SP~~standardised packaging/tobacco packaging, and *parallel* if it focused on other tobacco issues/was unrelated to tobacco. Evidence was classified as featuring '*quality indicators*' if it was either independent, published in a peer-reviewed journal or both.

RESULTS

Overview of evidence cited by TTCs in their submissions

143 unique pieces of formal written research evidence were referred to or included in the four TTCs' submissions (22 referenced by more than one company) (Table 2). ~~:~~ ~~Of~~ the 143 documents, TTCs promoted 131 as supporting their arguments and contested the methods, findings or accessibility of the remaining 12, all of which were included in the SR. 88 were cited to support arguments that ~~SP~~standardised packaging would not have beneficial impacts on public health; 36 cited to argue that ~~SP~~standardised packaging will have negative unintended consequences, half of which related to the illicit trade in tobacco; 19 cited to argue that the policy process – particularly the impact assessment ~~IA~~ – was 'flawed'. 77 pieces of evidence were used to promote the TTC argument that ~~SP~~standardised packaging 'won't work' and were therefore the subject of further analysis in this paper. ~~TTCs did not cite any research showing that the tobacco industry has extensively studied and holds considerable evidence attesting to the impact of packaging on smoking behaviour .~~

~~Of the 143 documents, TTCs promoted 131 as supporting their arguments and contested the methods, findings or accessibility of the remaining 12, all of which were included in the SR. 77 pieces of evidence were used to promote the TTC argument that SP 'won't work' and were therefore the subject of further analysis in this paper.~~

Among these 77 documents, TTCs did not cite any research showing that the tobacco industry has extensively studied and holds considerable evidence attesting to the impact of packaging on smoking behaviour (34-37). Instead, they cited industry-funded research which critiqued the SR papers, the impact assessment and the consultation document. And they cited a body of independent research into the drivers of youth smoking which, while published in peer-reviewed health and psychology journals with no apparent connection to the tobacco industry, did not explicitly address the role of packaging in youth uptake or prevalence.

Table 2 - Overview of formal written evidence cited by TTCs in their submissions to the UK SPstandardised packaging consultation 2012

Theme of evidence	~~SP~~Standardised packaging 'won't work': No	~~SP~~Standardised packaging 'will have negative unintended consequences'	The policy process was 'flawed'	Total

How cited by TTCs	evidence of impacts on smoking behaviour	*Economic*	*Illicit*	*IP/ Trade*	*Price*		
Promoted	77*	3	18	5	9	19	**131**
Contested	11	1	0	0	0	0	**12**
Total	**88**	4	18	5	9	**19**	**143**
		36					

*the evidence examined further in this paper

Comparison of TTC and Systematic Review~~SR~~ evidence on the impact of ~~SP~~standardised packaging on smoking behaviour

There are marked differences between the relevance and quality of the TTC and Systematic Review~~SR~~ evidence (Table 3, Figure 1). Only 17/77(22%) pieces of evidence promoted by the TTCs addressed ~~SP~~standardised packaging directly: the majority of which were industry-funded/linked (14/17, 82%)~~;~~, none were published in a peer-reviewed journal (0/17, 0%). The remaining 60 pieces of evidence (78% of the total, comprising the majority of the evidence the industry cites) did not address ~~SP~~standardised packaging. In contrast, 37/37 (100%) pieces of evidence included in the Systematic Review~~SR~~ focused on ~~SP~~standardised packaging, none (0/37, 0%) had a connection with the tobacco industry, and 21/37 (57%) were published in a peer reviewed journal. The results of a comparison of the TTCs' ~~SP~~standardised packaging subset of evidence (n=17) with the Systematic Review~~SR~~ evidence on ~~SP~~standardised packaging (n=37), using Fisher's Exact Test, illustrate the statistical significance of the different distribution of relevance and quality indicators: $p<0.0001$ on subject, independence and peer-review status.

Table 3 - Quality and relevance of Transnational Tobacco Corporation (TTC) and Systematic Review evidence

	Relevance – *Subject matter*				
	Standardised packaging		Other (TTC evidence only)		
Quality	**Systematic Review evidence (n=37)**	**TTC evidence (n=17)**	Tobacco packaging (n=9)	Tobacco, not packaging (n=45)	Unrelated to tobacco (n=6)
Independence					
Industry-funded	**0**	**12**	2	1	0
Industry-linked	**0**	**2**	1	2	1
Independent	**31**	**3**	6	37	5
No apparent connection to the tobacco industry	**6**	**0**	0	5	0
Publication route					
Peer-reviewed journal	**21**	**0**	1	26	4
Academic press	**0**	**0**	0	1	1
Conference paper	**2**	**1**	0	0	0
Government-commission	**8**	**0**	2	2	0
University research	**5**	**0**	1	2	0
Government internal research	**0**	**2**	1	12	0
Charity research	**1**	**1**	1	0	1
Private company	**0**	**13**	3	1	0

research					
Unpublished	**0**	**0**	0	1	0

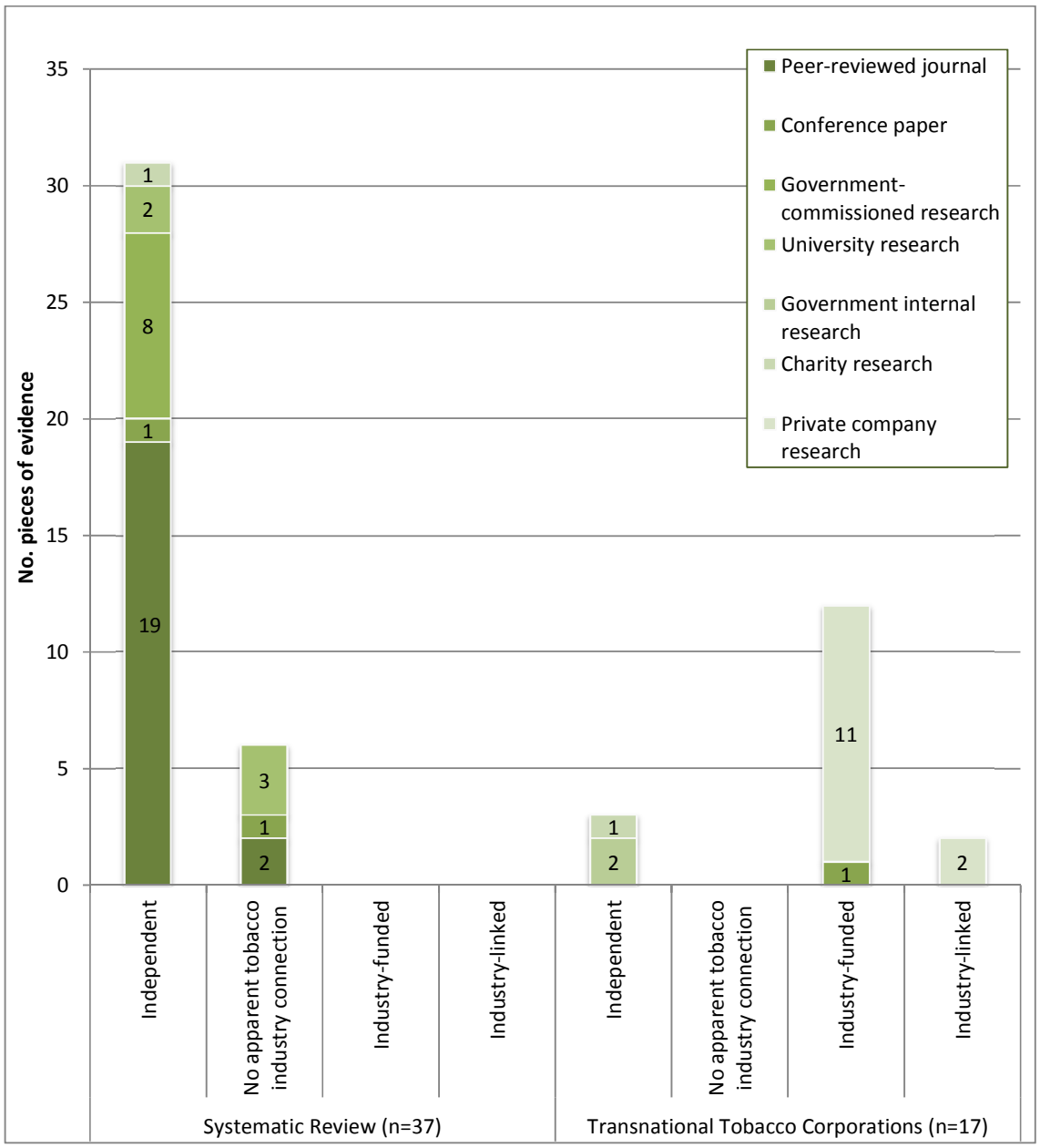

Figure 1 - Comparison of quality (independence and publication route) of Systematic Review and ~~transnational tobacco company~~ TTC evidence ~~on~~ directly addressing standardised packaging of tobacco products

Relationships between subject matter, independence and peer-review within the TTC evidence

A low proportion of TTCs' evidence relating to ~~SP~~standardised packaging was independent or peer-reviewed (Figure~~s~~ 1~~a/b~~). When evidence on tobacco packaging was added to the ~~SP~~standardised packaging evidence, the same pattern was found~~.~~: 9/26 (35%) were independent (independent/no

apparent tobacco industry connection); 1/26 (4%) was published in a peer reviewed journal (Tables 43a/b). However, a greater proportion of the 51 pieces of evidence the TTCs cited on parallel topics (including non-packaging drivers of youth and adult smoking behaviour, and drivers of youth behaviour in general) were independent (47/51, 92% independent/no apparent connection) and peer-reviewed (30/51, 59% published in peer reviewed journal). These differences are statistically significant (p<0.0001, Table 43a). We also found a clear relationship between the two indicators of quality – independence and peer-review – in the TTCs' evidence: industry-funded/linked studies cited by TTCs were significantly less likely to be published in a peer-reviewed journal (3/21, 14%) than independent/no apparent connection studies they cited (28/56, 50%) (p=0.0045, Table 43b).

