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A systematic review of research (2019-2020) exploring the response of consumers, retailers and tobacco companies to standardised packaging in the United Kingdom

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BE THE DIFFERENCE

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What this study adds:

- Standardised packaging was associated with increased warning salience and decreased pack appeal, but with respect to reduced perceptions of harm the findings were mixed.
- There was limited evidence on behavioural response to standardised packaging, with no study directly exploring cessation or relapse prevention, although there was some evidence to suggest that it may help deter some young people from smoking.
- Tobacco companies continued to promote their products in the run-up to standardised packaging and thereafter, with a number of pack modifications identified.
- Standardised packaging and concurrent changes in tobacco taxation were associated with increased prices for cigarettes and rolling tobacco for at least one year after the end of the transition period. There was evidence of declining sales.

Abstract

Introduction

The UK became the third country to fully implement standardised (or plain) packaging for cigarettes and rolling tobacco in May 2017, following a twelve-month transition period. In 2019 we conducted a systematic review of peer-reviewed research published in academic journals exploring consumer, tobacco company and retail response to this policy. This report provides an update to the 2019 review, focusing on evidence from the UK published between February 15th 2019 and September 28th 2020.

Methods

We searched for peer-reviewed published studies which explored consumer, retailer or tobacco company response to standardised packaging in the UK since the cut-off date (15th February 2019) of the previous review. Studies were screened against inclusion criteria. Data from included studies were extracted into standardised forms and each study was critically appraised. Findings were reported by narrative synthesis.

Results

Thirteen studies, reported in twelve publications, were included. Nine studies explored consumer responses to standardised packaging and four the response of tobacco companies and changes in the retail environment. Four consumer studies explored response to the on-pack warnings, with standardised packaging consistently associated with increased warning salience and effectiveness. Four studies examined appeal, with all studies finding standardised packs to be unappealing. Four studies examined harm, with three studies with teenagers providing some evidence that standardised packs were associated with greater harm, and one longitudinal survey with adults which found no differences in harm perceptions. Five studies examined anticipated changes to standardised packaging and behavioural outcomes. Standardised packaging was generally thought to deter never or occasional smokers. The number of households purchasing only cigarettes fell during the study while the number purchasing only rolling tobacco increased, with an increase in purchase of the cheapest cigarettes. No study directly explored cessation with smokers, or relapse prevention. Four studies explored tobacco companies' responses to standardised packaging and changes in the retail environment. One study explored tobacco industry marketing strategies, finding that they kept fully-branded packs on the market for as long as possible, changed variant names, modified packs, included extra sticks, and promoted tobacco products exempt from standardised packaging regulations. Two studies using Nielsen data found that for cigarettes and rolling tobacco prices rose and overall sales declined following full implementation of standardised packaging and concurrent taxation changes, although no decline in sales was observed for rolling tobacco.

Discussion

Standardised packaging in the UK appears to have increased warning salience and reduced pack appeal, with findings on perceptions of harm mixed. While teenagers considered standardised packaging a deterrent for young people, research exploring cessation or relapse prevention is needed. For cigarettes and rolling tobacco prices increased, contrary to tobacco industry arguments that they would decrease, and overall sales declined.

Executive Summary

Introduction

The 'Standardised Packaging of Tobacco Products Regulations' and 'Tobacco and Related Products Regulations' requires cigarettes and rolling tobacco in the UK to be sold in drab brown packs with large pictorial health warnings on the primary display areas and text warnings on the secondary display areas. Standardised packs are not permitted to feature any markings, financial incentives, information which creates an erroneous impression about product characteristics, or any reference to taste, smell or flavour. The legislation also sets a minimum pack size of 20 sticks for cigarettes and 30 grams for rolling tobacco. We hereafter refer to these as standardised packs. Tobacco companies were given a twelve-month sell-through period, between 20 May 2016 and 19 May 2017, to transition from fully-branded to standardised packs.

Aim

The aim was to conduct a systematic review of all published research exploring the response of consumers, tobacco companies and retailers to standardised packaging in the UK, updating our previous review which examined research published until February 15th 2019. The findings will inform the Department of Health and Social Care's Post-Implementation Review of the legislation in 2021.

Methods

The search strategy included searches for peer-reviewed studies in the academic literature from generic and topic-specific electronic databases from various fields (health, business and marketing, social sciences, psychology and anthropology) and contact with individuals who had previously been involved in work on tobacco packaging in the UK. The search results were screened against inclusion criteria to identify potentially relevant studies. All peer-reviewed research that had been published or accepted for publication (by September 28th 2020), and which explored consumer, retailer or tobacco company response to standardised packaging in the UK, was eligible for inclusion. There were no limits on study design, although work focusing exclusively on legal aspects of standardised packaging was not eligible for inclusion. Each included study was externally critically appraised. Data from studies identified as meeting the inclusion criteria were extracted into standardised data extraction forms. A narrative synthesis was employed as a meta-analysis was not feasible given the heterogeneity of outcome measures and study designs employed.

Key findings and conclusions

A total of 603 records were identified following initial searching, and after screening 12 journal articles, describing 13 studies, were included. Nine studies explored consumer responses to standardised packaging and four the response of tobacco companies and changes in the retail environment. Four consumer studies explored response to the on-pack warnings, with standardised packaging consistently associated with increased warning salience and effectiveness. Four studies examined appeal, with all studies finding standardised packs to be unappealing. Four studies examined harm, with three studies with teenagers providing some evidence that standardised packs were associated with greater harm, and one longitudinal survey with adults which found no differences in harm perceptions. Five studies examined anticipated changes to standardised packaging and behavioural outcomes. Standardised packaging was thought to deter never or occasional smokers. The number of households purchasing only cigarettes fell during the study while the number purchasing only rolling tobacco increased, with an increase in purchase of the cheapest cigarettes and rolling tobacco. No study directly explored cessation with smokers, or relapse prevention.

Four studies explored tobacco companies' responses to standardised packaging and changes in the retail environment. One study explored tobacco industry marketing strategies, finding that they kept fully-branded packs on the market for as long as possible, changed variant names, modified packs, included extra sticks, and promoted tobacco products exempt from standardised packaging regulations. Two studies which used Nielsen data to examine trends in pricing and sales of cigarettes and rolling tobacco found that prices rose and overall sales fell following full implementation of standardised packaging and concurrent taxation changes, although no decline was observed in sales of rolling tobacco.

The findings from this, and our previous review, suggest that the core aims of standardised packaging (an increase in warning salience, a reduction in appeal, and a reduction in misperceptions of harm) have largely been met, although additional research on harm perceptions would be beneficial. With respect to the impact of standardised packaging on smoking behaviour, young people typically viewed standardised packaging as a deterrent to starting but there was limited research on uptake, and no study directly explored cessation or relapse. That tobacco companies were able to promote their products post-standardised packaging highlights some of the deficiencies in the legislation. Tobacco prices increased, contrary to tobacco industry arguments that they would decrease, and overall sales declined.

1 Introduction

Despite the long-term decline in smoking prevalence and consumption in the UK, approximately 6.9 million adults (14.1%) continue to smoke.[1] While this is less than a third of the percentage of adults who smoked in 1974, smoking remains a leading cause of morbidity and mortality in the UK. There are an estimated 1,300 smoking-related admissions to hospital in England each day,[2] and between 2016 and 2018 approximately 95,000 deaths each year across the UK.[1] To tackle the harms associated with tobacco use, the UK Government and devolved administrations have introduced a series of tobacco control measures this century. Since 2007, the UK has been ranked the country in Europe with the strongest tobacco control.[3] Policies introduced include a comprehensive ban on tobacco marketing, a ban on the open display of tobacco products within tobacco selling retailers, and the inclusion of pictorial warnings on tobacco packaging (although only on the pack reverse). These policies greatly restricted the ability of tobacco companies to promote their products, although they were still able to do so through fully-branded packaging.

1.1 Standardised packaging

As of November 2020, at least 14 countries have fully implemented standardised (or plain) packaging. Australia was the first country to do so, in December 2012, followed by France in January 2017 and the UK in May 2017. In the UK the 'Standardised Packaging of Tobacco Products Regulations'[4] and 'Tobacco and Related Products Regulations'[5] were phased in between 20 May 2016 and 19 May 2017. The legislation requires cigarettes and rolling tobacco to be sold in 'drab brown' packs displaying pictorial warnings on at least 65% of the primary display areas, and a general warning (Smoking kills – quit now) and information message (Tobacco smoke contains over 70 substances known to cause cancer) on at least 50% of the secondary display areas. Packs can display a brand and variant name, but the position on the surface area on which they appear, as well as the font size, style and typeface, and text colour is standardised, see Figure 1. Standardised packs are not allowed to feature any other markings or financial incentives, or information which promotes a product or encourages consumption by creating an erroneous impression about its characteristics or any reference to taste, smell or flavour. The legislation also sets a minimum pack size of 20 sticks for cigarettes and 30 grams for rolling tobacco (also commonly referred to as roll-your-own tobacco). Cigarettes must come in flip-top packs or shoulder boxes (packs with a hinged lid at the base), and be cuboid shaped, although bevelled or rounded edges are permitted.

1.2 Objectives of standardised packaging

The primary aims of standardised packaging are to discourage initiation, encourage cessation, and help ex-smokers avoid relapse. It is predicted that standardised packaging will achieve this aim by reducing the appeal of tobacco products, increasing the effectiveness of the on-pack warnings, reducing the ability of the pack to mislead consumers about the harms of smoking, and having a positive effect on smoking-related attitudes, beliefs, intentions and behaviours.[6]

1.3 Previous reviews of the evidence on standardised packaging

There have been a number of previous reviews of the literature on standardised packaging. These include a systematic review of standardised packaging research,[7,8] an update of the literature,[9] and a Cochrane review.[10] However, none of these reviews were conducted prior to standardised packaging being introduced in the UK. A more recent systematic review explored how consumers, retailers and tobacco companies responded to standardised packaging in the UK, after this policy had been implemented.[11] The cut-off for this review was February 15th 2019. The current review provides an update of any new published research (post-15th February) exploring consumer, retailer or tobacco company response to standardised packaging in the UK.

Figure 1: Examples of fully-branded packs and standardised packs

2 Project Aim

2.1 Aim

The aim of the project was to synthesise research exploring how consumers, retailers and tobacco companies responded to standardised packaging in order to help understand the impacts of the policy, including any unintended consequences.

2.2 Research questions

To meet the project aim, the following research questions were considered:

1. What effect, if any, does standardised packaging have on socio-cognitive outcomes, including changes in the salience of health warnings, appeal of packaging, and perceptions of product strength and harm?
2. What effect, if any, does standardised packaging have on smoking-related behavioural intentions and behavioural outcomes, including cessation, cessation-related behaviours (e.g. accessing a cessation service), consumption and switching to other products (e.g. non-combustible nicotine containing products, illicit tobacco)?
3. Are there any differential effects in response to standardised packaging by sex, age, socio-economic status and ethnicity?
4. Have tobacco companies and retailers altered their pricing practices in response to standardised packaging, and if so how?
5. To what extent have tobacco companies and retailers complied with standardised packaging regulations?
6. Have tobacco companies and retailers continued to promote tobacco products following the introduction of standardised packaging, and if so how?

3 Design and Methods

To be consistent with the previous review of UK evidence,[11] the design and methods of the current review remained as similar as possible.

3.1 Inclusion and exclusion criteria

To understand the impacts of standardised packaging, peer-reviewed research that had been published or accepted for publication in an academic journal, and which explored consumer, retailer or tobacco company response to standardised tobacco packaging in the UK, was eligible for inclusion.[11] Peer-reviewed conference abstracts, while providing less detail, were also eligible.

All primary study designs and data collection methods were eligible for inclusion, although we excluded work focusing exclusively on legal aspects of standardised packaging, and reviews, editorials and news items were ineligible. Studies not accepted for publication were excluded.

3.2 Search strategy and study selection procedure

The search strategy involved systematic searches for peer-reviewed studies in the academic literature from generic and topic-specific electronic databases from various fields (health, medicine, business and marketing, social sciences, psychology and anthropology). These included: Business Source Complete, Cochrane Library, Medline, PsycINFO, SocINDEX, World Advertising Research Center, Web of Science Core Collection. The search terms were a combination of tobacco-related terms, pack-related terms, and terms for the UK (see Appendix 1 for a sample search strategy). Databases' standardised subject terms were checked for updated terms since the last review. The Bielefeld Academic Search Engine (BASE) for online institutional repositories and the Society for Research on Nicotine and Tobacco (SRNT) Europe 2019 and SRNT 2020 conference programmes were also searched with a selection of these terms. A Web of Science Citation Search was made for publications citing previous reviews of standardised packaging,[8,10,12-14] and those citing any of the 11 articles included in the previous review.[11] We also contacted individuals who had previously been involved in work on tobacco packaging in the UK to identify any research that had not been retrieved in the searches.

All searches were run on 28 May 2020, with results limited to records published since August 2018 (or the beginning of 2018 for some databases). The date range was overlapped with that of the previous review to allow any studies published in the relevant timeframe, but entered late into the database, to be identified. No language limitations were applied. All results were uploaded to a RefWorks database and duplicate records were removed. All the searches were re-run on 28 September 2020 with results limited to records published since the beginning of 2020 and/or added to the database since 2020. Results were uploaded to the same RefWorks database and duplicate records were removed.

Study titles and abstracts were screened by one reviewer against the inclusion criteria to identify potentially relevant studies. Potentially relevant studies identified at this stage were obtained in full text and screened for relevance by one reviewer. A second reviewer checked all the inclusion/exclusion decisions made at both screening stages. Those not meeting the inclusion criteria were excluded.

3.3 Critical appraisal

Each study was appraised for methodological soundness, using the same process as the previous review.[11] The assessment was completed by two external assessors (AOE and DK, from the EPPI-Centre, Institute of Education, University College London) due to the potential conflict of interest resulting from the researchers in the systematic review team being co-

authors on some included studies. The two external assessors conducted independent critical appraisals using EPPI-Reviewer 4 software.[15] They met after the first study appraised to discuss the appraisal tool, make adaptations to enhance clarity of the tool, and reconcile any disagreements in the appraisal. The external assessors then met to discuss and reconcile their appraisals after every few studies.

Four different quality tools were developed for the previous review, depending on the type of study being assessed, as described in section 3.3.1.

3.3.1 Development and description of the critical appraisal tools

It was determined that there were four broad categories of research design in the sample of studies:

1. Qualitative analysis of interview data
2. Quantitative analysis of sales data (including price data)
3. Quantitative analysis of data from human participants (two sub-types: survey data and experimental data)
4. Structured observations of documents or places

For the previous review, the external assessors concluded that no existing tools were completely fit for purpose and therefore they developed and used new tools. They refined the tools further to appraise the methodological soundness of the studies in this review, as summarised below.

For *qualitative analysis of interview data* studies, they used an adapted version the Critical Appraisal Skills Programme (CASP)[16] Checklist for qualitative studies. The final "qualitative" tool contained 11 items under five domains: Aims, Data collection, Analysis, Contributions and Conclusions, and an Overall Summary; see Appendix 2.

The external assessors developed and refined a new tool for studies using *quantitative analysis of sales data*, as described previously.[11] For this review, two additional items were added by the external assessors to make the structure and items comparable to the other tools, one to assess whether ethical issues were addressed in the study and a new overall item summarising concerns about the study's 'inferences and conclusions'. The final "sales data" tool contains 24 items under six domains: Aims, Data, Analysis, Inferences and Conclusions, Ethics and an Overall Summary (Appendix 2).

For the studies using *quantitative analysis of data from human participants,* the external assessors developed and refined a new tool.[11] The core items applied to all quantitative studies with human participant data and they constructed an additional, optional sub-section specifically for appraising experimental studies. An additional item to assess whether ethical issues were addressed in the study was added by the external assessors to make the structure and items comparable to the other tools. The final "human participants" tool contains 19 items under six domains: Aims, Data, Analysis, Inferences and Conclusions, Ethics and an Overall Summary; plus, an additional section on "Experiment" consisting of five items; see Appendix 2.

For the *structured observations studies* which reflected structured data collection from documents and site visits, the external assessors developed and tested a "structured observations" tool, as described in the previous review.[11] An additional item to assess whether ethical issues were addressed in the study was added by the external assessors to make the structure and items comparable to the other tools. The final "structured observations" tool contains 24 items under six domains: Aims, Data, Analysis, Inferences and Conclusions, Ethics and an Overall Summary; see Appendix 2.

3.3.2 Basis of assessment

The critical appraisals focused largely on the methodological procedures employed in the studies, and the link between the methods and the aims and conclusions of the study. It was therefore important to conduct an appraisal of each methodological component of a given study, as the rigour might differ from component to component. The critical appraisal assessed 14 methodological components of 13 different studies reported across 12 publications, see Appendix 3.

It is important to note that the critical appraisals were conducted at the level of the methodological components of the studies (column 3 in Appendix 3). As such, the overall assessments (i.e. ratings of soundness) are not based on individual findings. Several items of the critical appraisals pertained to whether methods were suitable given the study aims, and whether the conclusions were appropriate given the methods; it was these items that tended to generate the most concern about the studies. For example, the conclusions of some studies generalised beyond the sample included in the study in a way that was inappropriate given the sampling methods used. Whilst this may make the inferences made by the researchers unsound, the actual results of the analysis are not *necessarily* unsound. In any systematic review, the results and findings are extracted from the studies to be included in the synthesis and, taken in isolation, might therefore not be subject to the same concerns as the original study *if* the systematic reviewers do not make the same inferential overstatements that the original study authors made.

In other words, the soundness ratings are indicative of the potential risks in taking the original studies at face value. The systematic review offers an opportunity take these concerns into account in interpreting the findings.

3.4 Data extraction

Data from studies identified as meeting the inclusion criteria were extracted into a standardised data extraction form. The data extracted included: general information (author, publication year, funder, conflict of interests); study characteristics (aims, design, data collection method and period); sample characteristics and study setting; any theoretical basis; outcome measures and results.

3.5 Method for synthesis

A narrative synthesis was employed as neither a quantitative meta-analysis nor a qualitative meta-ethnography was feasible given the heterogeneity of the outcome measures and study designs. The studies were initially grouped by those measuring consumer responses and those measuring industry and retailer responses. The extracted outcome measures were then grouped by those measuring similar actions. No outcomes measured the same action in the same way, so the extracted results are reported rather than synthesised in the following narrative. Study findings which have examined consumer responses to standardised packaging, are presented separately from findings which have examined industry responses to standardised packaging and the retail environment. The overall critical appraisal ratings for individual studies' methodological soundness are also reported in the main findings. In our synthesis (Section 4), we label each study by the first author's surname, year of publication, and a distinguishing letter where required (e.g. Moodie 2020[17]).

3.6 On-going research on standardised packaging in the UK

We contacted authors of past tobacco packaging research in the UK to ask about involvement with, or awareness of, research assessing standardised packaging in the UK. Some studies that are not included in this review were identified; this is not intended to be an exhaustive list:

- The ‘Youth Tobacco and E-cigarette Survey’, conducted in England and Scotland in 2017 (July-August) and 2018 (August-September). Study contact: David Hammond, University of Waterloo.
- A focus group study, as part of the ‘Youth Tobacco Policy Survey’ (YTPS), with 11-16 year olds in Scotland, England and Wales between June and July 2018. Study contact: Anne Marie Mackintosh, University of Stirling.
- A qualitative study with 13-18 year olds from youth organisations in Scotland and England between March and December 2018, as part of the ‘Young people’s perceptions and experiences of standardised tobacco packaging and e-cigarettes’ study. Study contact: Amanda Amos, University of Edinburgh.

An additional study has been published since our final search:

- ‘Introduction of standardised packaging and availability of illicit cigarettes: a difference-in-difference analysis of European Union survey data 2015-2018’ in *Thorax* by Dr Anthony Laverty (lead author), Imperial College, London.[18]

4 Main Findings

Findings are presented in three sections. Section 4.1 presents an overview of the search results and the studies included in the review. Section 4.2 presents findings from studies which have examined consumer responses to standardised packaging, and section 4.3 presents findings from studies which have examined tobacco company responses and changes in the retail environment.

4.1 Overview of included studies

The searches produced 603 unique records to be screened against our criteria (see flowchart in Appendix 4), with 44 of these assessed as full-text articles. 32 articles were excluded as not meeting all our criteria, with 12 articles reporting on 13 studies included for narrative synthesis. One included article[19] also reported findings for a qualitative study[20] included in the previous review,[11] however the article provided no additional findings to those synthesised previously.

Characteristics of included studies are shown in Appendix 5. Four studies took place in Scotland,[20-23] one in England (and six other European countries),[24] two in Britain,[25] and six across the UK[17,26-29] (one of these studies was also conducted in the US, Canada and Australia).[30] The earliest data were collected from March 2011,[25] and the latest from June 2019;[17] all studies had to include data from after May 2016, the start of the twelve-month transition period for standardised packaging. One of the studies was published as a letter to a journal,[17] two were in a multi-chapter report[19,23] (one study[23] was in the report and a journal article) and the rest were full journal articles, many with online supplementary files. Seven studies were funded by Cancer Research UK,[25-27] with three of these part funded by the British Heart Foundation.[17,28,29] Two studies were funded by the National Institute for Health Research (NIHR) Public Health Research Programme,[19,23] two by the University of Stirling,[21,22] and one the Australian Government Research Training Program Scholarship and College of Medicine and Dentistry, James Cook University (Australia).[30] One study was funded from various sources (European Union Horizon 2020, University of Waterloo, Canadian Institutes of Health Research, Ontario Institute for Cancer Research, Government of Catalonia, Instituto Carlos III, European Regional Development Fund, Government of Spain, US National Cancer Institute, Canadian Institutes of Health Research and German Federal Ministry of Health).[24]

The authors of all but two studies declared no conflicts of interest. In the Aleyan[24] study it was reported that one author served as an expert witness on behalf of governments in litigation involving the tobacco industry, another received grants and personal fees from the Polish League Against Cancer, and a different author was a senior researcher for NIHR. In the Hiscock[29] study, it was declared that one of the authors had shares in the tobacco industry interests, but that these were for health purposes.

Nine studies involved consumers and four explored tobacco companies' response to standardised packaging and changes in the retail environment. Of the nine consumer studies, three were longitudinal surveys,[17,24,25] four cross-sectional surveys,[19,22,25] one of which allowed free text,[30] and two focus group studies.[21,23] Four studies were with young people (12-17 years),[19,21-23] one with those aged 16 and over,[17] and four with adults (18+ years),[24,30] although two of these were with household panels and the age of those using tobacco within the households is not reported.[25] Sample sizes ranged from n=41[21] to n=82[23] in the qualitative studies, and from n=155[30] to n=19,271[24] in the quantitative studies.

Four consumer studies were conducted with smokers only,[24,25,30] one with smokers and ex-smokers,[17] and four with samples with mixed smoking status.[19,21-23] Of the four studies exploring tobacco company responses and changes in the retail environment, three studies used price and sales data from a commercial source (Nielsen data from over 75,000 stores).[27-29] One study used pack purchases, tobacco adverts in the retail press, and a review of the commercial literature (trade press, market analyst and tobacco company publications).[26]

Six consumer studies asked about, or only exposed participants to, standardised cigarette packs,[19,21-24,30,] with seven exploring responses to standardised cigarette and roll-your-own (RYO) packs.[17,25-29] The results of the independent appraisals of the methodological soundness of the included studies by the EPPI-Centre are shown in Appendix 6. Of the 13 included studies, 11 clearly stated their aims [***we are awaiting appraisals for two studies[17,24] and therefore these appraisals are not given when referring to each study or within the relevant sections on consumer response***]. The appraisers had 'no concerns' about the soundness of one study[28] plus one component each of a second[25] and third study;[26] 'some minor concerns' about the soundness of six studies[19,21-23,27,29] plus one component of another study;[26] and 'major concerns' about the soundness of one study.[30]

4.2 Consumer responses to standardised packaging

This section presents evidence from studies which examined consumer response to standardised packaging. Nine studies were identified, two conducted late in the twelve-month transition period (the last six months),[19,23] four after cigarettes and RYO were required to be sold in standardised packs,[21,22,25,30] and three before or during the transition period and post-standardised packaging.[17,24,25] Two studies employed focus groups,[21,23] four cross-sectional surveys,[19,22,25,30] and three longitudinal surveys.[17,24,25] Findings are reported under three headings: socio-cognitive and indirect behavioural outcomes (4.1.1), anticipated changes and purchasing behaviour (4.1.2), and other outcomes (4.1.3).

4.2.1 Socio-cognitive and indirect behavioural outcomes

Five studies reported on socio-cognitive and indirect behavioural outcomes.[21-24,30] The outcomes examined were attention to health warnings, and perceptions of harm and appeal. In the appraisal of the methodological soundness of the studies, three studies raised some minor concerns and one study raised major concerns.

Drovandi[30] conducted an online cross-sectional survey (with a free text item) with 155 smokers aged 19 to 74 years (mean 43 years) in the UK, as well as 532 adult smokers in the US, Canada and Australia. The survey was conducted in June 2018, approximately one year after standardised packaging in the UK became mandatory. The aim was to investigate the perceived effectiveness of warnings currently displayed on cigarette packs and the potential effectiveness of warnings on cigarette sticks across the four countries. The study was appraised as raising some major methodological concerns relating to the sample, unclear reporting, conflation between outcome variables and the appropriateness of inferences drawn.

Aleyan[24] conducted longitudinal surveys with smokers in England and six other European countries (Germany, Greece, Hungary, Poland, Romania and Spain). The surveys were conducted in England with 9,547 adult smokers (18 and over) at Wave 1 (July-September 2016, the first six months of the transition period) and 9,724 adult smokers at Wave 2 (February-July 2018, 9-14 months post-standardised packaging). The study examined the impact of standardised packaging on warning salience, relative harms of different brands, and perceptions of pack and brand appeal.

Mitchell[22] conducted a cross-sectional survey (with identical online or paper versions) with 507 never smokers aged 12-17 year olds in secondary schools in three regions of Scotland. Three-quarters (76%) of participants were categorised as high socio-economic status. The study was conducted between November 2017 and November 2018. The aim was to explore adolescent never-smokers' reactions to standardised cigarette packaging, whether permitted variations in pack structure (e.g. slim packs or bevelled-edged packs) influenced reactions to standardised packs, and what association if any there was between pack reactions and susceptibility to smoking. Some minor concerns were raised for the methodological soundness of Mitchell,[22] about the purposive sample, that teachers maybe be primed and that potential clustering in schools was not accounted for.

Mitchell[21] conducted eight focus groups with 41 pupils aged 16-17 from four secondary schools in Scotland from November 2017 and November 2018, with between four and six participants per group. There were four female groups (two ever smokers, two never smokers) and four male groups (one ever smokers, three never smokers). The aim of the study was to explore awareness of standardised packaging, how it was perceived, reactions to different standardised pack structures (e.g. a slim pack and shoulder box), and perceptions of brand variant name. In the appraisal of the methodological soundness of the studies, some minor concerns were raised for Mitchell[21] about the recruitment and lack of reporting on the role of the researcher in the groups.

MacGregor[23] conducted 16 focus groups with 82 pupils aged 13-16 in four secondary schools in Scotland (two in large urban areas and two in small towns) from February to March 2017, with between three and eight participants per group. Groups were segmented by gender and age (13-14, 15-16). Of the 82 participants, 28 were current smokers, 16 had tried smoking, and 38 were never smokers. The aim of the study was to explore awareness of, and exposure to, standardised packs, perceptions of these packs as to their appeal and potential impact on attitudes to smoking and smoking behaviour. Some minor concerns were raised for the methodological soundness of MacGregor,[23] regarding the appropriateness of using qualitative research for some outcomes, and the conclusions the authors drew from the results.

(i) Attention to health warnings

Improving attention to warnings on packs, a prerequisite for effectiveness, is one of the key objectives of standardised packaging. Warnings on standardised packs were new, larger than on fully-branded packs, started from the top of the pack (rather than the bottom), displayed pictorial images on both the front and back of the pack (rather than just the pack reverse), and had images that were rotated annually. For the four studies which examined warning salience,[21,22,24,30] participants were asked about warnings using no visual prompts, or they were shown images of, or actual, standardised packs.

In the Drovandi[30] survey, participants from the UK, as well as from the US, Canada and Australia, were shown two examples of warnings from their respective countries and asked about the effectiveness (on a 5-point Likert scale) of these warnings in prompting them to quit. Open-text comment boxes allowed additional views on perceived strengths and limitations of the warnings. The UK had the highest mean score, of the four countries, for effectiveness of warnings (UK 2.98, Canada 2.87, Australia 2.54, USA 2.07). Over a third (36.1%) of UK participants considered current warnings 'not at all' (1) or 'minimally' effective (2) in prompting smokers to quit (72.3% in the US, 51.0% in Australia, 35.1% in Canada). Illustrative comments from participants from most countries were generally negative on the effectiveness of the warnings. Only a single comment from a participant in the UK was given: "*Worst case scenario portrayed on packs, minimal effect on quitting"* (Male, 63, UK).

In the Aleyan[24] longitudinal survey, at each of the two waves participants were asked what they noticed first when they looked at cigarette packs, the warnings or the branding. There was a 27.6% increase from Wave 1 (W1) (early transition period) to Wave 2 (W2) (post-standardised packaging) in the percentage of participants from England reporting that they usually notice warnings first (from 18.3% to 45.9%, $p<.001$). There was also an increase from W1 to W2 in the percentage of participants from Poland (13.9% higher), Romania (15.3% higher) and Hungary (17.0% higher) in noticing warnings first, but the change between waves was significantly greater in England than in each of the six countries ($p<.05$).

In Mitchell's[21] focus groups with school pupils aged 16-17, prior to seeing any pack stimuli the warnings were consistently one of the first things recalled about cigarette packs. Participants often mentioned the warnings and recalled seeing certain images, including how smoking damages the lungs, heart, and other people, including young children and babies. When subsequently shown a set of five standardised packs, the warnings were considered clear, noticeable and believable, although within one female ever-smoker group it was felt that they exaggerated the associated harms. Most participants, irrespective of smoking status, felt that

the warnings reduced the appeal of smoking and agreed that they would put them off smoking. While participants most frequently commented on the pictorial warnings on the front and back of packs, there was mention of the text warnings on the side of the slim standardised pack being smaller.

MacGregor's[23] focus groups, with 13-16 year old school pupils, explored the warnings on standardised packs. Participants unprompted awareness of warnings ranged from general descriptions, such as a "*wee picture of, like, lungs*", to more detailed descriptions of the different images. There was a perception that standardised packaging disrupted brand image by focusing attention on the drab colour and what were considered more prominent warnings. Most negative views expressed related to the warnings, with images described as "*disgusting*", "*minging*", "*nasty*" and "*horrible*". The images on two of the four standardised packs shown (the tracheotomy, coughing up blood) provoked the most negative reactions, with most groups agreeing that these were "*the most horrible ones*". The pack featuring the tracheotomy triggered the most extreme, often visceral aversive responses, with some participants refusing to look at the image or moving the pack out of sight. Some felt that the images were so shocking that younger children should be protected from them. Participants generally accepted these two warnings as being real, although some had to explain to others that the hole in the throat was due to cancer. However, two groups where all participants were smokers, questioned the authenticity of these images. The images on the other two packs (body in body bag, man intubated in hospital) provoked more muted or in some cases no comments, which appeared to reflect the view that these images were less gruesome and not necessarily associated with smoking. They were not considered memorable, and thought to be less likely to affect young people.

(ii) Perceptions of harm

Encouraging more accurate perceptions of the harms of smoking is another key objective of standardised packaging. For the four studies which examined harm,[21-24] participants were asked about harm using no visual prompts, or they were shown images of, or actual, standardised packs.

In the Aleyan[24] longitudinal survey, at each of the two waves participants were asked whether their usual or current brand might be a little less harmful, no different, or a little more harmful, compared to other cigarette brands, and additionally if their brand was harsher or smoother on their throat compared to other brands. There was no significant change in England from W1 (transition period) to W2 (post-standardised packaging) in reporting that one's own brand was no different in harmfulness compared to other brands (78.1% W1, 78.6% W2) or that one's own brand was no different in being smoother or harsher compared to other brands (30.4% W1, 32.6% W2). In terms of the other six countries, the only country with a significant change from W1 to W2 in the percentage reporting one's own brand was no different in harmfulness compared to other brands was Romania, where there was a decrease of 6.9%. The finding in England was significantly different than in Romania (AOR=1.42), but not significantly different than in each of the other five countries. The only countries with a significant change from W1 to W2 in the percentage reporting that their own brand was harsher on the throat compared to other brands were Romania (a decrease of 7.2%) and Spain (an increase of 17.2%). The finding in England was significantly different than in Romania (AOR=1.48), Poland (AOR=1.46) and Spain (AOR=0.53) but not significantly different than the changes in the other three countries.

In Mitchell's[22] cross-sectional survey of never smokers, participants were shown four images of standardised packs (a straight-edged pack, bevelled-edged pack, slim pack and shoulder box) and asked how harmful to your health, if at all, do you think that the cigarettes in each pack would be. Reactions to the four packs were consistently towards the negative end of each scale (i.e. harmful), with no significant differences in ratings between the four packs. Sub-group analysis, controlling for demographics and family and peer smoking, showed no association between harm ratings and smoking susceptibility.

In Mitchell's[21] focus groups with 16-17 year old school pupils, the colour of standardised packs was thought, by some, to reflect the harm caused by smoking. It was suggested that the cigarettes inside the slim standardised pack might be less harmful, due to the thinness of the pack. In MacGregor's[23] focus groups, with 13-16 year old school pupils, it was suggested that the removal of "*clean*" and "*fresh*" colours may indicate a change in perceived harmfulness of certain brands, even if this was not stated explicitly.

(iii) Appeal

Reducing the appeal of the packaging and smoking is another key objective of standardised packaging. For the four studies which examined appeal,[21-24] participants were asked about appeal or different facets of appeal (e.g. quality, prestige, coolness, popularity) with no visual prompts shown, or they were shown images of, or actual, standardised packs.

In the Aleyan[24] longitudinal survey, at each of the two waves participants were asked the extent to which they like the look of their cigarette pack, the quality of their cigarettes, and how much brands differ in terms of how prestigious they are. In England, there was a 41.0% increase from W1 (transition period) to W2 (post-standardised packaging) in the percentage who did 'not at all' like the look of their cigarette pack (from 13.9% to 54.9%, p<.001). There was also an increase from W1 to W2 in the percentage of participants from Germany (4.7% higher), Hungary (9.6% higher) and Poland (14.2% higher) who did 'not at all' like the look of their cigarette packs, but the change between waves was significantly greater in England than in each of the six countries (p<.05). Among participants from England, there was an increase of 4.1% in reporting that the quality of their cigarettes was high/very high from W1 to W2 (from 34.8% to 38.9%, p=.013). There was a decrease of 3.2% in reporting how much brands differed in how prestigious they are among participants from England (from 87.1% to 83.9%, p=.01). The changes observed between W1 and W2 for cigarette quality and prestige in England were not significantly different from changes in the other six countries.

In Mitchell's[22] cross-sectional survey of never smokers, participants were shown four images of standardised packs (a straight-edged pack, bevelled-edged pack, slim pack and shoulder box) and asked to rate each pack on attractiveness (Unattractive/Attractive), coolness (Cool/Uncool) and price (Cheap/Expensive), and to rate the type of person that would smoke each pack on fashion (Unfashionable/Fashionable), popularity (Unpopular/Popular) and interest (Interesting/Boring). The four packs, and users of these packs, were consistently rated negatively (i.e. unattractive, uncool, cheap, unfashionable, unpopular and boring). The shoulder box was rated as significantly less unattractive (p<.001) and less cheap (p<.001) than the regular (straight-edged) pack, with smokers of the shoulder box considered less unfashionable (p<.001) and less unpopular (p=.006). There were no significant differences in reactions between the regular pack and the slim pack or the bevelled-edged pack. Comparing appeal ratings among the three standardised packs with different structures, the shoulder box was rated as significantly less unattractive (p<.001) and less cheap (p<.001) than the slim pack and the bevelled-edged pack. The slim pack was rated as significantly less cheap (p<.001) than the bevelled-edged pack. Participants indicated that the smoker of a shoulder box would be significantly less unfashionable (p<.001), less boring (p=.004) and less unpopular (p<.001) than the smoker of a slim pack. They also thought that a person who smoked the shoulder box would be significantly less unfashionable (p<.001) than a bevelled-edged pack smoker. Sub-group analysis, controlling for demographics and family and peer smoking, found no association between appeal ratings for any of the packs and smoking susceptibility.