Table 4a - Relationship between policy relevance and two ~~measures~~ indicators of quality in the TTC evidence, number and per cent in parenthesis

	Policy relevance: Subject matter		
Qualityindicators	*Relevant: Standardised packaging/Tobacco packaging (n=26)*	*Parallel: Tobacco not packaging/Unrelated to tobacco (n=51)*	*Fisher's p-value*
Independent of/no apparent tobacco industry connection	9/26 (35%)	47/51 (92%)	p<0.0001
Published in a peer-reviewed journal	1/26 (4%)	30/51 (59%)	p<0.0001

Table 4b - Relationship between two ~~measures~~ indicators of quality in the TTC evidence, number and per cent in parenthesis

Peer review status	*Independent of/no apparent tobacco industry connection (n=56)*	*Connected with the tobacco industry (n=21)*	*Fisher's p-value*
Published in a peer-reviewed journal	28/56 (50%)	3/21 (14%)	p0.0045

TTCs' evidence was classified into four typologies (~~Figure 2~~Table 5): relevant/quality indicators, relevant/no quality indicators, parallel/quality indicators, parallel/no quality indicators. While 100% of the Systematic Review ~~SR~~ evidence was both relevant and featured at least one of the two quality indicators, only 12% of evidence cited by TTCs in their submissions qualified for this category.

Table 5 - Distribution of TTC evidence across typologies

	Quality	**Quality indicators**	**No quality indicators**
Relevance		*Either independent, peer-reviewed or both*	*Neither independent nor peer-reviewed*
Relevant	*Standardised packaging and other tobacco packaging*	**12%** (100% Systematic Review evidence)	**22%**

Parallel	*Tobacco, not packaging and unrelated to tobacco*	**65%**	**1%**

DISCUSSION

Four main findings are apparent. TTCs cited a large volume of evidence in their submissions to the UK ~~SP~~standardised packaging consultation. They commissioned 15 studies to support their case that ~~SP~~standardised packaging 'won't work'. The quality of TTC evidence on ~~SP~~standardised packaging is significantly lower, as judged by independence and peer-review, than that included in the Systematic Review~~SR~~. Finally, the evidence cited by TTCs is shown, with few exceptions, to fit one of two typologies – *either* relevant/no quality indicators *or* parallel/quality indicators (Figure 1~~2~~).

These findings raise a number of concerns ~~about~~ regarding the potential impact of Better Regulation on tobacco control policymaking in jurisdictions around the world. First, our findings highlight how Better Regulation, with its requirement for public consultations and impact assessment~~IA~~s, imposes costs on government departments in the earliest stage of policy development. Just as TTCs habitually launch legal challenges in the post-decision phase of policy-making (48), so too can they use their resource advantage to exploit Better Regulation processes by both commissioning new research and submitting extensive and complex responses in the pre-decision phase of the policy process, effectively frontloading their opposition. The combination of a requirement for due diligence and the volume and nature of responses may have contributed to the eleven month delay in publication of the Department of Health's consultation report.

Second, Better Regulation's requirement that policymakers consider alternative policy options, with its underlying intention of preventing unnecessary regulation, imposes additional upfront costs on governments. In the case of ~~SP~~standardised packaging, this requirement ~~was explicitly addressed via the consultation questions and effectively~~ encouraged extensive citation of evidence beyond the focus of the policy proposal. This may partly explain why nearly two thirds of the evidence the TTCs cited to claim that ~~SP~~standardised packaging 'won't work' addressed non-packaging drivers of youth and adult smoking: studies which do not consider ~~SP~~standardised packaging in their methodology or analysis. A second possible explanation is that the level of independence and peer-review of this parallel evidence is significantly higher than that of the evidence they cite on tobacco packaging and its inclusion may therefore have been intended to add legitimacy to TTC arguments.

Third, the absence of guidelines requiring a declaration of any conflict of interest ~~regarding the declaration of any connection~~ between ~~TTCs~~ corporations and the evidence they cite enable tobacco industry-funded/linked work to be cited by TTCs in such a way that any link is undeclared, implying independence. For example, BAT, IT and PM all cited tobacco industry-funded/linked evidence in their submissions without explicitly acknowledging their connection to it (27, 29, 30). This speaks to a lack of transparency in the policy process regarding the provenance of evidence submitted by corporate interests.

Fourth, the lack of clarity regarding whether or how civil servants assess the policy relevance and quality of evidence is reflected by an equivalent lack of clarity regarding how governments handle the absence of evidence. We have identified a clear omission in the TTCs' submissions of evidence regarding the importance TTCs place on tobacco packaging in the marketing of their products.

Taken collectively, evidence present in and absent from the TTCs' submissions highlights an important transparency deficit within Better Regulation processes. This deficit obscures the view of policymakers, potentially preventing them from identifying and taking account of the ~~the lack of provision in Better Regulation processes for policymakers to take transparent account of the~~ judicious selection and exclusion of evidence ~~in consultation submissions from~~by corporate actors with vested interests in policy outcomes. Because Better Regulation requires evidence-based impact assessments and invites evidence-based submissions to public consultations, the potential exists for corporations to exert undue and unnoticed influence on the policy process.

Considering the statutory requirement imposed by Article 5.3 of the FCTC -to 'protect' tobacco control policies 'from commercial and other vested interests of the tobacco industry' (21)~~protect tobacco control policy from tobacco industry influence~~, it would be advisable for the 177 ~~governments~~states which are party to the Convention to implement and publish clear guidelines on how TTC submissions to public consultations, and evidence cited within, should be managed by policymakers. Two steps could be taken by governments to achieve this. First, conflict of interest declarations regarding evidence cited could be made a mandatory element of public consultations. Second, ~~One way of achieving this would be for~~ policymakers ~~to~~ could adopt a similar methodology to that used in this research. Adopting a process of classifying evidence for subject matter, independence and peer-review status may help policymakers to systematically prioritise good quality, policy-focused evidence; and to flag evidence about which they need to be more sceptical, such as that which is not policy-focused, not independent or not peer-reviewed.

These~~is~~ recommendations ha~~ves~~ relevance across government departments in all states which are signatories to the FCTC. It ~~may be~~would also be appropriate to explore applying ~~whether~~ this critical perspective ~~ought also to be applied~~ to the development of non-tobacco public health regulation – for example, of the alcohol and food industries – where corporate interests also seek to influence policy being developed for the public good (49, 50).

What has been learned from the UK Government's 2013 decision to postpone any decision on ~~SP~~standardised packaging until further evidence is available is that Better Regulation ensures that evidence occupies a critical instrumental role in policymaking. Thus, how government departments handle and interpret evidence in the development of public health policy, and what evidential relevance and quality thresholds are set for policy progression in the context of Better Regulation, are of vital importance.

CONTRIBUTORSHIP STATEMENT

JH, GF and AG conceived the idea for this study. JH was responsible for data gathering, coding, analysis and write-up. GF and KER were responsible for secondary coding. JH, GF, KER, ZT and AG were involved in discussion of findings and ~~, and~~ commented on and edited drafts of the paper.

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ABG is a member [unpaid] of the Council of Action on Smoking and Health, and was a member of the WHO Expert Committee convened to develop recommendations on how to address tobacco industry interference with tobacco control policy.

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DATA SHARING STATEMENT

Extra data is available by emailing j.hatchard@bath.ac.uk

~~A comparison of the subject matter and independence of evidence cited in TTCs' submissions (n=77) and the SR (n=37)~~
~~Figure 1b: A comparison of the subject matter and peer review status of evidence cited in TTCs' submissions (n=77) and the SR (n=37)~~
~~Figure 2: Four Typologies of TTC evidence (n=77)~~

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A critical evaluation of the volume, relevance and quality of evidence submitted by the tobacco industry to oppose standardised packaging of tobacco products

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A critical evaluation of the volume, relevance and quality of evidence submitted by the tobacco industry to oppose standardised packaging of tobacco products

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ABSTRACT

BACKGROUND: Better Regulation is an overarching governance structure requiring early stakeholder consultation and evidence-based impact assessment of policies. In 2012, four transnational tobacco companies (TTCs) responded to a UK consultation on standardised packaging of tobacco products, citing extensive evidence. Following the Government's evidence-based rationale to postpone any decision on standardised packaging, this paper aims to examine the volume, relevance and quality of TTCs' evidence that the policy 'won't work'.

METHODS: Evidence cited in the TTC submissions and a systematic review of the potential impacts of standardised packaging was counted and coded for relevance (subject matter) and quality (independence and peer review). Fisher's Exact Test was used to assess differences in the quality of the evidence between the TTC and systematic review evidence and between TTC evidence on packaging compared with their evidence on other topics.

RESULTS: 77/143 pieces of TTC-cited evidence were used to promote their claim that standardised packaging 'won't work'. 17/77 addressed standardised packaging: 82% tobacco industry connected; 0% published in a peer-reviewed journal. In comparison, 37/37 studies included in the systematic review addressed standardised packaging: 0% had tobacco industry connections; 57% published in a peer-reviewed journal. The difference in quality of the systematic review and TTC evidence on standardised packaging was found to be statistically significant ($p<0.0001$). TTCs' evidence on standardised packaging/packaging (26/77) was found to be of lower quality than their evidence on topics unconnected to tobacco packaging (51/77) ($p<0.0001$).

CONCLUSION: With few exceptions, evidence promoted by TTCs to promote their claim that standardised packaging 'won't work' lacks *either* policy relevance *or* key indicators of quality. Policymakers could use these three criteria – subject matter, independence and peer-review status – to critically assess evidence submitted to them by corporate interests via Better Regulation processes.

A critical evaluation of the volume, relevance and quality of evidence submitted by the tobacco industry to oppose standardised packaging of tobacco products

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ARTICLE SUMMARY

Article Focus

- Better Regulation dictates that public policy ideas which may impact on businesses must be subject to public consultation and evidence-based impact assessment prior to policy progression.
- There is extensive evidence to support the case for standardised packaging of tobacco products as a contributor to the reduction in overall smoking prevalence.
- Transnational tobacco companies have been instrumental in promoting Better Regulation, and have a historical record of seeking to delay and prevent tobacco control regulations.

Key Messages

- Using Better Regulation processes, transnational tobacco corporations have legitimately sought to use evidence as a tool to influence the policy outcome on standardised packaging in the UK.
- The evidence tobacco manufacturers cited in their consultation submissions was not as relevant or as high quality as the evidence supporting packaging regulation.
- Improving the transparency of evidential management and interpretation strategies and thresholds may help address the potential conflict between Better Regulation and the Framework Convention on Tobacco Control.

Strengths and Limitations

- This study builds on the existing literature on corporate influence over public health policy and evidence.
- Further investigation of policymakers' perceptions of corporate evidence would be beneficial to corroborate the relevance of our findings.

INTRODUCTION

Standardised packaging of tobacco products entails the prohibition of logos, brand imagery, symbols, other images, colours and promotional text from tobacco products and tobacco product packaging. Despite the common use of the term 'plain packaging' in media coverage of this issue, graphic and textual health warning labels would still feature prominently on packs and key anti-counterfeiting marks would be retained.

Standardised packaging would further restrict the already limited opportunities of transnational tobacco companies (TTCs) to market their products. The policy's objective is to deter smoking initiation, particularly among young people, and promote cessation among existing smokers. Its introduction in Australia in December 2012 (1) sparked a wave of interest: Ireland and New Zealand gave strong indications of their intentions to introduce standardised packaging. In contrast, the UK government announced on July 12th 2013 that it had decided to wait for '*emerging evidence'* from Australia on impacts of standardised packaging before taking a policy decision. This announcement followed a lengthy debate which began in 2011 (2), included a four month public consultation ending in August 2012 (3), and was subject to nearly a year's deliberation within the Department of Health before the consultation report was published (4). The consultation aimed to inform policy development and gather additional evidence for an impact assessment. The impact assessment was rated amber (needing more work) by the Regulatory Policy Committee (RPC) in February 2012 (5).

Public consultations and impact assessments are processes within a global governance innovation termed *Better Regulation* (also known as *Smart Regulation* or *Better Lawmaking*). Drawing heavily on American Administrative Law and the cost-benefit approach to regulatory review in the US (6, 7), versions of Better Regulation are in place, for example, in multiple EU states (UK, Netherlands, Czech Republic, Sweden and Germany) (8), in the EU itself (9), and in Canada (10) and Australia (11). A key impetus for Better Regulation has been pressure put on governments and inter-governmental organisations by TTCs and other transnational corporations to reduce regulatory business costs and prioritise business interests in the policy process (8, 12).

Public consultations effectively frontload problem-resolution in the policy process by offering affected businesses and other interested parties an early opportunity to comment on policy ideas and proposals, and to submit evidence supporting their views (13, 14). Examples of consultation systems elsewhere include 'notice and comment' in the US (15) and the European Commission's 'Your voice in Europe' (16). Evidence gathered from consultations can then be taken into account in developing impact assessments, which entail quantitative evidence-based assessments of the potential effects of proposed regulations and consideration of alternative policy options (17). Evidence plays a key role in the policy process, and, in practice, Better Regulation underpins a form of evidence-based policy making which is deliberately open to stakeholder, and particularly business, influence (18, 19).

In the UK, these processes contribute to the attainment of five features of good governance: proportionality, accountability, consistency, transparency and targeting (14, 20). Under New Labour (18) and the Coalition Government (8), Better Regulation has formalised evidence-based policy making, which is now subject to two stages of scrutiny: first, by the RPC (a body sponsored by the Department of Business Innovation and Skills); and, subsequently, by the Cabinet's Reducing Regulation Committee (RRC) . The upfront costs to government of this process are intended to be offset by an associated reduced impact on businesses post-implementation.

New tobacco control policies developed by the Department of Health are subject to Better Regulation. Thus, TTCs can make submissions to public consultations on tobacco control policies, citing evidence regarding impacts on their businesses, wider impacts, and in support of alternative policies. Yet, the Government is also required to meet an international commitment made under

Article 5.3 of the Framework Convention on Tobacco Control (FCTC) to take steps to ensure that: '…in setting and implementing their public health policies with respect to tobacco control, Parties shall act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law' (21). A key rationale for this provision lies in the overwhelming evidence of the tobacco industry's efforts to bias the evidence base of health impacts of tobacco products and public health policies in its favour (22-25). Uniquely in the case of tobacco, the co-existence of these two governance regimes raises the possibility of a regulatory conflict between commitments to include businesses in policy development and commitments to exclude them (26).

The UK's consultation (3) and impact assessment (5) on standardised packaging provides an opportunity to consider how these two sets of commitments are reconciled by governments. The four largest TTCs in the UK market – Imperial Tobacco (IT), Japan Tobacco International (JTI), Philip Morris Ltd (PM) and British American Tobacco (BAT) – submitted lengthy consultation responses (1521 pages in total, of which 328 comprised their main responses and 1193 provided supplementary materials) (27-30). These were just 4 of 668,433 responses the Department of Health received (2,444 were 'detailed responses') (4). Associated time and resource costs raise the question of how governments can effectively make a balanced, informed and transparent assessment of the policy relevance and quality of all evidence cited in submissions (31).

A systematic review of the evidence for standardised packaging, commissioned by the Department of Health, concluded that there is 'strong evidence' that standardised packaging would reduce the appeal of tobacco products and increase the prominence of health warnings (32). However, in their submissions, the TTCs rejected the findings of the systematic review on the grounds that there is no evidence that standardised packaging would reduce smoking prevalence or initiation. (27-30). They cited extensive evidence to support their arguments, claimed that key evidence on smoking behaviour had not been considered in the systematic review, and pointed to the absence of real-world evidence as problematic: the UK consultation preceded implementation of standardised packaging in Australia in December 2012. TTCs have maintained that advertising and promotional material – including packaging – only stimulate brand switching among current smokers (27, 29, 30, 33). Yet, overwhelming evidence from the tobacco industry's own marketing documents suggests this claim is highly disingenuous (34-37).

In this paper, we aim to examine the volume, policy relevance and quality of the evidence TTCs cited in their submissions and compare it with that included in the systematic review (further work is underway to investigate the TTCs' interpretation of the evidence itself). We use this analysis to explore the challenges public consultations and impact assessments for tobacco control policies present to governments and begin to unpack the conflict between the Better Regulation agenda and the FCTC. We suggest evidential management strategies for governments developing tobacco control policies in this multi-level governance context.

METHODS

Defining 'evidence'

The comparative analysis methodology employed in this research required that 'evidence' was interpreted narrowly as formal written research sources, such as reports or journal articles. This restriction enabled a comparison of similar evidence in the two data sets: TTC citations and systematic review evidence. Other forms of evidence (eg. opinion, political statements, legal rulings, press coverage) cited in the 4 TTCs' submissions, were excluded.

Selecting and recording TTC evidence

Details [author, title, date, source] of each piece of evidence cited by the TTCs in their submissions were extracted into an Excel spreadsheet and categorised under three main arguments made by the TTCs: there is no evidence of the beneficial impact of standardised packaging on public health – standardised packaging 'won't work'; standardised packaging will have negative unintended consequences (including economic impacts on businesses, growth in illicit trade in tobacco products, reduction in the price of cigarettes, or contravention of existing trade and intellectual property rules); and the policy process was 'flawed'. Evidence was also categorised as to whether it was promoted by the TTCs as supporting their argument, or contested by them. Only evidence used by the TTCs to promote their argument that standardised packaging 'won't work' was obtained and examined further.

Evidence from the systematic review

Details of the papers cited in the systematic review were recorded in Excel and obtained for further analysis of their relevance and quality.

Criteria for assessing evidence

Three criteria, identified via a review of similar studies of the quality of evidence used to oppose tobacco regulation (24, 38-42), were used to assess the policy relevance and quality of the evidence: subject matter, independence and peer-review (Table 1). These criteria represent an objective and practical means for policymakers to assess the policy relevance and quality of large quantities of evidence cited in submissions to public consultations prior to considering their content.

The *subject matter* of the evidence speaks to its relevance to the policy issue (31). Similar work has coded policy position, argument, topic and conclusion (40-42). On *independence*, research indicates that connection of research with a financially vested interest group can produce results which favour the sponsor, casting doubt on the independence, and therefore quality, of the evidence (40, 43, 44). The tobacco industry's efforts to discredit the science on environmental tobacco smoke and bias evidence on the impacts of smokefree legislation provide historical examples of this (22-25, 45). On *peer-review status*, articles which appear in peer-reviewed journals have been shown to be of superior quality to other research outputs in terms of study design, reporting and interpretation (40, 46). For example, peer review enables studies to be assessed by experts who are knowledgeable in the subject area, provides strong incentives for authors to heed advice and improve papers and acts as a filter which aims to prevent poorly designed studies from being published. Some alternative publication routes also include external peer-review (eg. government-commissioned research, academic press volumes and conference papers); others rely on internal peer-review (eg. charity and university research reports); research funded and published by the tobacco industry tends not to be subject to external peer-review: '[T]he tobacco industry has had a long-standing strategy of funding research and disseminating it through their sponsored, non-peer-reviewed publications.' (47, 48)

Table 1 - Coding framework for classifying evidence

	Evidential Criteria	*Use in previous studies*	Data coding framework	Coding categories

Relevance	**Subject matter**	*What is the topic, argument, position or conclusion of the evidence? [Montini et al. 2002; Bero et al. 2001; Barnes and Bero 1997]*	What issue does the research address?	• Standardised Packaging of tobacco • Tobacco Packaging, eg. graphic health warnings • Tobacco, not packaging • Unrelated to tobacco
Quality	**Independence**	*Who funded the evidence? Are authors affiliated to the tobacco industry? [Montini et al. 2002, Scollo et al. 2003, Bero et al. 2001, Barnes and Bero 1996]*	Who funded the research? Has the author of the research any connection with the tobacco industry?	• Tobacco industry-funded (Statement included that the research was funded by the tobacco industry) • Tobacco industry-linked (No statement that the research was funded by the tobacco industry, but evidence of other connection: for example, author or funder have prior links to the tobacco industry) • Independent of the tobacco industry (Statement included that the research was funded by a source independent of the tobacco industry) • No apparent tobacco industry connection (No information provided about funding source and no evidence of prior connection with the tobacco industry)
	Peer-review status	*Has the evidence been peer-reviewed? What is the impact factor of the journal and date of publication? [Montini et al. 2002, Scollo et al. 2003, Bero et al. 2001, Barnes and Bero 1997]*	Was the research published in peer-reviewed journal? If not, where was the research published?	• Peer-reviewed journal • Academic press volume • Conference paper • Government-commissioned research • University research report • Government internal research • Charity research report • Private company research report • Unpublished

Evidential coding

Each piece of evidence was obtained via online searches, (general search engines and the research database Scopus), with non-digital documents obtained from library sources. Researchers read abstracts, introductions, conclusions, funding statements and cover pages of all evidence documents, and searched documents for key terms ('plain', 'pack*', 'standard*', 'tobacco', 'smok*'). Additional web searches were conducted (eg. the Legacy Library of tobacco industry documents and Scopus) to clarify independence and peer-review status of evidence.