Mitchell's[21] focus groups with 16-17 year old school pupils explored appeal of regular (straight-edged) standardised packs, standardised packs that differed structurally from the regular pack, and also brand variant names. When shown a set of five regular standardised packs, which participants were permitted to handle and examine, the consensus was that they all looked the same (although this may have been influenced by the fact that all packs contained the same warning on the front of the pack), being unappealing, disgusting, and off-putting. Some participants mentioned the lack of branding on the packs, which made them less

noticeable, with the colour described as dirty, dull, or boring. Several, mostly female, participants suggested that they would feel embarrassed having one of the standardised packs or that they would not use them. Several males suggested that they would feel uncomfortable about using these packs. The packs were viewed negatively in all groups. When shown, and allowed to handle, a second set of four standardised packs (a bevelled-edged pack, rounded-edged pack, slim pack and shoulder box) that had a different structure to the regular straight-edged pack, they were generally considered more appealing. Participants often described the shoulder box as weird, cool, or different. It was generally viewed positively, being considered more expensive due to the opening style, with some participants suggesting that it might encourage purchase. The slim pack was also viewed positively, with several, mostly female, participants considering it the most attractive pack. Some were curious about the cigarettes inside and opened the slim pack. Among those that did, ever-smokers and males were more likely to suggest that they looked nicer, compared them to confectionary cigarettes, or suggested that they would make them feel better about smoking. Several male ever-smokers and never smokers also noted that the slim pack would be easier to hide. Few participants noticed the bevelled or rounded-edged packs. However, after being prompted, some suggested that these packs were more attractive or felt better to hold than a straight-edged pack, in particular males and female ever smokers. Some female ever smokers suggested that the Marlboro pack with rounded edges was "*chic*" and a "*fashion statement*" because of the novelty. Several male never smokers said that because the second set of packs differed in structure there was more of a choice than if they were all identical, and that these structural features provided a way to create appeal.

Participants' responses to brand variant names were also gauged, with some considering the brand and variant names on the standardised packs they were shown appealing, particularly Embassy Number 1 Red, Lambert and Butler Crushball, JPS Legendary Black and Mayfair Sky Blue. Favoured brand names were considered "*classy*" and "*cool*", particularly by males. Females were less likely to notice brand variant name, or think that there were any differences. Several participants noted that the brand and variant name was the only thing left on the pack to create appeal, while others commented that variant names with colours might be an attempt to remind people of the colours that were previously used on fully-branded packs.[21]

In MacGregor's[23] focus groups, with 13-16 year old school pupils, when presented with four standardised cigarette packs, participants' reactions echoed earlier unprompted comments, with the packs described as "*really ugly*". This was attributed, in part, to the drab, "*dark*", "*manky*" (*dirty and unpleasant*) colour. For some participants the removal of key elements of branding resulted in packs that "*all look similar*", thereby greatly reducing the ability of the pack to act as a brand heuristic. These changes were perceived to have reduced pack appeal and the attractive "*cool*" brand image. Participants struggled to identify the brands of the packs shown, with those less familiar with standardised packs asking the facilitator or other participants how you could tell what the brand was. It was felt that the brand had been reduced to "*a name*", stripped of its distinctiveness. That three of the four standardised packs shown were the same brand (Chesterfield) may have influenced responses however. In comparison, the fully-branded packs that were previously on sale in the UK were considered "*nicer*" and they "*knew what they were*". Others talked about how pack design and colour had been used not only to identify brands and brand variants but to convey positive brand imagery and attributes about the product, such as "*what it is like*" and its "*coolness*", which users could draw on to "*look sort of different*" and achieve a positive and sought-after smoker identity. The removal of attractive pack colours and the inclusion of new warnings meant that packs were not something that they would want to be seen with, or be proud of. As a result, the ability of a brand to promote or project a specific image or "*smoker identity*" was considerably reduced. Only one group viewed the colour change positively, although this was specifically in relation to Golden Virginia rolling tobacco, as they thought the traditional brand yellow and green colours projected a negative brand and user image.

4.2.2 Anticipated changes and behavioural outcomes

Five studies reported on anticipated changes and behavioural outcomes.[21-23,25] The outcomes examined were anticipated response and purchasing behaviour. In the appraisal of the methodological soundness of the studies, three studies raised some minor concerns and one study raised no concerns.

MacGregor[23] conducted 16 focus groups with 82 pupils aged 13-16 in four secondary schools in Scotland (two in large urban areas and two in small towns) from February to March 2017, with between three and eight participants per group. Groups were segmented by gender and age (13-14, 15-16). Of the 82 participants, 28 were current smokers, 16 had tried smoking, and 38 were never smokers. The aim of the study was to explore awareness of, and exposure to, standardised packs, perceptions of these packs as to their appeal and potential impact on attitudes to smoking and smoking behaviour. Some minor concerns were raised for the methodological soundness of MacGregor[23], regarding the appropriateness of using qualitative research for some outcomes, and the conclusions the authors drew from the results.

Mitchell[21] conducted eight focus groups with 41 pupils aged 16-17 from four secondary schools in Scotland from November 2017 and November 2018, with between four and six participants per group. There were four female (two ever smokers, two never smokers) and four male groups (one ever smoker, three never smokers). The aim of the study was to explore awareness of standardised packaging, how it was perceived, reactions to different standardised pack structures (e.g. a slim pack and shoulder box), and perceptions of brand variant name. In the appraisal of the methodological soundness of the studies, some minor concerns were raised for Mitchell[21] about the recruitment and lack of reporting on the role of the researcher in the groups.

Mitchell[22] conducted a cross-sectional survey (with identical online or paper versions) with 507 never smokers aged 12-17 year olds in secondary schools in three regions of Scotland. Three-quarters (76%) of participants were categorised as high socio-economic status. The study was conducted between November 2017 and November 2018. The aim was to explore adolescent never smokers' reactions to standardised cigarette packaging, whether permitted variations in pack structure (e.g. slim packs or bevelled-edged packs) influenced reactions to standardised packs, and what association if any there was between pack reactions and susceptibility to smoking. Some minor concerns were raised for the methodological soundness of Mitchell,[22] about the purposive sample, that teachers maybe be primed and that potential clustering in schools was not accounted for.

Breton[25] used a longitudinal survey, with data from 11,695 households where cigarettes, RYO, cigars or cigarillos, pipe tobacco, e-cigarettes or nicotine replacement therapy (NRT) had been purchased, from March 2011 to December 2017. Households starting the panel as purchasers of only e-cigarettes, NRT, cigars, pipe tobacco, or dual cigarette/RYO users were excluded from the analysis. The data was from Kantar Worldpanel, a longitudinal panel of approximately 30,000 households recruited using stratified sampling to represent Britain by region, household size, age of main shopper and socioeconomic status. Between March 2011 and December 2017, the number of households averaged 1741 (range 1332 to 2186). After a peak in May 2012, each month an average of 88 households joined the panel and 125 households stopped purchasing tobacco/nicotine products or left the panel. The aim was to explore the effect of standardised packaging and minimum pack sizes on switching behaviour, comparing trends in household tobacco and non-tobacco nicotine product purchases before, during and after the introduction of standardised packaging, and estimating changes in the likelihood of switching to a different tobacco product, non-nicotine tobacco product and to different price segments. There were no concerns about the methodological soundness of Breton.[25]

Breton[25] used a cross-sectional survey with 1061 participants from Kantar Worldpanel, a longitudinal panel of approximately 30,000 households recruited using stratified sampling to represent Britain by region, household size, age of main shopper and socioeconomic status. Participants were those identified as having purchased tobacco products between four weeks and six months before the survey. Data were collected from March to May 2018. The aim was

to explore consumer choices after changes in product availability associated with standardised packaging.

(i) Anticipated changes

Three studies examined anticipated changes to standardised packaging.[21-23] In MacGregor's[23] focus groups, views diverged about the likely behavioural impact of plain packaging. The most commonly expressed view was that the packs would affect never or occasional smokers, but that established smokers, including some of the participants, would continue to smoke. Reasons offered for this were that the health effects of smoking were widely known, changing the pack would not discourage addicted smokers, and smokers could ignore packs or hide them inside a pocket or bag. Never or occasional smokers were thought to be more susceptible to the negative imagery, warnings and unattractive appearance, and therefore less likely to want to try smoking or become an established smoker. However, several participants suggested that as tobacco products in shops are not openly displayed, this could dilute the impact of standardised packaging as they would only be visible post-purchase.

In Mitchell's[21] focus groups with 16-17 year old school pupils, participants, particularly never-smokers, viewed standardised packs off-putting, primarily because of the warnings. The slimmer standardised pack and shoulder box, and to a lesser extent the bevelled-edged and rounded-edged packs, were considered less of a deterrent. Several participants suggested that the packs would be off-putting for people thinking about taking up smoking, in particular young people, but not for established, addicted smokers. Some males said they would engage in avoidant behaviours by hiding or concealing packs.

In Mitchell's[22] cross-sectional survey with never smokers, participants were shown four images of standardised packs (a regular straight-edged pack, bevelled-edged pack, slim pack and shoulder box) and asked the extent to which each pack would put them off smoking and which, if any, they would select. All packs were considered off-putting. However, compared to those who were not susceptible to smoking, those who were susceptible were significantly more likely to think that the packs would not put them off smoking (regular pack AOR=3.22, p=.006; bevelled-edged pack AOR=3.22, p=.006; slim pack AOR=3.69, p=.002; shoulder box AOR=2.73, p=.015), although only a relatively low number of participants (n=33 to 55) did not consider the packs off-putting. The vast majority (87%) indicated they would select none of the packs. Of those who selected a pack, most selected the shoulder box (55%), bevelled-edged pack (19%), slim pack (15%) and regular pack (11%). Those susceptible to smoking were significantly more likely than those not susceptible to select a pack (25% vs 7%), $\chi 2(1)=29.70$, $p<.001$. There were no significant differences by gender, socioeconomic status, age or ethnicity as to whether participants selected one of the four packs or none of them.

(ii) Purchasing behaviour

Breton's[25] cross-sectional survey explored purchasing behaviour, including pack size, price, product choice, and product switching. In May 2016 one-sixth (17%) of household purchases of cigarettes were in 20 packs, increasing slowly until January 2017 and then rapidly to 93% by May 2017, when 20 packs became the minimum pack size. In May 2016, approximately 70% of household purchases of roll-your-own (RYO) tobacco were in packs containing 30 grams or more, increasing slowly until January 2017, reaching 99% by May 2017, when 30 grams (g) became the minimum pack weight. The percentage of household purchases of 10 packs was relatively constant at around 13% between March 2011 and September 2016, after which purchasing fell rapidly to zero by August 2017. While there was a steep increase in the proportion of 11-19 packs purchased after April 2014, with this pack size accounting for an average of 68% of all purchases until January 2017, this decreased rapidly to around 2% by June 2017 and below 1% by December 2017. Purchases of packs with more than 20 cigarettes was negligible throughout.

Throughout the study the real price paid by pack size was highest for 10 packs and lowest for 11-19 packs. From March 2017, the price of cigarettes in 20 packs decreased significantly and became closer to those in 11-19 packs. Household purchases of cigarettes in the cheapest

quartiles (Q1 and Q2) increased throughout the study while those in the most expensive quartiles (Q3 and Q4) decreased, although from early 2014 to early 2017, when 11-19 packs accounted for most sales, the proportion of sales in Q3 and Q4 increased while those in Q2 decreased. Differences in average real price paid for cigarettes in each price quartile remained relatively constant until May 2017, when the cheapest prices (Q1 and Q2) converged and Q4 prices increased substantially. For RYO, the proportion of small pack purchases (<12.5g) and packs containing 12.5-29g was relatively stable until June 2016, when pouches containing 30g appeared on the market. Real prices per gram were similar across all pack sizes through most of the study, before lower (likely discounted) prices for the smallest packs immediately before their withdrawal in 2017. Household purchase of RYO in Q1 (lowest priced) decreased until February 2017 and then increased. Purchases in Q2 and Q3 increased throughout the study. The gap between the most expensive (Q3 and Q4) and cheapest quartiles (Q1 and Q2) increased over time.

For households starting as cigarette-only purchasers, the largest increase was observed in the likelihood of purchasing cigarettes from Q2, which increased in the last six months of the transition period (OR=2.03, 95% CI 1.73-2.38) and doubled after the end of the transition period (OR=2.16, 95% CI 1.98-2.37, p<.001), while the likelihood of purchasing the most expensive cigarettes (Q3 and Q4) decreased significantly. For households starting as RYO-only purchasers, the highest increase was observed for the cheapest products (Q1) in the last six months of the transition period (OR=2.25, 95% CI 1.86-2.72, p<.001) and after the end of the transition period (OR=4.00, 95% CI 3.30-4.84, p<.001), and for products in Q3, mainly in the last six months of the transition period (OR=1.71, 95% CI 1.53-1.92, p<.001) and after the end of the transition period (OR=1.61; 95% CI 1.42-1.82, p<.001). Purchase of the most expensive products (Q4) significantly decreased after the transition period (OR=0.60; 95% CI 0.52-0.69, p<.001).

From March 2011 to December 2017, the number of households purchasing only cigarettes fell from 875 to 459, as the number of households purchasing only RYO increased from 396 to 512. The number of households purchasing e-cigarettes went from zero in March 2013 to 149 in December 2017. Among households starting as cigarette-only, or RYO-only purchasers, most remained with this initial product. For households starting as cigarette-only purchasers, the odds of switching to a non-tobacco nicotine product increased significantly (p=.005) during the first six months of the transition period (OR=1.74, 95% CI 1.18-2.57) but not thereafter. The likelihood of switching out of the dataset increased during the last six months of the transition period (OR=1.30, 95% CI 0.08-1.58, p=.007) and doubled after May 2017 (OR=2.44, 95% CI 2.05-2.89, p<.001). For households starting as RYO-only purchasers, switching to other tobacco products became significantly (p=.044) less likely after the end of the transition period (OR=0.64, 95% CI 0.41-0.99). The likelihood of switching out of the dataset almost doubled after the end of the transition period (OR=1.96, 95% CI 1.64-2.36, p<.001). Overall, there was a marked increase in the number of households purchasing tobacco or non-tobacco nicotine products each month leaving the panel in the final months of the study.

In Breton's[25] cross-sectional survey, participants were asked what they would do if the product they usually purchase was not available when going to a store, and what factors determined their decision to purchase a different product or a different variant in that case. Only 350 (of the 1061) participants reported a tobacco purchase between four weeks and six months before the survey, with 127 participants reporting their most recent purchase to be an e-cigarette. Among those who made a tobacco purchase within the four weeks before the survey, 191 remained loyal to the product they used, primarily because of price and taste, with 46 reporting switching to a different tobacco brand and 29 switching to a different variant of the same brand.

(iii) Cessation behaviours

No study reported on cessation behaviour or relapse prevention.

4.2.3 Other outcomes

Three studies reported on awareness of standardised packs[19,21,23] and one study on support for standardised packs.[17] In the appraisal of the methodological soundness of the studies, three studies raised some minor concerns.[19,21,23]

Haw[19] conducted a cross-sectional survey in four secondary schools in Scotland (two in large urban areas and two in small towns) from January to March 2017 (the last six months of the transition period), with 12-17 year olds (n=3,861). The aim was to explore the impact of the ban on the open display of tobacco products at the point-of-sale in Scotland on young people's exposure to tobacco advertising, attitudes towards smoking, and smoking behaviour, and to identify any unintended consequences of the legislation. While the study was focused on point-of-sale, questions on awareness of standardised packs were included in 2017. In the appraisal of the methodological soundness of the studies, some minor concerns were raised for Haw[19] about the generalisability of the purposive sample and the representativeness of the schools.

Mitchell[21] conducted eight focus groups with 41 pupils aged 16-17 in four secondary schools in Scotland from November 2017 and November 2018, with between four and six participants per group. There were four female (two ever smokers, two never smokers) and four male groups (one ever smoker, three never smokers). The aim of the study was to explore awareness of standardised packaging, how it was perceived, reactions to the different standardised pack structures (e.g. a slim pack and shoulder box), and perceptions of brand variant name. In the appraisal of the methodological soundness of the studies, some minor concerns were raised for Mitchell[21] about the recruitment and lack of reporting on the role of the researcher in the groups.

MacGregor[23] conducted 16 focus groups with 82 pupils aged 13-16 in four secondary schools in Scotland (two in large urban areas and two in small towns) from February to March 2017, with between three and eight participants per group. Groups were segmented by gender and age (13-14, 15-16). Of the 82 participants, 28 were current smokers, 16 had tried smoking, and 38 were never smokers. The aim of the study was to explore awareness of, and exposure to, standardised packs, perceptions of these packs as to their appeal and potential impact on attitudes to smoking and smoking behaviour. Some minor concerns were raised for the methodological soundness of MacGregor[23] regarding the appropriateness of using qualitative research for some outcomes, and the conclusions the authors drew from the results.

Moodie[17] conducted a longitudinal online survey with a cohort of smokers aged 16 and older. The first wave was conducted in April-May 2016 (prior to the start of the transition period) with 6,233 smokers, the second wave in October-November 2017 (5-6 months post-standardised packaging) with 4,293 participants from the first wave completing the survey (3,629 current cigarette smokers, 607 ex-smokers, 36 used other forms of tobacco, 7 reported being a smoker but had not smoked in past 3 months, 14 who indicated 'Don't know' to smoking status), and the third wave in May-June 2019 (24-25 months post-standardised packaging), with 3,175 participants from the first wave completing the survey (2,412 current cigarette smokers, 700 ex-smokers, 44 used other forms of tobacco, 6 reported being a smoker but had not smoked in past 3 months, 13 who indicated 'Don't know' to smoking status). The study aim was to explore whether support for standardised packaging of cigarettes and rolling tobacco in the UK changed following the introduction of this policy.

(i) Awareness of, or attitudes towards, standardised packaging

Haw's[19] cross-sectional school survey asked participants whether they had seen any of the 'new greenish brown plain packs of cigarettes or tobacco' in the past 30 days, with an image of a standardised cigarette pack shown as an example, and if so where. Most participants (76.7%, n=2,812) indicated that they had not seen any of the new packs in the past 30 days. Of those who had seen a standardised pack, the most common place was on the ground or as rubbish (13.7%).

Mitchell's[21] focus groups with 16-17 year old school pupils explored awareness of standardised packaging, where participants see cigarette packs, who they see them with, and what cigarette packs look like. Most participants were generally aware of standardised packaging, with several mentioning that they are all the same colour and/or were all considered bland. There was awareness of standardised packaging in all three ever smoker groups, and two of the five never smoker groups. Participants said that they frequently saw cigarettes packs, mainly as litter or used by other people (e.g. family or friends).

In MacGregor's[23] focus groups there was a discussion about the community, local smoking behaviours and cultures, and standardised packaging. Participants' awareness, knowledge and views of standardised packaging were discussed if this was raised spontaneously during the discussion on smoking. Students in all but one of the 16 focus groups had seen, or were aware of, standardised packs. Several smokers had purchased cigarettes in standardised packs or been given cigarettes from standardised packs. For non-smokers, exposure to packs was mainly via family members or friends who smoked or seeing discarded packs as litter.