Analytical process

The researchers used a content analysis methodology to code and analyse the data. Each piece of evidence was accessed and coded by one researcher (JH) using the criteria outlined in Table 1. A second researcher (GF) blind coded a random sample of 20% of the data (n=21). This process achieved a 97% level of inter-coder reliability. Once all the data had been analysed, a third researcher [KER] blind coded 100% of the data. This process achieved a 94.7% level of inter-coder reliability. All disagreements were fully resolved between the coders.

Having quantified and coded the evidence, we compared the policy relevance (subject matter) and quality (independence and peer review) of the industry evidence with that of the evidence supporting standardised packaging in the systematic review (32). We also examined the relationship between policy relevance and quality by comparing the quality of the industry's evidence on tobacco packaging with its evidence on other topics. Differences were compared using a two-tailed Fisher's Exact Test. The results were used to develop relevance-quality typologies of TTC evidence. Evidence was classified as *relevant* if it focused on standardised packaging/tobacco packaging, and *parallel* if it focused on other tobacco issues/was unrelated to tobacco. Evidence was classified as featuring '*quality indicators*' if it was either independent, published in a peer-reviewed journal or both.

RESULTS

Overview of evidence cited by TTCs in their submissions

143 unique pieces of formal written research evidence were referred to or included in the four TTCs' submissions (22 referenced by more than one company) (Table 2). Of the 143 documents, TTCs promoted 131 as supporting their arguments and contested the methods, findings or accessibility of the remaining 12, all of which were included in the systematic review. 88 were cited to support arguments that standardised packaging would not have beneficial impacts on public health; 36 cited to argue that standardised packaging will have negative unintended consequences, half of which related to the illicit trade in tobacco; 19 cited to argue that the policy process – particularly the impact assessment – was 'flawed'. 77 pieces of evidence were used to promote the TTC argument that standardised packaging 'won't work' and were therefore the subject of further analysis in this paper.

Among these 77 documents, TTCs did not cite any research showing that the tobacco industry has extensively studied and holds considerable evidence attesting to the impact of packaging on smoking behaviour (34-37). Instead, they cited industry-funded research which critiqued the systematic review papers, the impact assessment and the consultation document. And they cited a body of independent research into the drivers of youth smoking which, while published in peer-reviewed health and psychology journals with no apparent connection to the tobacco industry, did not explicitly address the role of packaging in youth uptake or prevalence.

Table 2 - Overview of formal written evidence cited by TTCs in their submissions to the UK SPstandardised packaging consultation 2012

Theme of evidence / How cited by TTCs	Standardised packaging 'won't work': No evidence of impacts on smoking behaviour	Standardised packaging 'will have negative unintended consequences'				The policy process was 'flawed'	Total
		Economic	*Illicit*	*IP/ Trade*	*Price*		
Promoted	77*	3	18	5	9	19	**131**
Contested	11	1	0	0	0	0	**12**
Total	**88**	4	18	5	9	**19**	**143**
		36					

*the evidence examined further in this paper

Comparison of TTC and systematic review evidence on the impact of standardised packaging on smoking behaviour

There are marked differences between the relevance and quality of the TTC and systematic review evidence (Table 3, Figure 1). Only 17/77(22%) pieces of evidence promoted by the TTCs addressed standardised packaging directly: the majority of which were industry-funded/linked (14/17, 82%); none were published in a peer-reviewed journal (0/17, 0%). The remaining 60 pieces of evidence (78% of the total, comprising the majority of the evidence the industry cites) did not address standardised packaging. In contrast, 37/37 (100%) pieces of evidence included in the systematic review focused on standardised packaging, none (0/37, 0%) had a connection with the tobacco industry, and 21/37 (57%) were published in a peer reviewed journal. The results of a comparison of the TTCs' standardised packaging subset of evidence (n=17) with the systematic review evidence on standardised packaging (n=37), using Fisher's Exact Test, illustrate the statistical significance of the different distribution of relevance and quality indicators: $p<0.0001$ on subject, independence and peer-review status.

Table 3 - Quality and relevance of Transnational Tobacco Corporation (TTC) and systematic review evidence

	Relevance – *Subject matter*				
	Standardised packaging		Other (TTC evidence only)		
Quality	**Systematic review evidence (n=37)**	**TTC evidence (n=17)**	Tobacco packaging (n=9)	Tobacco, not packaging (n=45)	Unrelated to tobacco (n=6)
Independence					
Industry-funded	**0**	**12**	2	1	0
Industry-linked	**0**	**2**	1	2	1
Independent	**31**	**3**	6	37	5
No apparent connection to the tobacco industry	**6**	**0**	0	5	0
Publication route					
Peer-reviewed journal	**21**	**0**	1	26	4
Academic press	**0**	**0**	0	1	1
Conference paper	**2**	**1**	0	0	0
Government-commission	**8**	**0**	2	2	0
University research	**5**	**0**	1	2	0
Government internal research	**0**	**2**	1	12	0
Charity research	**1**	**1**	1	0	1
Private company research	**0**	**13**	3	1	0
Unpublished	**0**	**0**	0	1	0

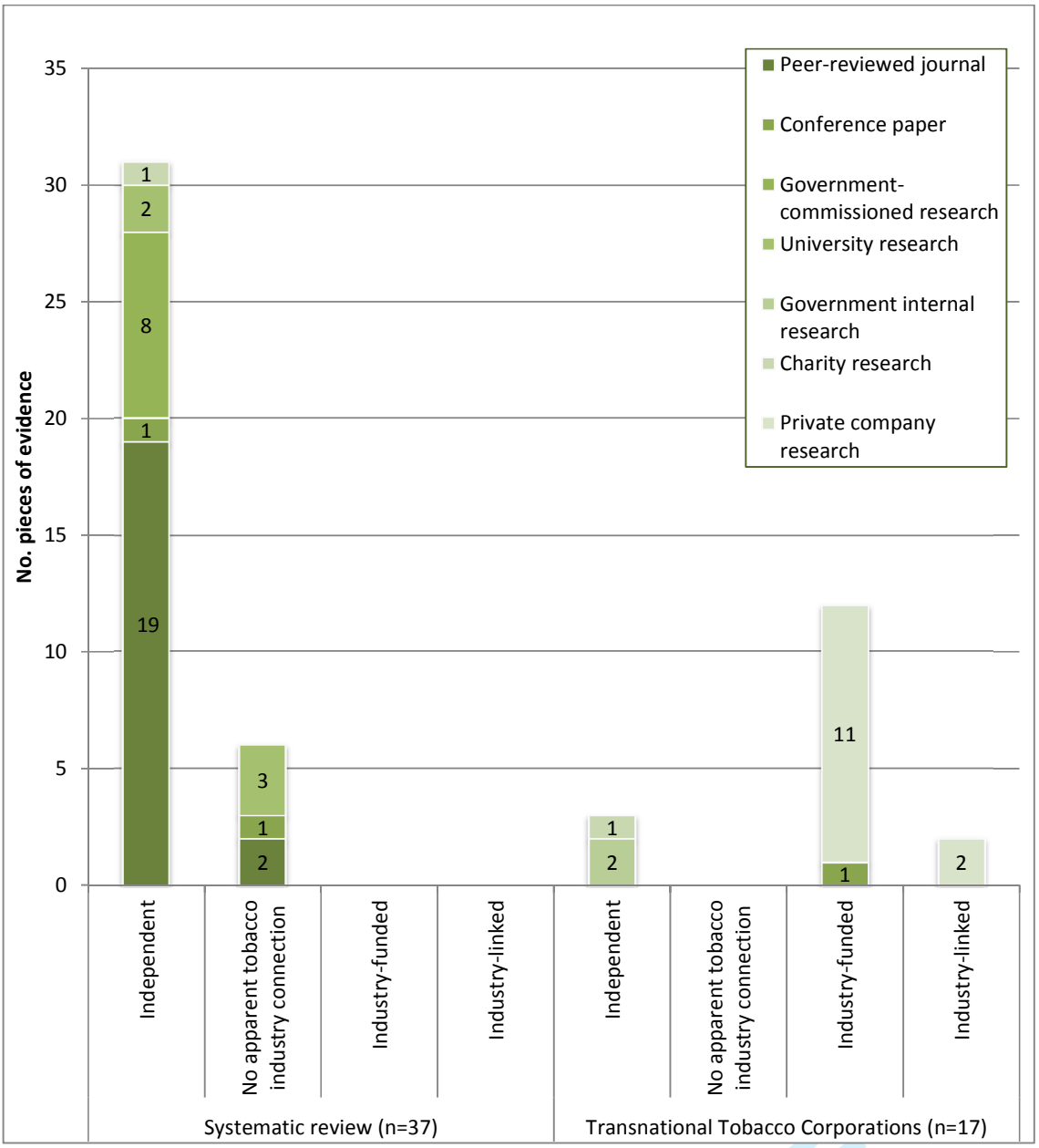

Figure 1 - Comparison of quality (independence and publication route) of systematic review and TTC evidence directly addressing standardised packaging of tobacco products

Relationships between subject matter, independence and peer-review within the TTC evidence

A low proportion of TTCs' evidence relating to standardised packaging was independent or peer-reviewed (Figure 1). When evidence on tobacco packaging was added to the standardised packaging evidence, the same pattern was found: 9/26 (35%) were independent (independent/no apparent tobacco industry connection); 1/26 (4%) was published in a peer reviewed journal (Tables 4a/b). However, a greater proportion of the 51 pieces of evidence the TTCs cited on parallel topics (including non-packaging drivers of youth and adult smoking behaviour, and drivers of youth behaviour in general) were independent (47/51, 92% independent/no apparent connection) and peer-reviewed (30/51, 59% published in peer reviewed journal). These differences are statistically significant ($p<0.0001$, Table 4a). We also found a clear relationship between the two indicators of

quality – independence and peer-review – in the TTCs' evidence: industry-funded/linked studies cited by TTCs were significantly less likely to be published in a peer-reviewed journal (3/21, 14%) than independent/no apparent connection studies they cited (28/56, 50%) (p=0.0045, Table 4b).

Table 4a - Relationship between policy relevance and two indicators of quality in the TTC evidence, number and per cent in parenthesis

	Policy relevance: Subject matter		
Qualityindicators	*Relevant: Standardised packaging/Tobacco packaging (n=26)*	*Parallel: Tobacco not packaging/Unrelated to tobacco (n=51)*	*Fisher's p-value*
Independent of/no apparent tobacco industry connection	9/26 (35%)	47/51 (92%)	p<0.0001
Published in a peer-reviewed journal	1/26 (4%)	30/51 (59%)	p<0.0001

Table 4b - Relationship between two indicators of quality in the TTC evidence, number and per cent in parenthesis

Peer review status	*Independent of/no apparent tobacco industry connection (n=56)*	*Connected with the tobacco industry (n=21)*	*Fisher's p-value*
Published in a peer-reviewed journal	28/56 (50%)	3/21 (14%)	p0.0045

TTCs' evidence was classified into four typologies (Table 5): relevant/quality indicators, relevant/no quality indicators, parallel/quality indicators, parallel/no quality indicators. While 100% of the systematic review evidence was both relevant and featured at least one of the two quality indicators, only 12% of evidence cited by TTCs in their submissions qualified for this category.

Table 5 - Distribution of TTC evidence across typologies

Quality / ***Relevance***		**Quality indicators**	**No quality indicators**
		Either independent, peer-reviewed or both	*Neither independent nor peer-reviewed*
Relevant	*Standardised packaging and other tobacco packaging*	**12%** (100% Systematic review evidence)	**22%**
Parallel	*Tobacco, not packaging and unrelated to tobacco*	**65%**	**1%**

DISCUSSION

Four main findings are apparent. TTCs cited a large volume of evidence in their submissions to the UK standardised packaging consultation. They commissioned 15 studies to support their case that standardised packaging 'won't work'. The quality of TTC evidence on standardised packaging is significantly lower, as judged by independence and peer-review, than that included in the systematic review. Finally, the evidence cited by TTCs is shown, with few exceptions, to fit one of two typologies – *either* relevant/no quality indicators *or* parallel/quality indicators (Figure 1).

These findings raise a number of concerns regarding the potential impact of Better Regulation on tobacco control policymaking in jurisdictions around the world. First, our findings highlight how Better Regulation, with its requirement for public consultations and impact assessments, imposes costs on government departments in the earliest stage of policy development. Just as TTCs habitually launch legal challenges in the post-decision phase of policy-making (49), so too can they use their resource advantage to exploit Better Regulation processes by both commissioning new research and submitting extensive and complex responses in the pre-decision phase of the policy process, effectively frontloading their opposition. The combination of a requirement for due diligence and the volume and nature of responses may have contributed to the eleven month delay in publication of the Department of Health's consultation report.

Second, Better Regulation's requirement that policymakers consider alternative policy options, with its underlying intention of preventing unnecessary regulation, imposes additional upfront costs on governments. In the case of standardised packaging, this requirement encouraged extensive citation of evidence beyond the focus of the policy proposal. This may partly explain why nearly two thirds of the evidence the TTCs cited to claim that standardised packaging 'won't work' addressed non-packaging drivers of youth and adult smoking: studies which do not consider standardised packaging in their methodology or analysis. A second possible explanation is that the level of independence and peer-review of this parallel evidence is significantly higher than that of the evidence they cite on tobacco packaging and its inclusion may therefore have been intended to add legitimacy to TTC arguments.

Third, the absence of guidelines requiring a declaration of any conflict of interest between corporations and the evidence they cite enable tobacco industry-funded/linked work to be cited by TTCs in such a way that any link is undeclared, implying independence. For example, BAT, IT and PM all cited tobacco industry-funded/linked evidence in their submissions without explicitly acknowledging their connection to it (27, 29, 30). This speaks to a lack of transparency in the policy process regarding the provenance of evidence submitted by corporate interests.

Fourth, the lack of clarity regarding whether or how civil servants assess the policy relevance and quality of evidence is reflected by an equivalent lack of clarity regarding how governments handle the absence of evidence. We have identified a clear omission in the TTCs' submissions of evidence regarding the importance TTCs place on tobacco packaging in the marketing of their products.

Taken collectively, evidence present in and absent from the TTCs' submissions highlights an important transparency deficit within Better Regulation processes. This deficit obscures the view of policymakers, potentially preventing them from identifying and taking account of the judicious selection and exclusion of evidence by corporate actors with vested interests in policy outcomes. Because Better Regulation requires evidence-based impact assessments and invites evidence-based submissions to public consultations, the potential exists for corporations to exert undue and unnoticed influence on the policy process.

Considering the statutory requirement imposed by Article 5.3 of the FCTC to 'protect' tobacco control policies 'from commercial and other vested interests of the tobacco industry' (21), it would

be advisable for the 177 states which are party to the Convention to implement and publish clear guidelines on how TTC submissions to public consultations, and evidence cited within, should be managed by policymakers. Two steps could be taken by governments to achieve this. First, conflict of interest declarations regarding evidence cited could be made a mandatory element of public consultations. Second, policymakers could adopt a similar methodology to that used in this research. Adopting a process of classifying evidence for subject matter, independence and peer-review status may help policymakers to systematically prioritise good quality, policy-focused evidence; and to flag evidence about which they need to be more sceptical, such as that which is not policy-focused, not independent or not peer-reviewed.

These recommendations have relevance across government departments in all states which are signatories to the FCTC. It would also be appropriate to explore applying this critical perspective to the development of non-tobacco public health regulation – for example, of the alcohol and food industries – where corporate interests also seek to influence policy being developed for the public good (50, 51).

The strength of the findings is limited by the use of indicators of quality, rather than a validated quality assessment framework, to assess the evidence. Peer-review status and independence from the tobacco industry are used as proxy indicators of quality. While we acknowledge that peer-review standards can and do vary in practice (52-55), our rationale for choosing these proxies is based on our interest in addressing the challenges policymakers face in assessing large volumes of evidence. Unlike quality assessment tools, the criteria we have selected do not require scientific expertise or lengthy data extraction processes and can be used systematically in the policy environment to assess the relevance and quality of evidence cited by consultation respondents. Where the need is identified, more in-depth analysis of study design, data and methods (38-40) can be undertaken to review key pieces of evidence.

What has been learned from the UK Government's 2013 decision to postpone any decision on standardised packaging until further evidence is available is that Better Regulation ensures that evidence occupies a critical instrumental role in policymaking. Thus, how government departments handle and interpret evidence in the development of public health policy, and what evidential relevance and quality thresholds are set for policy progression in the context of Better Regulation, are of vital importance.

CONTRIBUTORSHIP STATEMENT

JH, GF and AG conceived the idea for this study. JH was responsible for data gathering, coding, analysis and write-up. GF and KER were responsible for secondary coding. JH, GF, KER, SU and AG were involved in discussion of findings and commented on and edited drafts of the paper.

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COMPETING INTERESTS

ABG is a member [unpaid] of the Council of Action on Smoking and Health, and was a member of the WHO Expert Committee convened to develop recommendations on how to address tobacco industry interference with tobacco control policy.

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DATA SHARING STATEMENT

Extra data is available by emailing j.hatchard@bath.ac.uk

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ARTICLE TITLE:
A critical evaluation of the volume, relevance and quality of evidence submitted by the tobacco industry to oppose standardised packaging of tobacco products

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ABSTRACT

BACKGROUND: Better Regulation is an overarching governance structure requiring early stakeholder consultation and evidence-based impact assessment of policies. In 2012, four transnational tobacco companies (TTCs) responded to a UK consultation on standardised packaging of tobacco products, citing extensive evidence. Following the Government's evidence-based rationale to postpone any decision on standardised packaging, this paper aims to examine the volume, relevance and quality of TTCs' evidence that the policy 'won't work'.

METHODS: Evidence cited in the TTC submissions and a ~~Systematic Review~~systematic review of the potential impacts of standardised packaging was counted and coded for relevance (subject matter) and quality (independence and peer review). Fisher's Exact Test was used to assess differences in the quality of the evidence between the TTC and ~~Systematic Review~~systematic review evidence and between TTC evidence on packaging compared with their evidence on other topics.

RESULTS: 77/143 pieces of TTC-cited evidence were used to promote their claim that standardised packaging 'won't work'. 17/77 addressed standardised packaging: 82% tobacco industry connected; 0% published in a peer-reviewed journal. In comparison, 37/37 studies included in the ~~Systematic Review~~systematic review addressed standardised packaging: 0% had tobacco industry connections; 57% published in a peer-reviewed journal. The difference in quality of the ~~Systematic Review~~systematic review and TTC evidence on standardised -packaging was found to be statistically significant ($p<0.0001$). TTCs' evidence on standardised packaging/packaging (26/77) was found to be of lower quality than their evidence on topics unconnected to tobacco packaging (51/77) ($p<0.0001$).