Moodie's[17] longitudinal survey explored approval of standardised packaging among smokers and ex-smokers. Approval increased at each wave for cigarette smokers and ex-smokers, from 25.4% at W1 (pre-standardised packaging) to 35.7% at W2 (5-6 months post-standardised packaging) and 39.3% at W3 (24-25 months after standardised packaging). Disapproval decreased over time from 34.6% (W1) to 31.2% (W2) to 27.5% (W3). Adjusting for smoking status, there was a statistically significant increase in the proportion of participants who agreed that tobacco companies should be/continue to be required to sell cigarettes and rolling tobacco in standardised packs over time: W1 versus W2 (OR=1.50, 95% CI 1.23-1.82) and W1 versus W3 (OR=1.71, 95% CI 1.57-1.86). Among cigarette smokers, approval for standardised packaging increased at each wave, from 25.4% (W1) to 34.0% (W2) and 35.4% (W3), and disapproval decreased at each wave, from 34.6% (W1) to 32.8% (W2) and to 30.3% (W3). Among ex-smokers, approval for standardised packaging was 44.8% at W2 and increased to 52.0% at W3, with disapproval decreasing from 23.0% (W2) to 18.1% (W3).

4.3 Tobacco companies' responses and changes in the retail environment

This section examines evidence of how tobacco companies responded to standardised packaging and changes in the retail environment. Four studies examined how tobacco companies and retailers responded to the legislation.[26-29] Findings are presented under three headings: product strategies (4.3.1), trends in pricing (4.3.2), and trends in revenues and sales (4.3.3).

4.3.1 Product strategies

One mixed methods study examined strategies used by tobacco companies to mitigate the effects of the legislation during the transition period and up to seven months afterwards.[26] Three of the four study components' methods were appraised as raising some minor concerns (pack purchases, advertisements in the retail press, and review of commercial literature), related to the sampling frame for the study's purpose. There were no concerns for the methodological soundness of the Nielsen sales data analysis.

The study components were: (i) analysis of information from monthly pack purchases (between March 2016 and May 2017, eight top-selling cigarette and RYO products) supplemented by in-store observation of price lists and multipacks 'outers'; (ii) content analysis of tobacco advertisements in the retail press (between January 2015 and December 2017, n=195 ads in three magazines aimed at the retail and wholesale trade); (iii) review of commercial literature including trade press and articles and reports by industry analysts and tobacco companies (between January 2015 and December 2017, n=396 articles from online retail publications and annual reports from the four main tobacco companies: JTI, IMT, BAT and PMI); and (iv) analysis of Nielsen electronic point of sale (EPOS) data between July 2014

and November 2017 to assess legislation compliance and changes in pack features (e.g. removal of full branding, name changes, price-marking and small pack sizes). This data covered tobacco sales from nearly 90% of UK supermarkets and a stratified sample of 15% of convenience stores. In November 2017, the sales data showed 71 brands, 97 families, 241 variants and 1022 Stock Keeping Units (SKUs).

Triangulating data from the four sources, the study identified that tobacco companies responded to the legislation with a number of strategies.

(i) Strategy 1: keep fully-branded packs on the market as long as possible
Using Nielsen sales data, the study showed that six months into the transition period, in November 2016, most cigarettes (96%) and RYO products (82%) were still being sold in fully-branded packs, with 70% of cigarette packs and 82% of RYO packs switching to standardised packs between January and April 2017. By June 2017, one month after full-implementation, 97% of cigarette packs and 98% of RYO packs were sold in standardised packs. Non-compliant pack sales were 1% for cigarettes and negligible for RYO six months after full-implementation (November 2017). The study reported that the Nielsen data, review of commercial literature and retail press ads showed that during the transition period there was an increase in small pack sizes. To encourage sales of fully-branded packs, tobacco companies offered retailers incentives and promotions (e.g. cash rewards and loyalty points, for sales of fully-branded packs). In early 2017, articles in the commercial literature referred to a price-war between tobacco companies. The study also reported that tobacco companies had offered to buy back any non-compliant stock from retailers after the transition period.

(ii) Strategy 2: maintaining brand variant differentiation through name changes
The study reported that from July 2014 to November 2017, the sales data showed name changes for 35% of cigarette and RYO variants, 42% of which were legally required. Some of these changes may have occurred before the transition period however; the data are not separated in the paper. Most of the changes (n=47/123) involved the substitution of flavour terms with other terms, most frequently a colour, while others involved the removal of the term ‘natural’ (n=5/123). Notable changes were the substitution of ‘menthol’ with ‘green’, and ‘smooth’ to ‘bright’ or ‘sky blue’ for cigarettes and to ‘yellow’ for RYO. A larger number of name changes were observed in the sales data which were not legally required (n=71/123, 58%). The study reported that colour descriptors were introduced as a substitute for the previous pack colour, for example, Marlboro which previously featured a red chevron was renamed Marlboro Red. New adjectives were also introduced, notably with a colour, to differentiate brand variants, for example, ‘real blue’, ‘bright silver’ and ‘legendary black’.

(iii) Strategy 3: focus on lower price segments
The study also found that tobacco companies focused on lower price segments after the decision to implement standardised packaging. The sales data showed that from July 2014 to November 2017, a greater number of new RYO variants were brought to market than expected (p=0.018). Compared with baseline data from July 2014 (prior to the decision to implement standardised packaging), when the UK market comprised 81% cigarette variants and 19% RYO variants, the new variants introduced were 68% cigarettes and 32% RYO. New cigarette variants were under-represented among the premium and mid-price price segments (p=0.001) compared with the market composition in July 2014. Between July 2014 and November 2017, 50% of new variants were in the cigarette value and sub-value price segments, 22% were in the cigarette premium and mid-price segments, 15% in the RYO premium and mid-price segments and 13% in the RYO value segment.

For the same time frame, and compared with July 2014, the study reported that name changes were over-represented among the value and sub-value cigarette segments with this group representing 35% of variants in July 2014 but having 45% of the name changes between July 2014 and November 2017(p=0.048). However, name changes were under-represented among premium and mid-price cigarette segments, with this group representing 50% of variants at baseline but 33% of later variant name changes (p=0.002). These analyses

demonstrate that the name changes are disproportionate to market composition by price segment. However, as the rate of new variants is not measured in the pre-implementation period, this analysis cannot rule out the possibility that lower price segments have always had greater 'turn-over 'in variant names.

Greater focus on lower price segments was also found in retail press ads between January 2015 and December 2017. Most ads (64%) advertised value or sub-value cigarette or RYO brands, while 28% advertised mid-price cigarette or RYO brands and just under a fifth (19%) advertised premium cigarette or RYO brands (ads could feature more than one price segment). The study also observed that 79% of ads in the retail press were for new variants within the value or sub-value segments, while only one ad was for a new variant within the premium segment.

The study also observed the introduction of 'premium' pack features in lower priced cigarettes, such as a new 'firm' filter and bevelled edge box for the Chesterfield brand in December 2017. Between July 2014 and November 2017, a greater number of menthol or flavoured capsule variants (n=13) were introduced to lower priced segments compared with premium and mid-price segments (n=2). For this time period, the study reported that as tobacco companies focused on lower price segments, the sales data showed an overall decline in the number of brand families and brand variants.

(iv) Strategy 4: innovating exemptions to the legislation

Using data from the pack purchase study and commercial literature, the study observed that tobacco companies exploited legislation exemptions during the transition period by utilising pack modifications (for example, reusable tins, bevelled edges and new closing mechanisms), extra sticks (packs with 23 and 24 sticks), fully-branded outers, RYO accessories and other tobacco products. The study also reported that tobacco companies focused increased attention on cigars and cigarillos, which were not subject to standardised packaging legislation and could therefore be sold in fully-branded packs or as single sticks. The study reported growth in cigars and cigarillos sales volumes (390–494 million units) and value (£292–£348 million) from 2015 to 2018 using Euromonitor's models.

4.3.2 Trends in pricing

Two studies examined trends in pricing of tobacco products before, during and after the transition period.[27,28] In the appraisal of the methodological soundness of the studies, one study raised some minor concerns and one study raised no concerns.

Breton[27] examined trends in RYO and cigarette sales volumes and prices before, during and after the transition period, at which time cigarettes had to be sold in packs containing at least 20 sticks and RYO in packs with a minimum weight of 30 grams. The study examined Nielsen sales data from over 75,000 UK stores between March 2013 and June 2018 for 5,972 RYO products and 18,062 cigarette products - the same dataset was used to examine cigarette price and sales trends between March 2013 and June 2017,[31] reported in our previous review.[11] The current study also examined RYO prices, and included a further year of data (to June 2018). The Nielsen data provided estimated average retail prices, from which price per gram (for RYO) and price per cigarette was estimated as the arithmetic mean price divided by number of grams or the number of cigarettes per pack. Time trends were reported for average retail prices and total volume of sales by pack size over the five-year study period. The association between the proportion of standardised pack sales volumes and price per gram and per cigarette was then estimated using linear regression, for the period May 2015 to May 2018. Two regression models were used: one including all products on the market, and one including only pack sizes which were legal under standardised packaging (30 grams or more for RYO, 20 sticks for cigarettes). Both models were adjusted by a 'tax period' variable, which was constructed to control for changes in tax levels over time. These changes comprised both the annual increase in tobacco duty each year and an additional one of increase in minimum

duty in November 2017, the minimum excise tax (MET). Some minor concerns were raised for the methodological soundness of Breton,[27] regarding the modelling and interpretation of results.

Hiscock[28] conducted a series of analyses to assess the impact on tobacco prices of standardised packaging, the MET, and tax changes focused on narrowing the price gap between RYO and cigarettes, all of which were implemented within a 21-month period. The MET was first implemented in May 2017 (the end of the transition period), with the rate of duty increasing in November 2017 (six months after the transition period). RYO-focused tax changes, designed to close the price gap between cigarettes and RYO, were implemented in March 2016 (two months before the start of the transition period) and in November 2017. Nielsen data, scaled up to represent all shops selling tobacco in the UK, were obtained for May 2015 to April 2018 for products sold by at least 10% of retailers. The study extended previous studies of tobacco pricing following standardised packaging by covering a longer follow up period and using analyses which included weighted prices for volume sold. They employed additive mixed models which took into account the lack of independence between monthly prices (using an autoregressive structure to remove correlation in the model residuals) and allowing estimation of non-linear time trends. They examined time trends in different tobacco industry market segments (premium, mid-price, value and subvalue (i.e. the cheapest) cigarettes, and premium, mid-price and value RYO). There were no concerns for the methodological soundness of Hiscock.[28]

(i) Price trends for RYO compared with cigarettes

Breton[27] examined trends in RYO prices, compared with cigarette prices, before, during and after the transition period, at which time cigarettes had to be sold in packs containing at least 20 sticks and RYO in packs with a minimum weight of 30 grams (g).

The time trend data found that, pre-standardised packaging, RYO prices were relatively similar for different pack sizes, whereas cigarette prices were considerably more diverse for different pack sizes. At the start of the transition period, 30g packs of RYO were cheaper per gram when introduced but increased in price towards the end of the transition period. The regression analysis found that prices rose significantly for both RYO and cigarettes from the start of the transition period. This analysis compared the average price across discrete time periods. The time periods were defined by the percentage of sales that were in standardised packs. During the period where standardised pack sales accounted for over 75% of total sales (March 2017 to June 2018), inflation adjusted prices were 12% higher for RYO and 7% higher for cigarettes compared to the period May 2015 to May 2016, when there were no standardised packs. Between these two periods RYO prices increased from 34.9 pence to 38.8 pence per gram, with a mean difference of 4.26 pence (95% CI 3.99 to 4.53 pence), and cigarette prices increased from 38.6 pence to 41.13 pence per cigarette, with a mean difference of 2.53 pence (95% CI 2.24 to 2.83 pence). The analysis does not examine the time trend as rate of increase per unit time, i.e. increase in price per gram and price per cigarette per week or month, so that these figures can be directly compared between time periods. The graphs in Figure 2 indicate that the price per gram and price per cigarette were rising long before standardised packaging and therefore the existence of secular time trends and possible non-independence of observations could have been examined and controlled for in the analysis.

The authors suggest that the initial lower prices for RYO may have been to help customers adjust to the new cost of larger (30g) packs. Prices of both RYO and cigarettes increased once standardised packaging was mandatory. While RYO prices increased more steeply than for cigarettes, RYO nevertheless remained more affordable.

(ii) Price trends for different market segments (cigarettes and RYO)

Hiscock[28] examined the impact of standardised packaging and two simultaneous tax changes on prices in different market segments (cigarettes and RYO).

In terms of the impact of standardised packaging, the study found that between May 2015 and April 2018 the overall average (mean) weighted real price per stick increased significantly, by 0.4 pence, while the prices for both cigarettes and RYO rose by 1.6 pence. Prices for premium products increased more steeply. For example, the average monthly rise in price per stick (£) in the premium cigarettes segment was 0.0019 (95% CI 0.0018 to 0.0020) pre-implementation and 0.0030 (95% CI 0.0029 to 0.0032) post-implementation. In contrast, in the value cigarettes segment the average monthly rise was 0.0003 (95%CI 0.0003 to 0.0004) pre-implementation and 0.0016 (95% CI 0.0014 to 0.0017) post-implementation. The gap between cigarettes and RYO prices were similar at the start and end of the study period. In terms of the impact of the MET, a significant increase of 1.3 pence was observed in the prices of subvalue cigarettes between March 2017 (when the MET was announced) and July 2017 (two months after the end of the transition period). Overall, pricing and price growth of the cheapest (subvalue) cigarettes became more similar to that of value cigarettes.

The study also examined whether the tobacco industry responded to the legislative changes by overshifting and undershifting. Overshifting refers to increasing prices, over and above tax increases, on more expensive products to maximise profits, while undershifting refers to absorbing tax increases on cheaper products to reduce the impact on retail prices. This approach has previously allowed the industry to continue to increase profits despite declining sales overall while keeping cheaper products available at lower prices. By calculating net tobacco industry revenues over the period, the study found little evidence of undershifting following standardised packaging, the MET and RYO tax changes, while overshifting became more extensive. The authors suggest that the combination of standardised packaging, the MET and RYO tax changes did not lead to a long-term decline in tobacco prices (with price rises observed even for the cheapest cigarettes and RYO products by April 2018) and reduced the ability of the industry to undershift on the cheapest products.

4.3.3 Trends in sales

Two studies examined trends in tobacco sales[27,29] before, during and after the transition to standardised packaging. In the appraisal of the methodological soundness of the studies, some minor concerns were raised for both studies.

Breton[27] examined Nielsen sales data between March 2013 and June 2018 for 5,972 observations on RYO and 18,062 observations on cigarettes. The Nielsen data provided data on monthly volume sales. For RYO, this was measured in grams as the sum of grams per pouch multiplied by number of pouches per pack, for each month. For cigarettes, volume of sales was estimated as number of sticks (number of cigarettes in a packet multiplied by number of packs in a multipack). Time trends were reported for average retail prices and total volume of sales by pack size over the five-year study period. The association between the proportion of standardised pack sales volumes and price per gram and price per cigarette was then estimated using linear regression, for the period May 2015 to May 2018. Two regression models were used: one including all products on the market, and one including only pack sizes which were legal under standardised packaging (30 grams or more for RYO, 20 sticks for cigarettes). Both models were adjusted by a ‘tax period’ variable, which was constructed to control for changes in tax levels over time. These changes comprised both the annual increase in tobacco duty each year and an additional one of increase in minimum duty in November 2017, the MET. Some minor concerns were raised for the methodological soundness of Breton 2019, regarding the modelling and interpretation of results.

Hiscock[29] used the same datasets as in Hiscock[28] to analyse sales data from UK stores between May 2015 and April 2018. Additive mixed modelling was used to calculate trends in volume sold overall (for cigarettes and RYO overall, and for seven different market segments) and in company net revenues. Revenues were calculated by firstly calculating price per stick (using a weight of 0.5 g per stick for RYO), then calculating net revenue per stick as the price per stick minus taxes due, then multiplying net price per stick by volume sold. The 10-month period before the start of the transition period (June 2015 to March 2016) was compared with

the 10-month period after the end of the transition period and introduction of the MET (June 2017 to March 2018). For the volume of sales data, the unit of analysis was market segment and the analysis allowed for non-linear functions of time, autocorrelation of observations and seasonality effects. In the appraisal of the methodological soundness of the studies, some minor concerns were raised for Hiscock[29] regarding the concluded inferences from the analyses and results.

(i) Trends in RYO tobacco sales compared with factory made cigarette sales

Breton[27] examined monthly sales data between March 2013 and June 2018 for 5,972 RYO and 18,062 cigarette products. Time trend data found that monthly total volume of RYO sales increased (from 497.1 to 561.8 tons between March 2013 and June 2018), with an estimated monthly linear increase of 0.16%. In contrast, monthly total volume sales of cigarettes declined steadily over the same period, with an estimated monthly linear decrease of 0.32%. The authors suggested that the observed rise in RYO sales reflected the trend of price-conscious smokers downtrading to cheaper products in response to price rises.

(ii) Trends in RYO and factory-made cigarette sales in different market segments

Hiscock[29] analysed sales data from UK stores between May 2015 and April 2018 to calculate trends in volume sold overall (for cigarettes and RYO overall, and for seven different market segments) and in company net revenues.

The analyses showed that sales volumes overall fell from 3.29 billion sticks (95% CI 3.24 billion to 3.33 billion) in May 2015 to 3.16 billion (95% CI 3.11 billion to 3.20 billion) in April 2018. The rate of decline was on average 0.21% per month pre-implementation and 0.42% post-implementation. However, while the sales of cigarettes fell from 2.33 billion (95% CI 2.30 billion to 2.36 billion) to 2.04 billion (95% CI 2.01 billion to 2.07 billion) RYO sales grew from 0.95 billion (95% CI 0.93 billion to 0.98 billion) to 1.12 billion (95% CI 1.09 billion to 1.15 billion). The decline in FM volume was approximately 0.49% per month pre-implementation and 1.00% per month post-implementation. For RYO, volume was increasing at approximately 0.47% per month pre-implementation and 0.40% post implementation. Average monthly change in stick sales was compared for the period prior to implementation of standardised packaging and the MET with the period post full implementation. Overall, stick sales reduced each month, with the rate of decline doubling post-implementation. The average monthly decline was an extra 6.4 million (95% CI 0.1 million to 12.7 million) sticks post-implementation compared with pre-implementation. Sales of cigarettes declined significantly faster post-implementation, while RYO sales rose in both periods, with no significant change in the rate of growth.

Monthly sales volumes fell significantly throughout the study period for premium, mid-price, and value cigarettes. However, sales of subvalue cigarettes increased significantly from 409 million (95% CI 391 million to 427 million) to 780 million (95% CI 767 million to 793 million) in July 2017, but did not significantly increase afterwards. Sales of RYO premium and mid-price products did not change significantly over the study period, but RYO value sales increased significantly from 174 million (95% CI 16 1 million to 186 million) to 355 million (95% CI 343 million to 368 million). Tobacco industry monthly net revenues declined steadily from the start of the transition period by an estimated 13% (£31 million).

Overall, the findings suggest that the simultaneous implementation of standardised packaging and the MET steepened the pre-existing decline in tobacco sales and cigarette sales but produced no change in RYO sales. Sales of the cheapest (subvalue) cigarettes increased until the end of the transition period for standardised packaging and implementation of the MET, after which they stopped growing.