CONCLUSION: With few exceptions, evidence promoted by TTCs to promote their claim that standardised packaging 'won't work' lacks *either* policy relevance *or* key indicators of quality. Policymakers could use these three criteria – subject matter, independence and peer-review status – to critically assess evidence submitted to them by corporate interests via Better Regulation processes.

A critical evaluation of the volume, relevance and quality of evidence submitted by the tobacco industry to oppose standardised packaging of tobacco products

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ARTICLE SUMMARY

Article Focus

- Better Regulation dictates that public policy ideas which may impact on businesses must be subject to public consultation and evidence-based impact assessment prior to policy progression.
- There is extensive evidence to support the case for standardised packaging of tobacco products as a contributor to the reduction in overall smoking prevalence.
- Transnational tobacco companies have been instrumental in promoting Better Regulation, and have a historical record of seeking to delay and prevent tobacco control regulations.

Key Messages

- Using Better Regulation processes, transnational tobacco corporations have legitimately sought to use evidence as a tool to influence the policy outcome on standardised packaging in the UK.
- The evidence tobacco manufacturers cited in their consultation submissions was not as relevant or as high quality as the evidence supporting packaging regulation.
- Improving the transparency of evidential management and interpretation strategies and thresholds may help address the potential conflict between Better Regulation and the Framework Convention on Tobacco Control.

Strengths and Limitations

- This study builds on the existing literature on corporate influence over public health policy and evidence.
- Further investigation of policymakers' perceptions of corporate evidence would be beneficial to corroborate the relevance of our findings.

INTRODUCTION

Standardised packaging of tobacco products entails the prohibition of logos, brand imagery, symbols, other images, colours and promotional text from tobacco products and tobacco product packaging. Despite the common use of the term 'plain packaging' in media coverage of this issue, graphic and textual health warning labels would still feature prominently on packs and key anti-counterfeiting marks would be retained.

Standardised packaging would further restrict the already limited opportunities of transnational tobacco companies (TTCs) to market their products. The policy's objective is to deter smoking initiation, particularly among young people, and promote cessation among existing smokers. Its introduction in Australia in December 2012 (1) sparked a wave of interest: Ireland and New Zealand gave strong indications of their intentions to introduce standardised packaging. In contrast, the UK government announced on July 12th 2013 that it had decided to wait for '*emerging evidence'* from Australia on impacts of standardised packaging before taking a policy decision. This announcement followed a lengthy debate which began in 2011 (2), included a four month public consultation ending in August 2012 (3), and was subject to nearly a year's deliberation within the Department of Health before the consultation report was published (4). The consultation aimed to inform policy development and gather additional evidence for an impact assessment. The impact assessment was rated amber (needing more work) by the Regulatory Policy Committee (RPC) in February 2012 (5).

Public consultations and impact assessments are processes within a global governance innovation termed *Better Regulation* (also known as *Smart Regulation* or *Better Lawmaking*). Drawing heavily on American Administrative Law and the cost-benefit approach to regulatory review in the US (6, 7), versions of Better Regulation are in place, for example, in multiple EU states (UK, Netherlands, Czech Republic, Sweden and Germany) (8), in the EU itself (9), and in Canada (10) and Australia (11). A key impetus for Better Regulation has been pressure put on governments and inter-governmental organisations by TTCs and other transnational corporations to reduce regulatory business costs and prioritise business interests in the policy process (8, 12).

Public consultations effectively frontload problem-resolution in the policy process by offering affected businesses and other interested parties an early opportunity to comment on policy ideas and proposals, and to submit evidence supporting their views (13, 14). Examples of consultation systems elsewhere include 'notice and comment' in the US (15) and the European Commission's 'Your voice in Europe' (16). Evidence gathered from consultations can then be taken into account in developing impact assessments, which entail quantitative evidence-based assessments of the potential effects of proposed regulations and consideration of alternative policy options (17). Evidence plays a key role in the policy process, and, in practice, Better Regulation underpins a form of evidence-based policy making which is deliberately open to stakeholder, and particularly business, influence (18, 19).

In the UK, these processes contribute to the attainment of five features of good governance: proportionality, accountability, consistency, transparency and targeting (14, 20). Under New Labour (18) and the Coalition Government (8), Better Regulation has formalised evidence-based policy making, which is now subject to two stages of scrutiny: first, by the RPC (a body sponsored by the Department of Business Innovation and Skills); and, subsequently, by the Cabinet's Reducing Regulation Committee (RRC) . The upfront costs to government of this process are intended to be offset by an associated reduced impact on businesses post-implementation.

New tobacco control policies developed by the Department of Health are subject to Better Regulation. Thus, TTCs can make submissions to public consultations on tobacco control policies, citing evidence regarding impacts on their businesses, wider impacts, and in support of alternative policies. Yet, the Government is also required to meet an international commitment made under

Article 5.3 of the Framework Convention on Tobacco Control (FCTC) to take steps to ensure that: '…in setting and implementing their public health policies with respect to tobacco control, Parties shall act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law' (21). A key rationale for this provision lies in the overwhelming evidence of the tobacco industry's efforts to bias the evidence base of health impacts of tobacco products and public health policies in its favour (22-25). Uniquely in the case of tobacco, the co-existence of these two governance regimes raises the possibility of a regulatory conflict between commitments to include businesses in policy development and commitments to exclude them (26).

The UK's consultation (3) and impact assessment (5) on standardised packaging provides an opportunity to consider how these two sets of commitments are reconciled by governments. The four largest TTCs in the UK market – Imperial Tobacco (IT), Japan Tobacco International (JTI), Philip Morris Ltd (PM) and British American Tobacco (BAT) – submitted lengthy consultation responses (1521 pages in total, of which 328 comprised their main responses and 1193 provided supplementary materials) (27-30). These were just 4 of 668,433 responses the Department of Health received (2,444 were 'detailed responses') (4). Associated time and resource costs raise the question of how governments can effectively make a balanced, informed and transparent assessment of the policy relevance and quality of all evidence cited in submissions (31).

A ~~Systematic Review~~systematic review of the evidence for standardised packaging, commissioned by the Department of Health, concluded that there is 'strong evidence' that standardised packaging would reduce the appeal of tobacco products and increase the prominence of health warnings (32). However, in their submissions, the TTCs rejected the findings of the ~~Systematic Review~~systematic review on the grounds that there is no evidence that standardised packaging would reduce smoking prevalence or initiation. (27-30). They cited extensive evidence to support their arguments, claimed that key evidence on smoking behaviour had not been considered in the ~~Systematic Review~~systematic review, and pointed to the absence of real-world evidence as problematic: the UK consultation preceded implementation of standardised packaging in Australia in December 2012. TTCs have maintained that advertising and promotional material – including packaging – only stimulate brand switching among current smokers (27, 29, 30, 33). Yet, overwhelming evidence from the tobacco industry's own marketing documents suggests this claim is highly disingenuous (34-37).

In this paper, we aim to examine the volume, policy relevance and quality of the evidence TTCs cited in their submissions and compare it with that included in the ~~Systematic Review~~systematic review (further work is underway to investigate the TTCs' interpretation of the evidence itself). We use this analysis to explore the challenges public consultations and impact assessments for tobacco control policies present to governments and begin to unpack the conflict between the Better Regulation agenda and the FCTC. We suggest evidential management strategies for governments developing tobacco control policies in this multi-level governance context.

METHODS

Defining 'evidence'

The comparative analysis methodology employed in this research required that 'evidence' was interpreted narrowly as formal written research sources, such as reports or journal articles. This restriction enabled a comparison of similar evidence in the two data sets: TTC citations and ~~Systematic Review~~systematic review evidence. Other forms of evidence (eg. opinion, political statements, legal rulings, press coverage) cited in the 4 TTCs' submissions, were excluded.

Selecting and recording TTC evidence

Details [author, title, date, source] of each piece of evidence cited by the TTCs in their submissions were extracted into an Excel spreadsheet and categorised under three main arguments made by the TTCs: there is no evidence of the beneficial impact of standardised packaging on public health – standardised packaging 'won't work'; standardised packaging will have negative unintended consequences (including economic impacts on businesses, growth in illicit trade in tobacco products, reduction in the price of cigarettes, or contravention of existing trade and intellectual property rules); and the policy process was 'flawed'. Evidence was also categorised as to whether it was promoted by the TTCs as supporting their argument, or contested by them. Only evidence used by the TTCs to promote their argument that standardised packaging 'won't work' was obtained and examined further.

Evidence from the ~~Systematic Review~~systematic review

Details of the papers cited in the ~~Systematic Review~~systematic review were recorded in Excel and obtained for further analysis of their relevance and quality.