5 Contribution to PHPRU themes

5.1 Smoking

The UK is in the vanguard of tobacco control, with a series of tobacco control policies having been introduced this century. Smoking prevalence among adults is lower than at any point in the last 50 years and smoking prevalence among children is the lowest since records began. Nevertheless, smoking remains a leading cause of premature mortality and morbidity across the UK. This project is a continuation of the Public Health Research Consortium work on smoking, particularly the previous systematic reviews assessing standardised packaging.[7,8,11] This project supplements a previous systematic review,[11] which examined consumer, tobacco company and retailer response to standardised packaging in the UK after it was implemented. The cut-off date for this previous review was February 15th 2019. In this review we consider all new published research exploring consumer, tobacco company and retailer response to standardised packaging in the UK until September 28th 2020.

5.2 Incentives and regulation

With a growing number of countries implementing, or planning to implement, standardised packaging,[32] there is significant global interest in the actual impacts of this policy, particularly as research outside of Australia, the first country to introduce standardised packaging, is limited. The review provides evidence on consumer, tobacco company and retailer response to standardised packaging, helping to provide a more complete picture of not only how consumers have responded but also how tobacco companies have adapted their marketing strategy.

5.3 Health inequalities

Tobacco continues to be a leading contributory factor to overall health inequalities in the UK and across Europe.[33,34] Smoking rates remain considerably higher among more deprived populations.[1] Standardised packaging has the potential to affect this socio-economic patterning and to narrow or widen health inequalities. Where evidence exists on socio-economic and other differences in consumer responses to standardised packaging, this is synthesised in the review.

5.4 Translation to policy

Section 21 of the Standardised Packaging of Tobacco Products Regulations requires the Secretary of State to publish a report within five years of the regulations coming into force to assess the extent to which the objectives of standardised packaging are being met and whether those objectives remain appropriate.[35] The findings will inform this Post-Implementation Review.

6 Discussion

6.1 Summary of main findings

Thirteen studies on standardised packaging were included in this review. Nine explored consumer response to standardised packaging and four the response of tobacco companies and changes in the retail environment. In this section we summarise the key findings and discuss how they compare with findings from our previous systematic review.[11] We also discuss strengths and limitations of the review and identify remaining evidence gaps and research questions.

6.1.1 Consumer responses to standardised packaging

The nine consumer studies comprised six surveys and three focus group studies. Three studies reported on awareness of standardised packaging, one on support, five on socio-cognitive and indirect behavioural outcomes, and five on anticipated changes and behavioural outcomes.

Awareness of standardised packs

Three studies reported on awareness of standardised packs.[19,21,23] In Haw's[19] school survey, conducted during the late transition period (last six months), three-quarters of 12-17 year olds indicated that they had not seen any standardised packs in the last 30 days. In contrast, in MacGregor's[23] focus groups with 13-16 year olds, conducted during the same period, awareness was high with students in all but one of the 16 groups reporting having seen or being aware of standardised packs; the discrepancy may be due to the fact that more than half of participants in the groups were smokers or had tried smoking, the survey only specified exposure within the previous 30 days, the study design and/or the potential influence of other focus group participants. Another focus group study, with 16-17 year old school pupils, conducted 6-18 months post-standardised packaging, found that most participants, and all ever smoker groups, were aware of standardised packaging. Exposure to these packs was via purchase, through family, friends or others, or as detritus.[19,21,23]

In the previous systematic review[11], which captured UK evidence until 15th February 2019, three studies (cross-sectional surveys) conducted during the transition period assessed awareness of standardised packs.[36,37] Poundall's[36] survey of university students, conducted in the early transition period (first six months), found that almost 90% indicated that they had not seen a standardised pack or were unsure. Two surveys conducted in the late transition period, found that a third of adults[37] and a fifth of 11-15 year olds[37] had noticed changes to the tobacco packaging in the last six months. Among adults, changes in packaging in last six months were noticed more by smokers (83.7%) than ex-smokers (25.1%) and never smokers (20.7%),[37] and among 11-15 year olds they were noticed more by smokers (49.0%) than susceptible never smokers (25.6%) and non-susceptible never smokers (16.2%).[37]

The findings on awareness provide no insight into the impacts of standardised packaging but help to understand when standardised packs appeared on the market. Consistent with sales data[26,27,38] the findings show that standardised packs were not widely available until late in the transition period. For countries moving towards standardised packaging this suggests that a long (12 month) sell-through period will be used by tobacco companies to delay the introduction of standardised packs and continue to promote cigarettes and RYO,[39] particularly as there is evidence from other countries with standardised packaging which shows that they were able to comply with much shorter (2-3 months) sell-through periods.[40]

Support for standardised packaging

One study explored support for standardised packs.[17] Moodie's[17] longitudinal survey found that for cigarette smokers, approval for standardised packaging increased, and disapproval decreased, across the three survey waves (W1, pre-standardised packaging; W2, 5-6 months post-standardised packaging; W3, 24-25 months post-standardised packaging). Among ex-smokers at W2 (the sample comprised only smokers at W1), approval for standardised packaging was higher than for smokers, and increased between waves 2 and 3, as disapproval decreased. In a previous systematic review,[11] which captured evidence until 15th February 2019, no study assessed support. Despite only a single study assessing support, the increase in approval among smokers, the group most likely to be resistant to policy change, has been found for a raft of tobacco control policies.[41]

Response to the on-pack warnings

One of the core aims of standardised packaging is to increase the salience of the warnings on packs, a pre-requisite for effectiveness. In comparison to warnings on fully-branded packs, the warnings on standardised packs were new, larger (covering an average of 65% rather than 48% of the front and reverse of packs), started from the top of the pack (rather than the bottom), displayed coloured images on the front and reverse (rather than just the pack reverse), and had images that were rotated annually (compared to images that were not rotated). Four studies examined response to warnings.[21-24]

In Drovandi's[30] four country survey, the highest mean score for warning effectiveness was in the UK, followed by Canada, Australia and the US, with the lowest proportion considering current warnings 'not at all' or 'minimally' effective in prompting quitting in the UK and Canada, and the highest in Australia and the US. The study was appraised as having major concerns however, due to sampling issues and inferences made, and the images shown were presented differently between countries (e.g. only the warnings were shown in Canada and not the packaging, the front and back of packs pre- and post-standardised packaging were shown in Australia which was not the case in the other countries, and in the UK a mock pack that did not display a brand variant name was used). The Aleyan[24] seven country survey found that the percentage of participants in England reporting that they usually notice warnings on packs first increased from 18.3% during the early transition period to 45.9% post-standardised packaging, with this increase significantly greater than in each of the other six European countries.

Two focus groups with teenagers found that among this population the warnings on standardised packs were prominent, salient and off-putting.[21,23] In Mitchell's[21] focus groups with 16-17 year old school pupils, prior to seeing any packs the warnings were often recalled. When shown packs, the warnings were generally considered clear, noticeable and believable, with warnings thought to reduce the appeal of smoking and put them off smoking. In MacGregor's[23] focus groups with 13-16 year old school pupils, standardised packs were felt to increase the salience and potency of the warnings, with images described as "*disgusting*", "*minging*", "*nasty*" and "*horrible*". Reactions to warnings on standardised packs differed, with more gruesome images eliciting more negative reactions. In both studies, some questioned the authenticity of some of the warning images.[21,23]

In the previous systematic review,[11] which captured evidence from the UK until 15th February 2019, three studies (two cross-sectional surveys and an eye-tracking study) conducted during the transition period assessed warning salience.[17,36,42] The findings from these studies suggested that standardised packs increased attention to warnings. In Retzler's[42] eye tracking study, participants attended more to warnings on standardised packs than on fully-branded packs, with more eye fixations, and more 'first fixations', to the warnings on standardised packs, with these fixations for a longer duration for the warnings on standardised packs. Moodie's[43] cross-sectional survey, conducted in the late transition period, found that smokers using standardised packs were more likely than smokers who had never used standardised packs to notice warnings often/very often, and read and look closely at them often/very often. In Poundall's[36] survey, conducted in the early transition period, smokers and non-smokers

were more likely to report noticing warnings on a standardised pack than a fully-branded pack. Non-smokers were more likely to indicate that the warnings on a standardised pack, compared to on a fully-branded pack, deterred them from starting smoking, with smokers more likely to indicate that the warnings on a standardised pack, compared to on a fully-branded pack, made them want to quit.

The findings from the seven studies captured in the current and previous review suggest that standardised packaging increases warning salience and/or effectiveness. There were however major concerns with one of the studies,[30] two were conducted before standardised packs were widely available on the market and therefore low prior exposure may have increased attention to the new warnings,[36,42] and the qualitative research lacks generalisability and being conducted in schools may have influenced participants' responses.[21,23] However, while in past research in countries with standardised packaging the authors have cautioned that it is not possible to disentangle the role of the stronger (new, larger pictorial) warnings from the removal of full branding,[17,43-45] the Aleyan[24] study is able to do so. By comparing England, where standardised packaging was implemented alongside the stronger (new, larger pictorial) warnings required by the Tobacco Products Directive,[46] and six other European countries where the same stronger warnings were implemented but standardised packaging was not, Aleyan's[24] longitudinal survey provides, for the first time, real-world insight into the benefits of simultaneously removing full branding and introducing new warnings.

Appeal

Reducing the appeal of the pack and smoking is another key objective of standardised packaging. Four studies examined appeal.[21-24] The Aleyan[24] longitudinal seven country survey found that the percentage of participants in England who did not at all like the look of their cigarette pack quadrupled between waves (13.9% to 54.9%), with this increase significantly greater than in each of the other six European countries. Among participants in England, there was also a significant decrease between waves in reporting how much brands differed in how prestigious they are (from 87.1% to 83.9%), but a significant increase in reporting that the quality of their cigarettes was high/very high (from 34.8% to 38.9%). These changes in prestigiousness and quality were not significantly different in England than in the other six countries.

One survey and two qualitative studies explored appeal among young people. In Mitchell's[22] cross-sectional school survey with 12-17 year olds, reactions to standardised packs and the users of these packs were consistently negative. Similarly, in Mitchell's[21] focus groups with 16-17 year old school pupils, standardised packs were viewed negatively, seen as unappealing, disgusting, and off-putting, with the colour described as "*dirty*", "*dull*", or "*boring*". Some females commented that they would feel embarrassed having a standardised pack, or would not use them, with several males saying they would feel uncomfortable using these packs. In MacGregor's[23] focus groups with 13-16 year old school pupils, standardised packs were seen as "*really ugly*", partly due to the colour, and not something that they would want to be seen with. Given the uniformity of the packs, some participants struggled to identify brands, which they suggested had been reduced to a name. These changes were perceived to have diminished pack appeal, the ability to create or project a cool brand image and a positive smoker identity.

In the UK, as in other European countries with standardised packs (e.g. France, Norway, Ireland), they are permitted to be sold in shoulder boxes, be slimmer, or have rounded or bevelled edges.[40] Two studies, one cross-sectional survey[22] and one focus group study,[21] explored youth response to standardised packs with different pack structures. In the survey, while the reactions to all the packs they were shown were negative, a standardised shoulder box was rated significantly less unattractive and less cheap than a regular straight-edged standardised pack, with smokers of the shoulder box considered less unfashionable and less unpopular.[22] Similarly, in the focus groups standardised packs with a different structure to the regular straight-edged pack were generally considered more appealing.[21] Some considered

the slim pack the most attractive, and easier to conceal, with the shoulder box generally viewed positively, with some participants suggesting that it might encourage purchase. Participants' responses to brand and variant names on packs were also gauged, with some, mostly male, participants considering the brand and variant names on the packs they were shown appealing.

In the previous systematic review,[11] which captured evidence from the UK until 15th February 2019, no study assessed appeal. Nevertheless, the findings from these reviews suggest that standardised packaging has reduced appeal, with the Aleyan[24] longitudinal seven country survey providing the strongest evidence given that the increase in 'not at all' liking the look of their cigarette packs was greater than in the other six European countries that introduced the same warnings but not standardised packaging. The three studies with young people also suggest that standardised packs are seen as unappealing.[21-23] That a standardised shoulder box and slim pack were viewed less negatively than other standardised packs in two of these studies,[21,22] and some brand variant names were viewed positively by youth, suggests that there are still elements of standardised packs that may help create appeal, although there is limited research on the role of pack structure and brand name on appeal and the novelty of the shoulder box may have influenced how it was perceived.

Perceptions of harm

Encouraging more accurate perceptions of the harms of smoking is another key objective of standardised packaging. Four studies examined harm perceptions.[21-24] In the Aleyan[24] longitudinal multi-country survey, the percentage of participants in England who indicated that their brand was no different in harmfulness compared to other brands, and no different in being smoother or harsher on the throat compared to other brands, did not significantly change between waves. In Mitchell's[22] cross-sectional survey participants were shown four images of standardised packs (straight-edged pack, bevelled-edge pack, slim pack, shoulder box), with all packs consistently considered harmful. In Mitchell's[21] focus groups with 16-17 year old school pupils, the colour of standardised packs was thought, by some, to reflect the harm caused by smoking. It was suggested that the cigarettes inside the slim standardised pack might be less harmful, due to the thinness of the pack. In MacGregor's[23] focus groups, with 13-16 year old school pupils, it was suggested that the removal of "*clean*" and "*fresh*" colours may indicate a change in perceived harmfulness of certain brands, although participants did not appear to state this explicitly.

In the previous systematic review,[11] which captured evidence from the UK until 15th February 2019, one study (cross-sectional survey) assessed harm perceptions. The study, conducted during the transition period, when both standardised packs and fully-branded packs were on sale, found that smokers using standardised packs thought more about the health risks of smoking because of the look of the pack than did smokers who were using fully-branded packs.[43] The findings from the two reviews provide some, limited, support for standardised packs being associated with greater harm perceptions; they provide no evidence that standardised packaging was associated with lower harm perceptions. The Moodie[43] cross-sectional survey, conducted during the transition period, shows that standardised packs were associated with greater risk perceptions. The novelty of standardised packs at the time of the study does not undermine the findings but may have influenced responses, and the study did not explore whether this response may be sustained over time. The Aleyan[24] longitudinal survey, which did assess harm perceptions over time, found no change between waves. There were very few harm-related comments in the two qualitative studies, although any comments made appeared to suggest that the colour of standardised packs reflected the harms associated with smoking.[21,23] For Mitchell's[22] cross-sectional survey, participants were only shown images of standardised packs and therefore there was no direct comparison with fully-branded packs, but all the standardised packs they were shown were rated as harmful to health.

Anticipated changes and behavioural outcomes

Five studies reported on anticipated changes in response to standardised packaging and purchasing behaviour.[21-23,25] Two focus groups with teenagers found that standardised packs were viewed as most likely to deter never or occasional smokers or those thinking about taking up smoking, as they were considered most likely to be put off by the warnings, pack appearance, and the negative image created by the packs.[21,23] In a school survey, most (87%) never smokers asked to select one of the four standardised packs they were shown indicated that they would not select any of them.[22]

Two surveys explored household purchasing behaviour.[25] The first found that from March 2011 to December 2017 the number of households purchasing only cigarettes fell as the number of households purchasing only RYO increased, with the number of households purchasing e-cigarettes increasing from March 2013. Purchases of the cheapest cigarettes and RYO increased as purchases of the most expensive cigarettes and most expensive RYO decreased. Among households at baseline that were cigarette-only purchasers, or RYO-only purchasers, the most frequent purchasing behaviour was to remain with the same product. For both groups (cigarette-only purchasers, RYO-only purchasers) the likelihood of switching out of the dataset doubled after May 2017. From March to May 2018, only a third (350 of 1061) of households reported a recent tobacco purchase.[25]

In the previous systematic review,[11] which captured evidence from the UK until 15th February 2019, three studies (all cross-sectional surveys) assessed anticipated changes and behavioural outcomes, all conducted during the transition period. Poundall[36] found that smokers thought that their likely response to standardised packaging would be to cut down (60%), quit (46%) or switch to rolling tobacco (41%), a cheaper brand (28%) or e-cigarettes (19%). Bogdanovica[37] found that almost a third of smokers reported switching products within the last six months, with just over a half of these changing to a cheaper brand. Moodie[43] found that those currently using standardised packs, compared with previous users or never users, were more likely to report having visited a stop-smoking website in the last month, and more likely to indicate that they had contemplated quitting because of the look of the pack.

The findings from the eight studies captured in these two reviews provide some evidence that standardised packaging may deter youth from smoking, although these findings are limited to qualitative research and a survey in schools. [21-23] Smokers switched to cheaper cigarettes and RYO,[25,37] as was found in Australia post-standardised packaging.[47] With respect to behavioural change, standardised packaging was associated with increased thoughts of quitting, at least during the transition period, but there was no evidence on cessation or relapse prevention. The increase in the number of tobacco purchasing household panels exiting the Kantar Worldpanel when standardised packaging was fully-implemented[25] may reflect a decline in tobacco use, although it is not possible to determine whether this was the case.

6.1.2 Tobacco companies' responses and changes in the retail environment

Four studies examined the responses of tobacco companies and changes in the retail environment: a mixed methods study examining product strategies used by tobacco companies to mitigate the effects of the legislation,[26] and three studies using Nielsen price and sales data to examine trends up to a year after the transition period.[27-29]

Product strategies

The one study[26] which examined how tobacco companies attempted to mitigate the effects of standardised packaging reported on a range of strategies, including keeping fully-branded packs on the market as long as possible, maintaining brand differentiation through variant name changes, focusing on lower price segments, pack modifications (e.g. bevelled edges, reusable tins), packs with extra sticks (e.g. 23 and 24), and products not covered by standardised packaging (e.g. cigars and cigarillos).

In the previous systematic review,[11] which captured evidence from the UK until 15th February 2019, three studies examined how tobacco companies responded to standardised packaging by introducing changes to brand variants and names, pack sizes and designs.[31] The studies found evidence of multiple brand variant name changes during the transition period, particularly for cigarettes, some of which were in response to the ban on descriptors which may create an erroneous impression about a product's characteristics or make reference to taste, smell or flavour, with others appearing to have been made in an attempt to capture attention.[39] There was evidence of brand rationalisation in all three studies,[31,39,48,49] and limited-edition packs, pack modifications and new cigarette pack sizes (23 and 24 packs) were observed during the transition period.[39] Two studies in the previous review which examined implementation of, and/or compliance with, the legislation[31,38] found that tobacco companies delayed the introduction of standardised packs until late in the transition period.

Taken together, evidence from the 2019 review and the current review provide insight into how tobacco companies responded to the legislation. Although compliance was high by the end of the transition period,[11] tobacco companies kept fully-branded packs on the market as long as possible and used strategies such as name changes and pack modifications to attempt to continue differentiating brands. The current review provides further intelligence on tobacco company strategies, such as a focus on cigars and cigarillos and a strong focus on lower price segments (RYO, value and sub-value cigarettes) before, during and for several months after the one-year transition period.

Trends in pricing

Two studies examined trends in pricing of tobacco products before, during and after the transition period.[27,28] These studies provide evidence as to whether the increases in pricing reported on in the previous review[11] were sustained longer term. Breton[27] used the same dataset as was used for a study included in the 2019 review,[31] but extended the analysis period to May 2018, a year after the transition period. The study found that prices rose significantly for RYO and cigarettes from the start of the transition period, with inflation adjusted prices being 12% higher for RYO and 7% higher for cigarettes in the time period after standardised pack sales accounted for over 75% of total sales.

Hiscock[28] examined Nielsen data for 36 months, from 2015 to 2018, for all products sold by at least 10% of retailers. The study extended previous studies of tobacco pricing by covering a longer follow up period and using analyses which included weighted prices for volume sold and additive mixed models which took into account different tobacco industry market segments (premium, mid-price, value and subvalue cigarettes, and premium, mid-price and value RYO). In comparison to the Critchlow[49] study included in the previous review, it used analyses which enabled it to generate confidence intervals and make inferences about price changes. The study found that the combination of standardised packaging, the MET and RYO tax changes did not lead to a long-term decline in tobacco prices, with price rises being observed even in the cheapest cigarettes and RYO products by April 2018. The combined policies also appear to have reduced the ability of tobacco companies to undershift on the cheapest products.

In the previous systematic review,[11] which captured evidence from the UK until 15th February 2019, four studies examined how tobacco companies and retailers responded to the legislation in terms of pricing.[20,31,48,49] Critchlow[48] using EPoS data from 500 small retailers, found a small increase in the average difference between RRP and sales price between May 2016, when only fully-branded packs were sold, to October 2017, when standardised packs were mandatory. Breton[31] found that between May 2016 and June 2017, in comparison to standard priced fully-branded packs, standardised packaging was associated with significant increases in price per cigarette (regardless of pack size), and price per pack of 20 cigarettes. They found that lower-priced cigarettes became considerably more expensive with standardised

packaging, while the price of the most expensive products remained relatively stable. Critchlow et al[48] found that for cigarettes the average inflation-adjusted RRP-per-cigarette and the average inflation-adjusted sales price-per-cigarette increased in each price segment (premium, mid-price, value). For RYO products, the average inflation-adjusted RRP-per-gram and average inflation-adjusted sales price-per-gram also increased between May 2016 and October 2017. A qualitative study by Purves[20] found that, in general, retailers reported pricing their products in line with RRP to stay competitive, but did exercise some flexibility on setting prices, particularly for premium brands.

Taken together, the two reviews provide consistent evidence that, contrary to tobacco industry claims, standardised packaging did not lead to cheaper prices. While the previous review[11] found evidence of short-term price increases, the cut-off point for the studies using EPOS data meant that they could not capture longer-term trends in pricing, and did not capture the impact of the tax changes implemented in November 2017. The current review indicates that these price increases were sustained up to at least a year after the transition period. The studies included in this review provide more insight into pricing trends in different market segments, particularly RYO. They also take account of tax changes which occurred simultaneously with standardised packaging, with Hiscock[28,29] addressing these more comprehensively. Although there is consistent evidence from both reviews that tobacco prices rose rather than fell following standardised packaging, RYO prices remain proportionately lower than cigarette prices.

Trends in sales

Two studies examined trends in tobacco sales[27,29] before, during and after the transition period. Breton[27] found that monthly total volume sales of cigarettes declined steadily between March 2013 and June 2018, with an estimated monthly linear decrease of 0.32%. However, monthly total volume of RYO sales increased over the same period with an estimated monthly linear increase of 0.16%.

Hiscock[29] examined sales data and found that overall sales volumes, which were 3.29 billion sticks in May 2015, had fallen by 4% by April 2018. However, while cigarette sales fell by 12% from 2.33 billion to 2.04 billion, RYO sales grew by 18% from 0.95 billion to 1.12 billion. Average monthly change in stick sales was compared for the period prior to standardised packaging and the MET with the period after they were implemented. Overall, stick sales reduced each month, with the rate of decline doubling in the post-implementation period. The average monthly decline was an extra 6.4 million (95% CI 0.1 million to 12.7 million) sticks post implementation compared with pre-implementation. Sales of cigarettes declined significantly faster post-implementation, while RYO sales rose in both periods, with no significant change in the rate of growth.

Monthly sales volumes fell significantly throughout the study period for premium, mid-price, and value cigarettes but sales of subvalue cigarettes increased significantly, from 409 million (95% CI 391 million to 427 million) to 780 million (95% CI 767 million to 793 million) in July 2017; they did not significantly increase afterwards, i.e. after standardised packaging and the MET. Sales of RYO premium and mid-price products did not change significantly over the study period, but RYO value sales increased significantly from 174 million (95% CI 16 1 million to 186 million) to 355 million (95% CI 343 million to 368 million). Tobacco industry monthly net revenues declined steadily from the start of the transition period by an estimated 13% (£31 million).

Overall, the findings suggest that the simultaneous implementation of standardised packaging and the MET steepened the pre-existing decline in tobacco sales and cigarette sales. Sales of the cheapest cigarettes increased until the end of the transition period for standardised packaging and implementation of the MET, after which they stopped growing. The authors suggest that the overall decline in sales implies that the combination of the MET and

standardised packaging limited the options for price-conscious smokers to switch to cheaper products as a means of continuing to smoke. However, like the Breton[27] study, no decline was observed in RYO sales. This is consistent with the evidence on price trends, which indicate that RYO prices remained proportionately lower than those of cigarettes, thereby continuing to provide a switching option for price-conscious consumers. No evidence on sales was reported in the previous review.[11]

6.2 Strengths and limitations

The main strength of this review is that it synthesised all published research in the UK (since February 2019) exploring how consumers, tobacco companies and retailers responded to standardised packaging. We conducted a systematic review in which we attempted to capture every published study eligible for inclusion.

The review has a number of limitations. The heterogeneous range of outcomes examined limited the extent to which findings could be synthesised. We intentionally restricted the studies that could be included to peer-reviewed publications, but excluding the grey literature may have introduced a publication bias. As the data extraction process was conducted by a single reviewer, this could have introduced errors. That one or more authors of this report were involved in four (of the thirteen) studies identified in this review introduces a risk of researcher bias. However, to minimise this risk the methodological quality of the included studies was assessed externally, by the EPPI-Centre (University of London), where two external assessors developed their own assessment tools and independently assessed study quality before they agreed final ratings; the authors had no involvement in how studies were rated.

There are also limitations with the studies included, although most were quality appraised as raising only minor concerns. The exception was one consumer study,[30] which was appraised as raising major concerns about the soundness of the data (e.g. the sample and data collection were not described adequately) and analyses (e.g. the appropriateness and reporting of the analyses), see Appendix 6. Many of the negative ratings in the studies with minor concerns related to reporting being unclear or missing, which could mean that the results of the analyses were not unsound.

Two of the studies employed focus groups with teenagers. A limitation of qualitative research, while at an appropriate design for providing insight into youth response to, and perceptions of, standardised packaging, is the lack of representativeness and generalisability. Similarly, as several studies were conducted only in Scotland or England this limits the generalisability of the findings to the whole of the UK, although there is no reason to suspect that the response of youth or adult smokers to the packaging changes would differ between countries.

The consumer studies relied on self-report. Convenience or probability sampling was used in some studies. While some studies employed a longitudinal design, they did not directly explore behavioural outcomes and therefore are not able to provide any insight into the impact of standardised packs on behaviour change.

As standardised packaging in the UK involved the removal of full-branding, inclusion of new warnings on primary and secondary display areas, an increase in the minimum pack size of cigarettes and rolling tobacco, and a ban on potentially misleading variant names, it is challenging to disentangle the role of each of these changes. The primary difficulty highlighted by researchers in Australia and the UK has been that it is not possible to explore the removal of full branding from the addition of new, larger warnings on the primary display areas.[43-45] One longitudinal consumer study was however able to test this on warning salience, appeal and harm.[24] Standardised packaging was also implemented alongside tax changes, and for the studies using time series price data[28,29] it was not possible to extricate the effects of standardised packaging from the effects of specific tax changes introduced over the same time period.

As standardised packs only became widely available at the end of the transition period, then for participants in the two studies conducted during the transition period[19,23] the packs would have been novel, which can lead to stronger (whether positive or negative) responses and distort findings.[50]

6.3 Gaps in the evidence and future research

Unlike our previous systematic review,[11] where all consumer research was conducted during the transition period, some studies in this review explored smokers and ex-smokers views on standardised packaging up to two years post-implementation. Given that the UK Government typically calculates the benefits of tobacco policy changes over a ten-year period, as is the case for standardised packaging, research with consumers is necessary to understand the longer-term impacts of this policy. Similarly, longer-term research on how tobacco companies continue to market products required to be sold in standardised packs (cigarettes and RYO), and those that are not, is needed, particularly as research only extends to seven months post-standardised packaging.[26,39] Such findings are important for the UK Government to understand whether there may be a need to extend standardised packaging to other tobacco or non-tobacco nicotine-containing products, and whether further changes, such as 'dissuasive' cigarettes, a ban on filter innovation or a ban on the use of colour variant names may help to counter tobacco industry marketing strategies.[11] They are also important for governments moving considering introducing standardised packaging.

Longitudinal research following a cohort of smokers is needed to explore what impact, if any, standardised packaging has on smoking and cessation-related behaviours. Additionally, while relapse prevention is a key goal of standardised packaging, no study in the UK, or elsewhere to our knowledge, has explored the real-world impacts of standardised packaging on ex-smokers. As there are more ex-smokers than smokers in the UK, as in many other countries with or moving to standardised packaging, then understanding how this policy is viewed among this population and the effect, if any, on helping them to remain smoke-free, is necessary. For instance, following on from the study that found that approval was higher among ex-smokers than smokers, and increased between the post-standardised packaging waves,[17] research could explore the reasons for this high level of support, including whether it is because standardised packaging is considered helpful in preventing relapse. With respect to uptake, several studies which included or focused exclusively on youth never smokers were identified,[21-23] although typically with relatively small samples. As such, repeat cross-sectional or longitudinal research with larger youth samples exploring the impact of standardised packaging on smoking attitudes and uptake would be of value.

Research on illicit tobacco use is needed. A study, published after the cut-off date for inclusion, used data from the 2015 and 2018 Eurobarometer surveys to explore any increase in the proportion of smokers in the UK, Ireland and France (three countries that had fully-implemented standardised packaging between the two survey waves) in being offered 'black market' tobacco.[18] However, as the longstanding argument by the tobacco industry is that standardised packaging will increase use of illicit tobacco, research among smokers exploring use of illicit tobacco, frequency of use, and reasons for use, would be beneficial.

Aleyan[24] found a significant increase in the proportion of smokers considering their cigarettes to be higher quality post-standardised packaging, which is inconsistent with research pre-standardised packaging.[7,9] As research captured in this review,[26] a previous systematic review,[11] and from Australia[51,52] show that tobacco companies have increasingly focused on filter innovation it is possible that this may help, at least in part, explain these findings, however this merits further exploration.

No study explored emotional response to standardised packaging, which would be of interest as research has found stronger negative emotional responses to warnings on packs to be associated with cessation-related behaviours.[53,54] Continued research exploring how consumers respond to the warnings on packs in the UK is also needed because while the

findings consistently showed that warning salience and effectiveness increased or was evident up to 18 months post-standardised packaging, as desensitisation occurs with all warnings this needs monitored, particularly as tobacco companies will be required to introduce new warnings on packs in the UK from January 2021.[55] Research should explore whether these new warnings help prevent or minimise habituation.

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Outputs / Dissemination

The aim of this report was to provide findings to the Department of Health and Social Care in order to help inform their Post-Implementation Review.

Peer-reviewed publications

- We have no peer-reviewed publications from the project. It is however our intention to publish an article on consumer response to standardised packaging in the UK.

Conference papers and presentations

- We have no conference papers or presentations from the project.

Other dissemination

- We have no other dissemination to report, but the findings will be included within future presentations and teaching on tobacco control.

Appendices

Appendix 1: Sample search strategy

Medline via Ovid: searched 28th May 2020
Ovid MEDLINE® and Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Daily and Versions® 1946 to May 27, 2020

	Searches
1	(cigar* or smok* or tobacco).ab,ti,kw.
2	"Smoking Cessation"/ or "Smoking Prevention"/ or Smoking/ or "Tobacco Industry"/ or "Tobacco Products"/ or exp "Tobacco Smoking"/ or "Tobacco Use Cessation"/
3	1 or 2
4	((brand* or (colo?r adj1 schem*) or descriptor? or design? or graphic? or image? or imagery or logo? or trademark? or trade-mark?) adj3 (ban? or banned or banning or outlaw* or prohibit* or remov* or restrict* or without)).ab,ti,kw.
5	(("drab brown" or "drab green" or dissuasiv* or generic* or homogen?ous or neutral* or "olive green" or plain or standard* or unbranded or uniform*) adj3 (can? or canister? or carton? or container? or hardpack? or pack* or pouch or pouches or softpack? or tin?)).ab,ti,kw.
6	product packaging/ or product labeling/
7	4 or 5 or 6
8	exp United Kingdom/
9	(britain or british or england or english or gb or "G.B." or "GB." or "G.B" or ireland or irish or scotland or scottish or wales or welsh or "united king*" or uk or "U.K." or "UK." or "U.K").ab,gi,in,ti.
10	(nhs or "national health service").ab,gi,in,ti.
11	8 or 9 or 10
12	3 and 7 and 11
13	limit 12 to yr="2019-Current"
14	limit 12 to ed=20180801-20201231
15	limit 12 to ep=20180801-20201231
16	limit 12 to dt=20180801-20201231
17	limit 12 to ez=20180801-20201231
18	13 or 14 or 15 or 16 or 17

Fields: ab = abstract, kw = keywords, ti = title, in = institution, gi = grant information (displays information about awarded grants, may contain Grant Number (NO), Grant Acronym (GR), Grant Organization (GO) and Grant Country (GC)), ed = entry date, ep = electronic date of publication, dt = create date [phrase indexed], ez = entry date [phrase indexed], yr = year of publication.

Medline via Ovid: searched 28th September 2020
Ovid MEDLINE® and Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Daily and Versions® 1946 to September 25, 2020

#	**Searches**
1	(cigar* or smok* or tobacco).ab,ti,kw.
2	"Smoking Cessation"/ or "Smoking Prevention"/ or Smoking/ or "Tobacco Industry"/ or "Tobacco Products"/ or exp "Tobacco Smoking"/ or "Tobacco Use Cessation"/
3	1 or 2

4	((brand* or (colo?r adj1 schem*) or descriptor? or design? or graphic? or image? or imagery or logo? or trademark? or trade-mark?) adj3 (ban? or banned or banning or outlaw* or prohibit* or remov* or restrict* or without)).ab,ti,kw.
5	(("drab brown" or "drab green" or dissuasiv* or generic* or homogen?ous or neutral* or "olive green" or plain or standard* or unbranded or uniform*) adj3 (can? or canister? or carton? or container? or hardpack? or pack* or pouch or pouches or softpack? or tin?)).ab,ti,kw.
6	product packaging/ or product labeling/
7	4 or 5 or 6
8	exp United Kingdom/
9	(britain or british or england or english or gb or "G.B." or "GB." or "G.B" or ireland or irish or scotland or scottish or wales or welsh or "united king*" or uk or "U.K." or "UK." or "U.K").ab,gi,in,ti.
10	(nhs or "national health service").ab,gi,in,ti.
11	8 or 9 or 10
12	3 and 7 and 11
13	limit 12 to yr="2020-Current"
14	limit 12 to ed=20200501-20201231
15	limit 12 to ep=20200501-20201231
16	limit 12 to dt=20200501-20201231
17	limit 12 to ez=20200501-20201231
18	13 or 14 or 15 or 16 or 17

Fields: ab = abstract, kw = keywords, ti = title, in = institution, gi = grant information (displays information about awarded grants, may contain Grant Number (NO), Grant Acronym (GR), Grant Organization (GO) and Grant Country (GC)), ed = entry date, ep = electronic date of publication, dt = create date [phrase indexed], ez = entry date [phrase indexed], yr = year of publication.