Criteria for assessing evidence

Three criteria, identified via a review of similar studies of the quality of evidence used to oppose tobacco regulation (24, 38-42), were used to assess the policy relevance and quality of the evidence: subject matter, independence and peer-review (Table 1). These criteria represent an objective and practical means for policymakers to assess the policy relevance and quality of large quantities of evidence cited in submissions to public consultations prior to considering their content. ~~It was beyond the scope of this study to critically appraise the methodology used in evidence cited by TTCs. However where required, analysis of study design, data and methods could be used by policymakers on an ad hoc basis to review key pieces of evidence in more detail.~~

The *subject matter* of the evidence speaks to its relevance to the policy issue (31). Similar work has coded policy position, argument, topic and conclusion (40-42). On *independence*, research indicates that connection of research with a financially vested interest group can produce results which favour the sponsor, casting doubt on the independence, and therefore quality, of the evidence (40, 43, 44). The tobacco industry's efforts to discredit the science on environmental tobacco smoke and bias evidence on the impacts of smokefree legislation provide historical examples of this (22-25, 45). On *peer-review status*, articles which appear in peer-reviewed journals have been shown to be of superior quality to other research outputs in terms of study design, reporting and interpretation (40, 46). For example, peer review enables studies to be assessed by experts who are knowledgeable in the subject area, provides strong incentives for authors to heed advice and improve papers and acts as a filter which aims to prevent poorly designed studies from being published. Some alternative publication routes also include external peer-review (eg. government-commissioned research, academic press volumes and conference papers); others rely on internal peer-review (eg. charity and university research reports); research funded and published by the tobacco industry tends not to be subject to external peer-review: '[T]he tobacco industry has had a long-standing strategy of funding research and disseminating it through their sponsored, non-peer-reviewed publications.' (47, 48)

Table 1 - Coding framework for classifying evidence

	Evidential Criteria	*Use in previous studies*	Data coding framework	Coding categories

Relevance	**Subject matter**	*What is the topic, argument, position or conclusion of the evidence? [Montini et al. 2002; Bero et al. 2001; Barnes and Bero 1997]*	What issue does the research address?	• Standardised Packaging of tobacco • Tobacco Packaging, eg. graphic health warnings • Tobacco, not packaging • Unrelated to tobacco
Quality	**Independence**	*Who funded the evidence? Are authors affiliated to the tobacco industry? [Montini et al. 2002, Scollo et al. 2003, Bero et al. 2001, Barnes and Bero 1996]*	Who funded the research? Has the author of the research any connection with the tobacco industry?	• Tobacco industry-funded (Statement included that the research was funded by the tobacco industry) • Tobacco industry-linked (No statement that the research was funded by the tobacco industry, but evidence of other connection: for example, author or funder have prior links to the tobacco industry) • Independent of the tobacco industry (Statement included that the research was funded by a source independent of the tobacco industry) • No apparent tobacco industry connection (No information provided about funding source and no evidence of prior connection with the tobacco industry)
	Peer-review status	*Has the evidence been peer-reviewed? What is the impact factor of the journal and date of publication? [Montini et al. 2002, Scollo et al. 2003, Bero et al. 2001, Barnes and Bero 1997]*	Was the research published in peer-reviewed journal? If not, where was the research published?	• Peer-reviewed journal • Academic press volume • Conference paper • Government-commissioned research • University research report • Government internal research • Charity research report • Private company research report • Unpublished

Evidential coding

Each piece of evidence was obtained via online searches, (general search engines and the research database Scopus), with non-digital documents obtained from library sources. Researchers read abstracts, introductions, conclusions, funding statements and cover pages of all evidence documents, and searched documents for key terms ('plain', 'pack*', 'standard*', 'tobacco', 'smok*'). Additional web searches were conducted (eg. the Legacy Library of tobacco industry documents and Scopus) to clarify independence and peer-review status of evidence.

Analytical process

The researchers used a content analysis methodology to code and analyse the data. Each piece of evidence was accessed and coded by one researcher (JH) using the criteria outlined in Table 1. A second researcher (GF) blind coded a random sample of 20% of the data (n=21). This process achieved a 97% level of inter-coder reliability. Once all the data had been analysed, a third researcher [KER] blind coded 100% of the data. This process achieved a 94.7% level of inter-coder reliability. All disagreements were fully resolved between the coders.

Having quantified and coded the evidence, we compared the policy relevance (subject matter) and quality (independence and peer review) of the industry evidence with that of the evidence supporting standardised packaging in the ~~Systematic Review~~systematic review (32). We also examined the relationship between policy relevance and quality by comparing the quality of the industry's evidence on tobacco packaging with its evidence on other topics. Differences were compared using a two-tailed Fisher's Exact Test. The results were used to develop relevance-quality typologies of TTC evidence. Evidence was classified as *relevant* if it focused on standardised packaging/tobacco packaging, and *parallel* if it focused on other tobacco issues/was unrelated to tobacco. Evidence was classified as featuring '*quality indicators*' if it was either independent, published in a peer-reviewed journal or both.

RESULTS

Overview of evidence cited by TTCs in their submissions

143 unique pieces of formal written research evidence were referred to or included in the four TTCs' submissions (22 referenced by more than one company) (Table 2). Of the 143 documents, TTCs promoted 131 as supporting their arguments and contested the methods, findings or accessibility of the remaining 12, all of which were included in the systematic review~~SR~~. 88 were cited to support arguments that standardised packaging would not have beneficial impacts on public health; 36 cited to argue that standardised packaging will have negative unintended consequences, half of which related to the illicit trade in tobacco; 19 cited to argue that the policy process – particularly the impact assessment – was 'flawed'. 77 pieces of evidence were used to promote the TTC argument that standardised packaging 'won't work' and were therefore the subject of further analysis in this paper.

Among these 77 documents, TTCs did not cite any research showing that the tobacco industry has extensively studied and holds considerable evidence attesting to the impact of packaging on smoking behaviour (34-37). Instead, they cited industry-funded research which critiqued the ~~SR~~ systematic review papers, the impact assessment and the consultation document. And they cited a body of independent research into the drivers of youth smoking which, while published in peer-reviewed health and psychology journals with no apparent connection to the tobacco industry, did not explicitly address the role of packaging in youth uptake or prevalence.

Table 2 - Overview of formal written evidence cited by TTCs in their submissions to the UK SPstandardised packaging consultation 2012

Theme of evidence / How cited by TTCs	Standardised packaging 'won't work': No evidence of impacts on smoking behaviour	Standardised packaging 'will have negative unintended consequences'				The policy process was 'flawed'	Total
		Economic	*Illicit*	*IP/ Trade*	*Price*		
Promoted	77*	3	18	5	9	19	**131**
Contested	11	1	0	0	0	0	**12**
Total	**88**	4	18	5	9	**19**	**143**
		36					

*the evidence examined further in this paper

Comparison of TTC and ~~Systematic Review~~systematic review evidence on the impact of standardised packaging on smoking behaviour

There are marked differences between the relevance and quality of the TTC and ~~Systematic Review~~systematic review evidence (Table 3, Figure 1). Only 17/77(22%) pieces of evidence promoted by the TTCs addressed standardised packaging directly: the majority of which were industry-funded/linked (14/17, 82%); none were published in a peer-reviewed journal (0/17, 0%). The remaining 60 pieces of evidence (78% of the total, comprising the majority of the evidence the industry cites) did not address standardised packaging. In contrast, 37/37 (100%) pieces of evidence included in the ~~Systematic Review~~systematic review focused on standardised packaging, none (0/37, 0%) had a connection with the tobacco industry, and 21/37 (57%) were published in a peer reviewed journal. The results of a comparison of the TTCs' standardised packaging subset of evidence (n=17) with the ~~Systematic Review~~systematic review evidence on standardised packaging (n=37), using Fisher's Exact Test, illustrate the statistical significance of the different distribution of relevance and quality indicators: $p<0.0001$ on subject, independence and peer-review status.

Table 3 - Quality and relevance of Transnational Tobacco Corporation (TTC) and ~~Systematic Review~~systematic review evidence

	Relevance – *Subject matter*				
	Standardised packaging		Other (TTC evidence only)		
Quality	**~~Systematic Review~~Ssystematic review evidence (n=37)**	**TTC evidence (n=17)**	Tobacco packaging (n=9)	Tobacco, not packaging (n=45)	Unrelated to tobacco (n=6)
Independence					
Industry-funded	**0**	**12**	2	1	0
Industry-linked	**0**	**2**	1	2	1
Independent	**31**	**3**	6	37	5
No apparent connection to the tobacco industry	**6**	**0**	0	5	0
Publication route					
Peer-reviewed journal	**21**	**0**	1	26	4
Academic press	**0**	**0**	0	1	1
Conference paper	**2**	**1**	0	0	0
Government-commission	**8**	**0**	2	2	0
University research	**5**	**0**	1	2	0
Government internal research	**0**	**2**	1	12	0
Charity research	**1**	**1**	1	0	1
Private company research	**0**	**13**	3	1	0
Unpublished	**0**	**0**	0	1	0