Appendix 2: EPPI-Centre critical appraisal tools

Qualitative studies

- Not a qualitative study [stop]
- AIMS: Was there a clear statement of the aims of the research? [Yes / No]
  Consider:
  - *what the goal of the research was*
  - *why it is important*
  - *its relevance*
- DATA COLLECTION
  - Was the recruitment strategy appropriate to the aims of the research? [Yes / No / Unclear]
    Consider:
    - *if the researcher has explained how the participants were selected*
    - *if they explained why the participants they selected were the most appropriate to provide access to the type of knowledge sought by the study*
    - *if there are any discussions around recruitment (e.g. why some people chose not to take part).*
  - Were the data collected in a way that addressed the research issue? [Yes / No / Unclear]
    Consider:
    - *if the setting for data collection was justified*
    - *if it is clear how data were collected (e.g. focus group, semi-structured interview etc)*
    - *if the researcher has justified the methods chosen*
    - *if the researcher has made the methods explicit (e.g. for interview method, is there an indication of how interviews were conducted, did they used a topic guide?)*
    - *if methods were modified during the study. If so, has the researcher explained how and why?*
    - *if the form of data is clear (e.g. tape recordings, video material, notes etc.)*
    - *if the researcher has discussed saturation of data*
- ANALYSIS
  - Was the data analysis sufficiently described? [Yes / No / Unclear]
  - Was the data analysis sufficiently rigorous? [Yes / No / Unclear]
    Consider:
    - *if there is an in-depth description of the analysis process*
    - *if thematic analysis is used. If so, is it clear how the categories/themes were derived from the data?*
    - *whether the researcher explains how the data presented were selected from the original sample to demonstrate the analysis process*
    - *if sufficient data are presented to support the findings*
    - *to what extent contradictory data are taken into account*
    - *whether the researcher critically examined their own role, potential bias and influence during analysis and selection of data for presentation*
- CONTRIBUTIONS AND CONCLUSIONS
  - Was the research design appropriate to address the aims of the research? [Yes / No / Unclear or partial]
    Consider if the researcher has justified the research design (e.g. have they discussed how they decided which methods to use?)
  - Has the relationship between researcher and participants been adequately considered? [Yes / No / Unclear]
    Consider:
    - *whether it is clear if the researcher critically examined their own role, potential bias and influence during:*

    - *formulation of research questions*
    - *data collection, including sample recruitment and choice of location.*
  - *how the researcher responded to events during the study and whether they considered the implications of any changes in the research design*
- Have ethical issues been taken into consideration? [Yes / No / Unclear]
  Consider:
  - *if there are sufficient details of how the research was explained to participants for the reader to assess whether ethical standards were maintained*
  - *if the researcher has discussed issues raised by the study (e. g. issues around informed consent or confidentiality or how they have handled the effects of the study on the participants during and after the study)*
  - *if approval has been sought from the ethics committee*
- Is there a clear statement of findings? [Yes / No / Unclear]
  Consider:
  - *if the findings are explicit*
  - *if there is adequate discussion of the evidence both for and against the researcher's arguments*
  - *if the researcher has discussed the credibility of their findings (e.g. triangulation, respondent validation, more than one analyst.)*
  - *if the findings are discussed in relation to the original research questions*
- Are the conclusions appropriate given the analyses and results? [Yes / No / Unclear]

- OVERALL, are there concerns about the soundness of the study? [Yes, major concerns / Yes, some minor concerns / No]

Quantitative studies − Sales data

- Not a quantitative – sales data study [stop]
- AIMS: Was there a clear statement of the aims of the study? [Yes / No]
  Consider:
  - *what the goal of the research was*
  - *why it is important*
  - *its relevance*
- DATA
  - Was a commercial data set used? [Yes / No / Unclear]
  - What was the data collection method? [Scanner / Receipts / Other (specify) / Unclear]
  - Was the dataset complete? [Yes, no gaps obvious / No, gaps were obvious but data company or researchers described modelling / No, gaps were obvious and unclear how this was addressed / Unclear]
  - Were there apparent, unintended restrictions in the dataset in terms of tobacco products or sales points? [Yes (specify) / No / Unclear]
    Examples of limitations include:
    - *limited brands,*
    - *limited products,*
    - *limited pack sizes,*
    - *limited types of retailers*

    Must be limitations that are unintended (i.e., not deliberate because of the focus of the study). Deliberate/intended limitations (e.g., if the study has an explicit focus on corner stores and the dataset only sampled corner stores) are acceptable; use 'No' here.
  - Was the sampling method appropriate to the question/inference being made? [Yes / No / Unclear]
  - Was the data sample representative of intended population? [Yes / No / Unclear]
    E.g., limitations in locations, types of sales points, etc
  - Did the study report a priori power calculations (where appropriate)? [Yes / No / Unclear]
    Did the researchers consider whether the sample was going to be adequately powered for the analyses?
  - Was the timing of the data collection appropriate for the aims of the study? [Yes / No / Unclear]
    Were the data gathered at a time/s that the behaviours are expected to occur? Consider time of day, day of week
  - Duration of study: Were the data collected over a sufficient time period for the intended analysis? [Yes, sufficient / No, not sufficient / Unclear]
    Consider issues such as seasonal variation or longitudinal data analysis plans. E.g., "Study duration was less than one year in most of the reviewed studies, making it impossible to control for seasonal variations in prices and quantity purchased and difficult to examine changes in population consumption patterns over time"
  - Were all plausible variables of interest measured in the dataset? [Yes / No / Unclear]
    As a social scientist, do you think something is missing?
  - Are the measures/ variables adequately described? [Yes / No]
  - Overall, are there concerns about the soundness of the data for the purposes of the study? [Yes, concerns / No]
- ANALYSIS
  - Were the analyses appropriate given the stated aims? [Yes / No / Unclear]
    Does the analysis adequately test the hypothesis?
  - Was the size of the dataset sufficient for the analyses being conducted? [Yes / No / Unclear or partial]

Are there enough data points for the planned analyses?
    - Have the data been analysed appropriately? [Yes / No / Unclear]
      E.g., treating ordinal as continuous; not controlling for reasonable confounders
    - Overall, are there concerns about the analyses? [Yes / No]
- INFERENCES AND CONCLUSIONS
    - Are the inferences drawn from analyses appropriate given the sample relative to population? [Yes / No / Unclear or partial]
    - Are the inferences drawn appropriate given the analyses and results? [Yes / No / Unclear]
    - Is there an over-emphasis on statistical significance rather than magnitude/ direction of effect? [Yes / No / Unclear]
      (e.g. absence of descriptive data and effect sizes in presentation and discussion of results.)
    - Is there an appropriate emphasis of the real-world importance of the statistical results? [Yes / No / Unclear]
    - Overall, are there concerns about the inferences and conclusions drawn? [Yes / No] (NEW 2020)
- ETHICS (NEW 2020)
    - Have ethical issues been taken into consideration? [Yes / No / Unclear]
      Consider:
        - *if there are sufficient details of how the research was explained to participants for the reader to assess whether ethical standards were maintained*
        - *if the researcher has discussed issues raised by the study (e. g. issues around informed consent or confidentiality or how they have handled the effects of the study on the participants during and after the study)*
        - *if approval has been sought from the ethics committee*
- OVERALL, are there concerns about the soundness of the study? [Yes, major concerns / Yes, some minor concerns / No]

Quantitative studies − Human participants

- Not a quantitative − human participants study [stop]
- AIMS: Was there a clear statement of the aims of the study? [Yes / No]
  Consider:
    - *what the goal of the research was*
    - *why it is important*
    - *its relevance*
- EXPERIMENT (not applicable for all studies)
    - Not applicable (not an experiment)
    - Were participants aware of the study aims before the experiment? [Yes / No / Unclear]
      Check for priming
    - Were there sufficient instances of presentation of the stimulus? [Yes / No / Unclear]
      Were there enough presentations of the two conditions?
    - Does the measurement instrument seem appropriate? [Yes / No / Unclear]
    - Was the presentation of the stimulus materials randomised for each participant? [Yes / No / Unclear]
      To control for learning or fatigue effects
    - Overall, are the concerns about the experiment? [Yes / No]
- DATA
    - Was the sampling method appropriate to the question/inference being made? [Yes / No / Unclear or partial]

    - Did the study report a priori power calculations (where appropriate)? [Yes / No / Unclear]
      Did the researchers consider whether the sample was going to be adequately powered for the analyses?
    - Was the data sample representative of intended population? [Yes / No / Unclear]
    - Was the measurement of the dependent variable(s) likely to be reliably assessed and validated? [Yes / No / Unclear]
    - Was the measurement of the independent variable(s) likely to be reliably assessed and validated? [Yes / No / Unclear]
    - Was the response rate sufficient? [Yes / No / Unclear]
    - Were all variables of interest measured in the dataset? [Yes / No / Unclear]
    - Are the data adequately described? [Yes / No]
    - Overall, are there concerns about the soundness of the data for the purposes of the study? [Yes, concerns / No]
- ANALYSIS
    - Were the analyses appropriate given the stated aims? [Yes / No / Unclear or partial]
      Does the analysis adequately test the hypothesis?
    - Was the size of the dataset sufficient for the analyses being conducted? [Yes / No / Unclear]
      Are there enough data points for the planned analyses?
    - Have the data been analysed appropriately? [Yes / No / Unclear or partial]
      E.g., treating ordinal as continuous; not controlling for reasonable confounders
    - Overall, are there concerns about the analyses? [Yes, concerns / No]
- INFERENCES AND CONCLUSIONS
    - Are the inferences drawn from analyses appropriate given the sample relative to population? [Yes / No / Unclear]
    - Are the inferences drawn appropriate given the analyses and results? [Yes / No / Unclear or partial]
    - Is there an over-emphasis on statistical significance rather than magnitude/ direction of effect? [Yes / No / Unclear or partial]
      (e.g. absence of descriptive data and effect sizes in presentation and discussion of results)
- ETHICS (NEW 2020)
    - Have ethical issues been taken into consideration? [Yes / No / Unclear or partial]
      Consider:
        - *if there are sufficient details of how the research was explained to participants for the reader to assess whether ethical standards were maintained*
        - *if the researcher has discussed issues raised by the study (e. g. issues around informed consent or confidentiality or how they have handled the effects of the study on the participants during and after the study)*
        - *if approval has been sought from the ethics committee*
- OVERALL, are there concerns about the soundness of the study? [Yes, major concerns / Yes, some minor concerns / No]

Quantitative studies − Structured observation of documents or places

- Not a quantitative – structured observation study [stop]
- AIMS: Was there a clear statement of the aims of the study? [Yes / No]
  Consider:
    - *what the goal of the research was*
    - *why it is important*
    - *its relevance*
- DATA

- Were the parameters of the documents/websites/other data to be analysed made clear? [Yes / No / Unclear or partial]
- Were the data extracted/collected using a structured approach? [Yes, evidence of structured template / No structured template provided or described / Unclear or Not Applicable]
  Evidence of structured templates for data collection
- How were the data collected? [Manual recording and extraction of documents / Structured observation / Web scraping / Other (specify)]
- Were any validity checks imposed around data collection? [Yes / No / Unclear]
  E.g. two researchers extracting data or attempts to source unavailable products
- Were measures taken to address any issues in validity? [Yes / No / Unclear]
  E.g. to locate missing documents or records
- Were there gaps in the data in terms of range of observations? [No obvious gaps / Yes, gaps were obvious but it was taken into account/adjustments were made / Yes, gaps were obvious and unclear how this was addressed / Unclear]
  E.g. In terms of only sections of documents/websites analysed or in terms of only observing some outlets within supermarkets
- Were there apparent, unintended restrictions in the dataset in terms of tobacco products or data sources? [Yes (specify) / No / Unclear]
  Examples of limitations include:
  - *document sources,*
  - *limited brands,*
  - *limited products,*
  - *limited pack sizes,*
  - *limited types of retailers*

  Must be limitations that are unintended (i.e., not deliberate because of the focus of the study). Deliberate/intended limitations (e.g., if the study has an explicit focus on corner stores and the dataset only sampled corner stores) are acceptable; use 'No' here.
- Did the study provide an explanation of any sampling strategy imposed? [Yes / No / Unclear]
  Did the authors defend the sample design/ target selection of cases/documents?
  Description of study locations/areas and how and why chosen
  Description of population of interest and how sample selection relates to it (e.g. typical, extreme case, diverse constituencies etc.)
  Rationale for basis of selection of target sample / settings/documents (e.g. characteristics/features of target sample / settings / documents, basis for inclusions and exclusions, discussion of sample size/number of cases/setting selected etc.)
  Discussion of how sample/selections allowed required comparisons to be made
- If sampling method employed, was it appropriate to the question/inference being made? [Yes / No / Unclear]
  E.g. sampling every other month or every six months
  E.g. sampling supermarkets in particular areas
- Was the sample of structured observations representative of intended population? [Yes / No / Unclear]
  E.g., limitations in type of shops visited (in person or by website)
  E.g. limitations in coverage of trade press
- Was the period of data collection appropriate for the aims of the study? [Yes / No / Unclear]
  Were the data collected at a period that the behaviours are expected to occur?
- Were all plausible data of interest extracted and measured in the dataset? [Yes / No / Unclear]
  As a social scientist, do you think something is missing?
- Are the data (measured collected/extracted) adequately described or summarised? [Yes / No]

    - Overall, are there concerns about the soundness of the data for the purposes of the study? [Yes, concerns / No]
- ANALYSIS
    - Were the analyses appropriate given the stated aims? [Yes / No / Unclear]
      Does the analysis adequately test the hypothesis?
    - Was the size of the dataset sufficient for the analyses being conducted? [Yes / No / Unclear]
      Are there enough data points for the planned analyses?
    - Have the data been analysed appropriately? [Yes / No / Unclear]
      E.g., treating ordinal as continuous; not controlling for reasonable confounders
    - Overall, are there concerns about the analyses? [Yes / No]
- INFERENCES AND CONCLUSIONS
    - Are the inferences drawn from analyses appropriate given the sample relative to population? [Yes / No / Unclear or partial]
    - Are the inferences drawn appropriate given the analyses and results? [Yes / No / Unclear]
    - Is there an over-emphasis on statistical significance rather than magnitude/ direction of effect? [Yes / No / Unclear]
      (e.g. absence of descriptive data and effect sizes in presentation and discussion of results.)
- ETHICS (NEW 2020)
    - Have ethical issues been taken into consideration? [Yes / No / Unclear]
      Consider:
        - *if there are sufficient details of how the research was explained to participants for the reader to assess whether ethical standards were maintained*
        - *if the researcher has discussed issues raised by the study (e. g. issues around informed consent or confidentiality or how they have handled the effects of the study on the participants during and after the study)*
        - *if approval has been sought from the ethics committee*
- OVERALL, are there concerns about the soundness of the study? [Yes, major concerns / Yes, some minor concerns / No]

Appendix 3 List of studies and the related components critically appraised

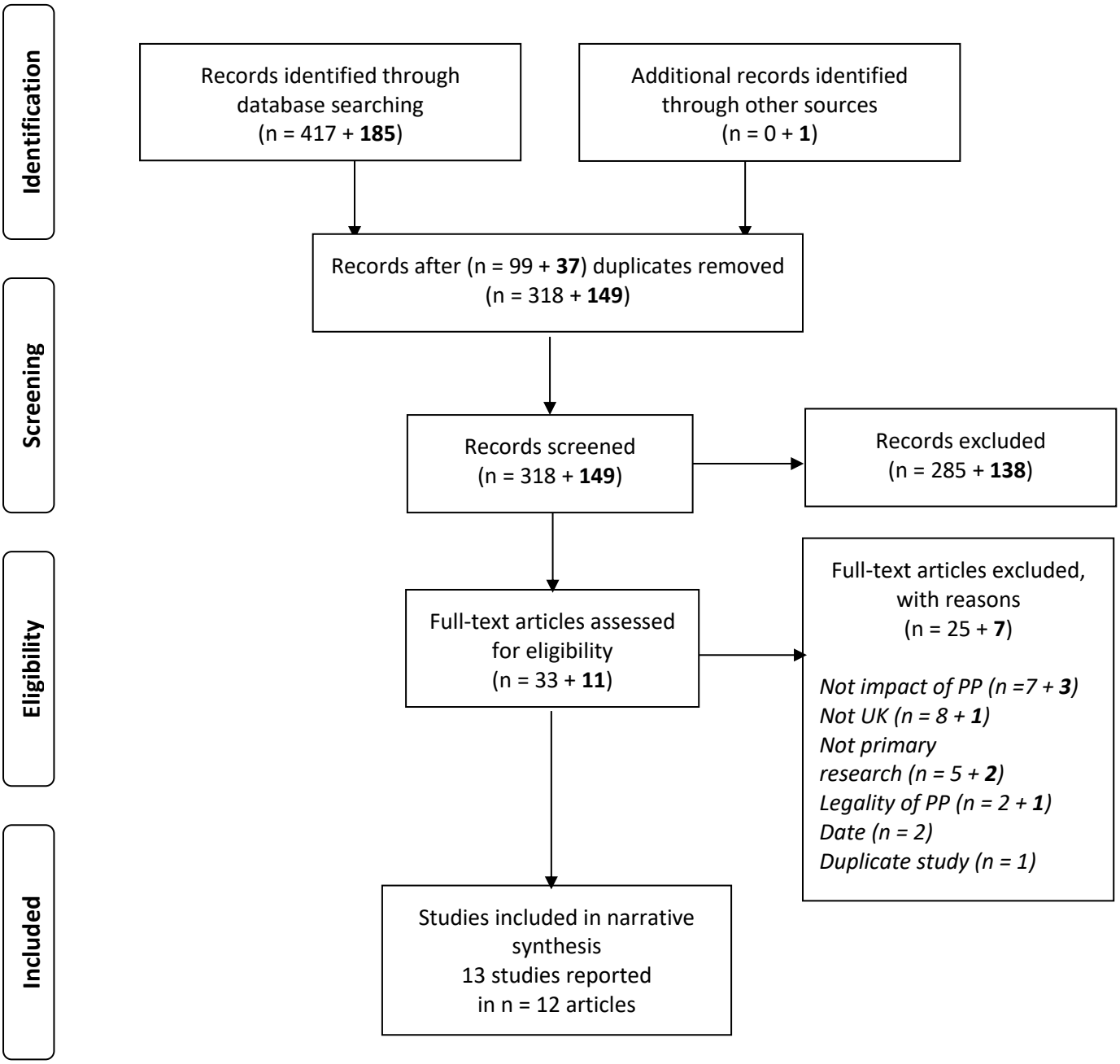
The included studies, any associated report(s)/publication(s) and the methodological components therein that were assessed in the critical appraisal process:

Study (n = 12)	Report (publication) title (n = 12)	Methodological component assessed (n = 14)
1. Aleyan et al. 2020	I. Evaluating the impact of introducing standardized packaging with larger health-warning labels in England: findings from adult smokers within the EUREST-PLUS ITC Europe Surveys.	i. Survey
2. Drovandi et al. 2019	II. Smoker perceptions of health warnings on cigarette packaging and cigarette sticks: A four-country study.	ii. Survey
3. Evans-Reeves et al. 2019 [Nielsen data]	III. Prospective longitudinal study of tobacco company adaptation to standardised packaging in the UK: identifying circumventions and closing loopholes.	iii. Sales data [Nielsen data]
		iv. Structured observations [Pack purchase, advertisements, commercial literature]
4. Haw et al. 2020[19]	IV. The impact of the point-of-sale tobacco display ban on young people in Scotland: before-and-after study. (Ch. 2 Methods and Ch. 8 Findings)	v. Questionnaires
5. Hiscock et al. 2020 (PLoS One pricing)	V. Standardised packaging, minimum excise tax, and RYO focussed tax rise implications for UK tobacco pricing.	vi. Sales data
6. Hiscock et al. 2020 (Tob Control sales volume)	VI. Longitudinal evaluation of the impact of standardised packaging and minimum excise tax on tobacco sales and industry revenue in the UK.	vii. Sales data
7. MacGregor et al. 2020	VII. 'It's like sludge green': young people's perceptions of standardized tobacco packaging in the UK. IV. The impact of the point-of-sale tobacco display ban on young people in Scotland: before-and-after study. (Ch. 2 Methods and Ch. 8 Findings)	viii. Qualitative
8. Mitchell et al. 2019	VIII. Adolescents' perceptions of standardised cigarette packaging design and brand variant name	ix. Qualitative

		post-implementation: a focus group study in Scotland.	
9. Mitchell et al. 2020	IX.	Reactions to standardized cigarette packs with varying structural designs, and the association with smoking susceptibility: a postimplementation cross-sectional survey with never-smoking adolescents in Scotland.	x. Survey
10. Moodie et al. 2020	X.	Increased support for standardised packaging in the UK: a longitudinal online survey.	xi. Survey
11. Breton et al. 2020 (Addiction mixed methods)	XI.	Effect of UK plain tobacco packaging and minimum pack size legislation on tobacco and nicotine product switching behaviour.	xii. Survey [Kantar longitudinal]
			xiii. Survey [Kantar cross-sectional]
12. Breton et al. 2020	XII.	Changes in roll-your-own tobacco and cigarette sales volume and prices before, during and after plain packaging legislation in the UK.	xiv. Sales data
**Hiscock et al. 2019 (conference abstract)*		*Introduction of standardised tobacco packaging and minimum excise tax on in the UK: a prospective study.*	*Sales data*
**Paper appraised but later categorised as a duplicate publication.*			

Appendix 4 Flow diagram depicting the flow of information through the different phases of the systematic review

Note: Numbers in regular font are for the May 2020 searches, numbers in bold font are for the September 2020 searches.