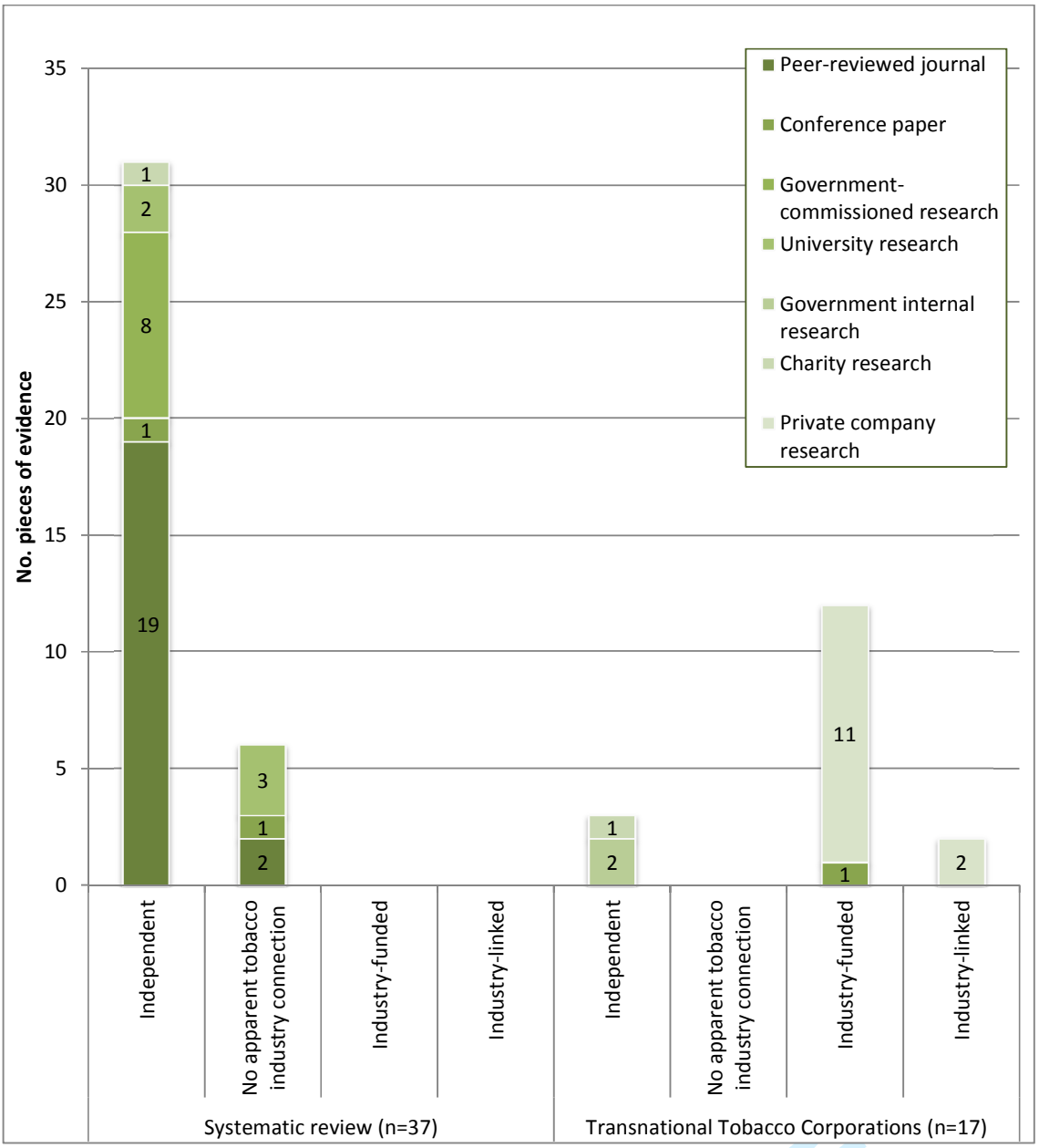

Figure 1 - Comparison of quality (independence and publication route) of ~~Systematic Review~~systematic review and TTC evidence directly addressing standardised packaging of tobacco products

Relationships between subject matter, independence and peer-review within the TTC evidence

A low proportion of TTCs' evidence relating to standardised packaging was independent or peer-reviewed (Figure 1). When evidence on tobacco packaging was added to the standardised packaging evidence, the same pattern was found: 9/26 (35%) were independent (independent/no apparent tobacco industry connection); 1/26 (4%) was published in a peer reviewed journal (Tables 4a/b). However, a greater proportion of the 51 pieces of evidence the TTCs cited on parallel topics (including non-packaging drivers of youth and adult smoking behaviour, and drivers of youth behaviour in general) were independent (47/51, 92% independent/no apparent connection) and peer-reviewed (30/51, 59% published in peer reviewed journal). These differences are statistically significant ($p<0.0001$, Table 4a). We also found a clear relationship between the two indicators of

quality – independence and peer-review – in the TTCs' evidence: industry-funded/linked studies cited by TTCs were significantly less likely to be published in a peer-reviewed journal (3/21, 14%) than independent/no apparent connection studies they cited (28/56, 50%) (p=0.0045, Table 4b).

Table 4a - Relationship between policy relevance and two indicators of quality in the TTC evidence, number and per cent in parenthesis

	Policy relevance: Subject matter		
Qualityindicators	*Relevant: Standardised packaging/Tobacco packaging (n=26)*	*Parallel: Tobacco not packaging/Unrelated to tobacco (n=51)*	*Fisher's p-value*
Independent of/no apparent tobacco industry connection	9/26 (35%)	47/51 (92%)	p<0.0001
Published in a peer-reviewed journal	1/26 (4%)	30/51 (59%)	p<0.0001

Table 4b - Relationship between two indicators of quality in the TTC evidence, number and per cent in parenthesis

Peer review status	*Independent of/no apparent tobacco industry connection (n=56)*	*Connected with the tobacco industry (n=21)*	*Fisher's p-value*
Published in a peer-reviewed journal	28/56 (50%)	3/21 (14%)	p0.0045

TTCs' evidence was classified into four typologies (Table 5): relevant/quality indicators, relevant/no quality indicators, parallel/quality indicators, parallel/no quality indicators. While 100% of the ~~Systematic Review~~systematic review evidence was both relevant and featured at least one of the two quality indicators, only 12% of evidence cited by TTCs in their submissions qualified for this category.

Table 5 - Distribution of TTC evidence across typologies

		Quality	**Quality indicators**	**No quality indicators**
Relevance			*Either independent, peer-reviewed or both*	*Neither independent nor peer-reviewed*
Relevant	*Standardised packaging and other tobacco packaging*		**12%** (100% ~~Systematic Review~~Ssystematic review evidence)	**22%**

Parallel	*Tobacco, not packaging and unrelated to tobacco*	**65%**	**1%**

DISCUSSION

Four main findings are apparent. TTCs cited a large volume of evidence in their submissions to the UK standardised packaging consultation. They commissioned 15 studies to support their case that standardised packaging 'won't work'. The quality of TTC evidence on standardised packaging is significantly lower, as judged by independence and peer-review, than that included in the ~~Systematic Review~~systematic review. Finally, the evidence cited by TTCs is shown, with few exceptions, to fit one of two typologies – *either* relevant/no quality indicators *or* parallel/quality indicators (Figure 1).

These findings raise a number of concerns regarding the potential impact of Better Regulation on tobacco control policymaking in jurisdictions around the world. First, our findings highlight how Better Regulation, with its requirement for public consultations and impact assessments, imposes costs on government departments in the earliest stage of policy development. Just as TTCs habitually launch legal challenges in the post-decision phase of policy-making (49), so too can they use their resource advantage to exploit Better Regulation processes by both commissioning new research and submitting extensive and complex responses in the pre-decision phase of the policy process, effectively frontloading their opposition. The combination of a requirement for due diligence and the volume and nature of responses may have contributed to the eleven month delay in publication of the Department of Health's consultation report.

Second, Better Regulation's requirement that policymakers consider alternative policy options, with its underlying intention of preventing unnecessary regulation, imposes additional upfront costs on governments. In the case of standardised packaging, this requirement encouraged extensive citation of evidence beyond the focus of the policy proposal. This may partly explain why nearly two thirds of the evidence the TTCs cited to claim that standardised packaging 'won't work' addressed non-packaging drivers of youth and adult smoking: studies which do not consider standardised packaging in their methodology or analysis. A second possible explanation is that the level of independence and peer-review of this parallel evidence is significantly higher than that of the evidence they cite on tobacco packaging and its inclusion may therefore have been intended to add legitimacy to TTC arguments.

Third, the absence of guidelines requiring a declaration of any conflict of interest between corporations and the evidence they cite enable tobacco industry-funded/linked work to be cited by TTCs in such a way that any link is undeclared, implying independence. For example, BAT, IT and PM all cited tobacco industry-funded/linked evidence in their submissions without explicitly acknowledging their connection to it (27, 29, 30). This speaks to a lack of transparency in the policy process regarding the provenance of evidence submitted by corporate interests.

Fourth, the lack of clarity regarding whether or how civil servants assess the policy relevance and quality of evidence is reflected by an equivalent lack of clarity regarding how governments handle the absence of evidence. We have identified a clear omission in the TTCs' submissions of evidence regarding the importance TTCs place on tobacco packaging in the marketing of their products.

Taken collectively, evidence present in and absent from the TTCs' submissions highlights an important transparency deficit within Better Regulation processes. This deficit obscures the view of

policymakers, potentially preventing them from identifying and taking account of the judicious selection and exclusion of evidence by corporate actors with vested interests in policy outcomes. Because Better Regulation requires evidence-based impact assessments and invites evidence-based submissions to public consultations, the potential exists for corporations to exert undue and unnoticed influence on the policy process.

Considering the statutory requirement imposed by Article 5.3 of the FCTC to 'protect' tobacco control policies 'from commercial and other vested interests of the tobacco industry' (21), it would be advisable for the 177 states which are party to the Convention to implement and publish clear guidelines on how TTC submissions to public consultations, and evidence cited within, should be managed by policymakers. Two steps could be taken by governments to achieve this. First, conflict of interest declarations regarding evidence cited could be made a mandatory element of public consultations. Second, policymakers could adopt a similar methodology to that used in this research. Adopting a process of classifying evidence for subject matter, independence and peer-review status may help policymakers to systematically prioritise good quality, policy-focused evidence; and to flag evidence about which they need to be more sceptical, such as that which is not policy-focused, not independent or not peer-reviewed.

These recommendations have relevance across government departments in all states which are signatories to the FCTC. It would also be appropriate to explore applying this critical perspective to the development of non-tobacco public health regulation – for example, of the alcohol and food industries – where corporate interests also seek to influence policy being developed for the public good (50, 51).

The strength of the findings is limited by the use of indicators of quality, rather than a validated quality assessment framework, to assess the evidence. Peer-review status and independence from the tobacco industry are used as proxy indicators of quality. While we acknowledge that peer-review standards can and do vary in practice (52-55), our rationale for choosing these proxies is based on our interest in~~: first,~~ addressing ~~examining~~ the challenges policymakers face in assessing large volumes of evidence. Unlike quality assessment tools, the criteria we have selected do not require scientific expertise or lengthy data extraction processes and can be used systematically in the policy environment ~~; and, second, exploring practical techniques for~~ to assess~~ing~~ the relevance and quality of evidence cited by consultation respondents. ~~These criteria are relatively easy to use systematically in a policy environment; w~~Where the need is identified, more in-depth analysis of study design, data and methods (38-40) can be undertaken to review key pieces of evidence~~. in more detail.~~

What has been learned from the UK Government's 2013 decision to postpone any decision on standardised packaging until further evidence is available is that Better Regulation ensures that evidence occupies a critical instrumental role in policymaking. Thus, how government departments handle and interpret evidence in the development of public health policy, and what evidential relevance and quality thresholds are set for policy progression in the context of Better Regulation, are of vital importance.

CONTRIBUTORSHIP STATEMENT

JH, GF and AG conceived the idea for this study. JH was responsible for data gathering, coding, analysis and write-up. GF and KER were responsible for secondary coding. JH, GF, KER, ~~ZT~~ SU and AG were involved in discussion of findings and commented on and edited drafts of the paper.

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ABG is a member [unpaid] of the Council of Action on Smoking and Health, and was a member of the WHO Expert Committee convened to develop recommendations on how to address tobacco industry interference with tobacco control policy.

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Extra data is available by emailing j.hatchard@bath.ac.uk

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