Appendix 5 Characteristics of the included studies

Study **Relevance, Overall quality rating, Clear statement of aims** **Funder, Conflict of interests**	**Country/ies** **Study sample**	**Aim** **Design & Data collection methods** **Data collection period**	**Outcome measures**
Aleyan 2020 (EurJPublicHealth) **Relevance:** High **Quality:** [tbc] **Aims clearly stated:** [tbc] **Funders:** European Union Horizon 2020, University of Waterloo, Canadian Institutes of Health Research, Ontario Institute for Cancer Research, Government of Catalonia, Instituto Carlos III, European Regional Development Fund, Government of Spain, US National Cancer Institute, Canadian Institutes of Health Research and German Federal Ministry of Health. **COIs:** GTF has served as an expert witness on behalf of governments in litigation involving the tobacco industry. KP reports grants and personal fees from the Polish League Against	England (plus Germany, Greece, Hungary, Poland, Romania and Spain) **Sample:** 9,547 adult smokers (W1) and 9,724 adult smokers (W2) **Age:** 18+ years (W1: 23% 18-24, 25% 25-29, 27% 40-54, 26% 55+) **Gender:** 44.7% female (W1) **Household income:** 22% low, 44% moderate, 26% high, 8% NR (W1) **Education:** 29% low, 41% moderate, 30% high (W1) **Smoking status: Nicotine dependence** 38% low (HSI 0-1), 45% medium (2-3), 17% high (4-6); **Past year quit attempts** 52% no, 48% yes (W1) **Sample type:** representative sample	The study examined the impact of standardized packaging on perceptions of (i) pack/brand appeal; (ii) salience of HWLs; and (iii) relative harms of different brands. The authors hypothesised that standardised packaging would reduce pack appeal, enhance the salience of HWLs and reduce misperceptions of harm associated with different brands. Longitudinal survey Face-to-face interviews (the England arm of the ITC 4CV plus ITC 6E), W1 (July-September 2016), W2 (February-July 2018) July 2016 to July 2018	**Consumer response** Pack/brand appeal: • asked, 'To what extent do you like the look of your cigarette pack?' 15 response options were dichotomized into 'not at all' vs. otherwise (i.e. 'a little/somewhat/quite a lot/very much/I don't know'). • asked, 'Now, thinking about the quality of your cigarettes, would you describe them as: very high quality, high quality, medium quality or low quality?' 15 response options were dichotomized into 'very high/high' vs. otherwise (i.e. 'medium/low quality/I don't know'). • asked, 'How much do brands differ in terms of how prestigious they are?' Response options were dichotomized into 'a little/somewhat/very different' vs. otherwise (i.e. 'not at all/I don't know'). Salience of health warning labels: • asked, 'When you look at a cigarette pack, what do you usually notice first—the warning labels, or other aspects of the pack, such as branding?' Responses were dichotomized into 'warning labels' vs. otherwise (i.e. 'other aspects of the pack/I don't know'). Perceived relative harm of different brands: • asked, 'Based on your experience of smoking, do you think that [your usual brand/the brand you are

Cancer, outside the submitted work. AM is a UK National Institute for Health Research (NIHR) Senior Investigator.			currently smoking] might be a little less harmful, no different, or a little more harmful, compared to other cigarette brands?' 16 responses were dichotomized into 'no different' vs. otherwise (i.e. 'a little less/a little more/I don't know'). • asked, 'Is your brand harsher or smoother on your throat compared to other brands?' Response options were dichotomized into 'about the same' vs. otherwise (i.e. 'harsher/smoother/I don't know').
Drovandi 2019 (TobInducedDis) **Relevance:** Medium **Quality:** Major concerns **Aims clearly stated:** Yes **Funders:** Australian Government Research Training Program Scholarship and College of Medicine and Dentistry, James Cook University, Townsville, Australia **COIs**: none	United Kingdom (plus Australia, Canada and the USA) **Sample:** 155 adult smokers **Gender:** mixed (57% female) **Age:** mean 43 years (range 19-74 years) **Ethnicity:** 90% Caucasian, 5% Black British, 2% Asian, 3% Other (Afro-Caribbean, African or Middle Eastern) or No response **Education**: mixed (59% High School/Vocational, 41% university) **Smoking status:** **Cigs/day:** 9% <daily, 37% 1-10, 37% 11-20, 13% 21-30, 4% ≥31; **Intentions to quit:** 13% No intentions, 35% Intends to (no plan), 38% Within 12 months 14% Within 3 months; **Perceptions of harm from smoking:** 1% Not at	"To investigate the perceived effectiveness of current cigarette packaging warnings and the potential effectiveness of cigarette-stick warnings across four countries." Cross-sectional survey without an experimental design Online questionnaire June 2018	**Consumer response** *[Prompt: two examples of country-specific cigarette packaging warnings, representative of the main themes of tobacco control messages used in their country]* • effectiveness of these warnings in prompting them to quit (5-point Likert from 'Not at all effective' (1) to 'Very effective' (5)). • open-text comment boxes on specific strengths or shortcomings of cigarette packaging warnings used in UK.

	all harmful, 3% Minimally harmful, 12% Moderately harmful, 29% Quite harmful, 55% Very harmful. **Sample type:** convenience		
Haw 2020[19] (PublicHealthRes_Ch2+8) **Relevance:** Medium **Quality:** Some minor concerns **Aims clearly stated:** Yes **Funder:** National Institute for Health Research (NIHR) Public Health Research **COIs**: none	Scotland, UK **Sample size:** 3,861 [2017 survey response rate] **Age:** 12- to 17-year-olds (Secondary 1 to 6) **SES:** 4 secondary schools in mainland Scotland serving 4 community catchment areas: two 'large urban', one with high and one with medium/low socioeconomic deprivation; two 'small town', one with high and one with medium/low socioeconomic deprivation. **Smoking status:** 1-24% regular (weekly) smoking, 4-47% ever smoked (2015-1017 surveys, S1-S6) **Sample type:** representative sample	"To determine the impact of the Scottish point-of-sale legislation on young people's exposure to tobacco advertising, their attitudes towards smoking and their smoking behaviour; and to identify any 'unintended consequences' of the legislation. … In response to the changing retail and sociocultural landscape, … questions on awareness of standardised packs were included in 2017." Cross-sectional survey without an experimental design Anonymous self-complete questionnaire administered by class teachers under exam conditions during Personal and Social Education (PSE) class-time. January to March 2017	**Consumer response** *[Prompt: colour picture of a standardised pack]* • In the past 30 days, have you seen any of these new greenish brown plain packs of cigarettes or tobacco (similar to above)? • Follow-up question, where seen?
MacGregor 2020 (Addiction + PublicHealthRes_Ch8) **Relevance:** High	Scotland, UK **Sample size:** 82 S2 and S4 students	To explore young Scottish people's awareness of and exposure to standardized packs in the United Kingdom, their perceptions of these	**Consumer response** Topic guide included:

Quality: Some minor concerns **Aims clearly stated:** Yes **Funder:** National Institute for Health Research (NIHR) Public Health Research, UK **COIs**: none	**Age:** S2 (aged 13–14 years) and S4 (aged 15–16 years) **Gender:** single-sex focus groups, one female and one male group per year group (two year groups), per school (4 schools) **SES:** 4 secondary schools in mainland Scotland serving 4 community catchment areas: two 'large urban', one with high and one with medium/low socioeconomic deprivation; two 'small town', one with high and one with medium/low socioeconomic deprivation. **Smoking status:** n=28 current smokers, n=16 tried smoking, n=38 never-smokers **Sample type:** purposive sample (to include students who were smokers or had regular contact with family members or friends smoked).	packs as to their appeal and probable impact on attitudes to smoking and smoking behaviour among young people. Thematic analysis of focus group data using an inductive approach Focus groups (16 single-sex focus groups of 3-8 participants conducted by a female facilitator. Average length 40 minutes.) February to March 2017	• general discussion about the community, local smoking behaviours and cultures, and the introduction of standardized packaging. • participants' awareness, knowledge and views of standardized packaging if this was raised spontaneously when talking about smoking. *[Prompts: four examples of standardized cigarette packs]* • participants' reactions and views about the prompt explored.
Mitchell 2019 (BMCPublicHealth) **Relevance:** High **Quality:** Some minor concerns	Scotland **Sample size:** 41 adolescents **Age:** 16-17 year-olds	To explore to what extent (if at all) adolescents were aware of standardised packaging, and how it was perceived. We also explored their reactions to the different pack structures permitted for standardised	**Consumer response** The interviews examined: • awareness of standardised packaging: where they see cigarette packs, who they see them with, what

Aims clearly stated: Yes **Funder:** University of Stirling, Scotland **COIs**: none	**Gender:** single-sex focus groups, four female groups (2 ever smokers, 2 never smokers) and four male groups (1 ever smokers, 3 never smokers) **Smoking status:** 3 groups of ever-smokers ('I have smoked a few times before', 'I smoke at least once a month', 'I smoke at least once a week' and 'I smoke every day') and 5 groups of never smokers ('I have never smoked not even a puff or two') **Sample type:** convenience sample	packs in the UK (e.g. slim packs and shoulder boxes), and the role of brand variant names as a mechanism to differentiate products or create appeal. Thematic analysis of focus group data using an inductive approach Focus groups (8 single-sex focus groups of 4-6 students conducted by a female facilitator; 30-45 minutes; in school, no teacher present.) November 2017 to November 2018	cigarette packs look like, and how they feel about them. *[Prompts: five standardised packs given to participants to handle and examine]* • responses to standardised packs: feelings, thoughts about colour, whether packs made them feel differently about smoking, if off-putting, feelings about using the packs and displaying in public, how other people would react to them using the packs, liked or disliked any packs, and opinions of warnings. • responses to variant names: whether communicated anything about cigarettes inside. *[Prompts: four standardised packs given to participants to handle and examine]* • responses to standardised packs which varied in pack structure: comment on comparisons for the slim pack, packs with bevelled or rounded edges, and the shoulder box, alongside the standard straight-edged flip-top pack. • responses to warnings and whether impacted by pack structure. Findings were reported under the following themes: • awareness of standardised packaging, • responses to standardised packs • perceptions of brand variant name • perceptions of pack structure • health warning salience • perceived impact on smoking behaviour
Mitchell 2020 (NicotineTobRes) **Relevance:** High **Quality:** Some minor concerns **Aims clearly stated:** Yes	Scotland (Edinburgh, South Lanarkshire & Stirling) **Sample size:** 507 adolescent never smokers **Age:** 12-17 year-olds (39% 12-13 year-olds,	To explore adolescents never-smokers' post-implementation reactions to standardized cigarette packaging, whether permitted variations in structure influence reactions to the standardized packs (e.g. slim packs or bevelled-edges), and what association (if any) there is	**Consumer response** *[Prompt: colour picture of four standardised cigarette packs of varying structure]* • reactions to each of the 4 cigarette packs (all items on 5-point scales; *reverse coded): *What do you think about each of these packs?* scales for: 1. Unattractive/Attractive; 2. Cool/Uncool*; 3. Cheap/Expensive

Funder: University of Stirling, Scotland **COIs**: none	36% 14-15 year-olds, 26% 16-17 year-olds) **Gender:** mixed (53% female) **SES:** 1 school (South Lanarkshire) in most deprived 10% and 2 schools in the least deprived 10% of areas in Scotland (SIMD 2016). 76% high SES, 24% medium/low SES. **Ethnicity:** 82% White British, 18% Other Ethnicities **Smoking status:** all never-smokers ('I have never smoked, not even a puff or two'); 70% nonsusceptible to smoking (would 'definitely not' accept cigarette from a friend or be smoking next year or be smoking at 18) **Sample type:** convenience sample	between pack reactions and susceptibility to smoking. Cross-sectional survey without an experimental design Online or paper survey administered by teachers under exam conditions during designated class-time. November 2017 to November 2018	*What do you think the person that smokes each pack would be like?* scales for: 1. Unfashionable/ Fashionable; 2. Unpopular/Popular; 3. Interesting/Boring* *How harmful to your health do you think that the cigarettes in each pack would be, if at all?* scale for: 1. Harmful/Not harmful *To what extent, if at all, does each pack put you off smoking?* scale for: 1. Puts me off smoking/Does not put me off smoking. • pack selection: pick one or none of the 4 packs • parental/guardian, sibling and friends' smoking.
Moodie 2020 (TobControl) **Relevance:** High **Quality:** [tbc] **Aims clearly stated:** [tbc] **Funders:** Cancer Research UK, British Heart Foundation, and the UK Department of Health and Social Care	United Kingdom **Sample size:** 6,233 current cigarette smokers (W1), of these, 4,293 (W2), 3,175 (W3) **Age:** 16+ years **Smoking status: W1:** 6,233 current cigarette smokers; **W2:** 3,629 current cigarette smokers,	To explore whether support for standardised packaging of cigarettes and rolling tobacco in the UK changed following the introduction of this policy on May 20th 2017. Longitudinal survey Online (the 'Adult Tobacco Policy Survey'), W1 (April-May 2016), W2	**Consumer response** *[Prompt: shown an image of standardised packs]* • To what extent, if at all, do you agree or disagree that tobacco companies should be/continue to be required to continue to sell cigarettes and rolling tobacco in standardised packs – that is, in packs which all look the same except for the brand and variant name? (Approval (Strongly agree/Agree), Neutral (Neither

through the Public Health Research Consortium **COIs**: none	607 ex-smokers, 36 used other forms of tobacco, 7 reported being a smoker but had not smoked in past 3 months, 14 'Don't know'; **W3:** 2,412 current cigarette smokers, 700 ex-smokers, 44 used other forms of tobacco, 6 reported being a smoker but had not smoked in past 3 months, 13 'Don't know'. **Sample type:** representative sample	(October-November 2017) and W3 (May-June 2019). April 2016 to June 2019	agree nor disagree) and Disapproval (Strongly disagree/Disagree).
Breton 2020 (Addiction) study 1 **Relevance:** High **Quality:** No concerns **Aims clearly stated:** Yes **Funder:** Cancer Research UK **COIs**: none	Great Britain (East, North, Midlands, London, South and West England, Wales and Scotland) **Sample size:** 11,695 households who had purchased cigarettes, RYO tobacco, cigars/cigarillos and pipe tobacco, e-cigarettes and NRT **Households:** between March 2011 and December 2017, the number of households averaged at 1741 (range 1332 to 2186). After a peak in May 2012, an average of 125 households departed (stopped	To study the effect of UK plain packaging and minimum pack size legislation on consumer's switching behaviour, comparing trends in household tobacco and non-tobacco nicotine product purchases before, during and after the introduction of plain packaging in the UK; and estimating changes in the likelihood of switching to a different tobacco product, to non-nicotine tobacco products and to different tobacco price segments. Natural experiment: descriptive analysis of longitudinal survey data using stacked bars graphs and line graphs to compare monthly trends and logistic regression analysis. March 2011 to December 2017	**Consumer response** Product type purchases: all purchases of tobacco (cigarettes, RYO tobacco) and non-tobacco (e-cigarettes and NRT) nicotine products by household by month. (Cigar/cigarillo and pipe purchases excluded from analysis.) Change in purchased pack size: calculated the total number of cigarettes and grams of RYO purchased by household by month, then calculated % purchased by pack size category (4 cigarette pack size categories: 10s, 11-19s, 20s, >20s; and 4 RYO categories: <12.5g, 12.5-29g, 30g, ≥30g). Extent of standardised packaging policy implementation: line graph (fig 1) plots the percentage of cigarettes and grams of RYO purchased in legal minimum plain pack size May 2016 to Dec 2017. Monthly trends in household purchases: stacked bars graph to compare number of households purchasing each product type (fig 2b) March 2011 – December 2017.

	purchasing tobacco/nicotine products or left the panel) and 88 households joined each month. **Data source:** Kantar Worldpanel, a longitudinal panel of ~30,000 households recruited using stratified sampling to represent GB by region, household size, age of main shopper and socioeconomic status.		Price: calculated the monthly average real price paid per cigarette and per gram of RYO (by pack size and price quartile) by averaging across all households each month. (Quartile 1 = least and Quartile 4 =most expensive products.) Monthly trends in household purchases **by pack size** and price paid: used stacked percentage graphs to compare purchases by pack size (fig. 3a and 3c) for both cigarettes and RYO tobacco and line graphs to compare average price paid by pack size (fig. 3b and 3d) for both cigarettes and RYO tobacco March 2011 – December 2017. Monthly trends in household purchases **by price quartile** and price paid: used stacked percentage graphs to compare purchases by price quartile (fig. 4a and 4c) for both cigarettes and RYO tobacco and line graphs to compare average price paid by price quartile (fig. 4b and 4d) for both cigarettes and RYO tobacco March 2011 – December 2017. Product type switching: sample split into two groups, those households purchasing only cigarettes (Group 1) and those purchasing only RYO tobacco (Group 2) during their first observed month. Three changes in household state identified by comparing consecutive months: 1. switching to a different tobacco product or combination of tobacco products; 2. switching to any non-tobacco nicotine product (including dual tobacco and non-tobacco use); 3. switching out of the dataset, where no tobacco or non-tobacco purchase observed. Monthly trends in household purchases by product type switching behaviour: used stacked percentage graphs to compare purchases by switching patterns (fig. 5a and 5b) for those households purchasing only cigarettes (Group 1) and those purchasing only RYO tobacco (Group 2) during their first observed month, March 2011 – December 2017. Standardised packaging and switching behaviour: used logistic regression to estimate the Group 1 and Group 2

			households' likelihood (OR) of switching (to other tobacco product, to non-tobacco nicotine product or out of our dataset), during and after standardised packaging implementation. Changes in price quartile purchasing patterns: using the price quartiles defined for cigarettes in Group 1 and for RYO tobacco in Group 2. Standardised packaging and changes in price quartile purchasing behaviour: logistic regression to estimate the Group 1 and Group 2 households' likelihood (OR) of changing price quartile purchasing patterns during and after standardised packaging implementation.
Breton 2020 (Addiction) study 2 **Relevance:** High **Quality:** [tbc] **Aims clearly stated:** Yes **Funder:** Cancer Research UK **COIs**: none	Great Britain **Sample size:** 1061 participants **Sample characteristics:** Participants from the total number of households in the panel that KWP identified as those who had purchased tobacco products recently (between four weeks and six months before the survey), who had, within the past month, changed the tobacco brand or brand variant they used, or switched to a different tobacco product or to a non-tobacco nicotine product, or bought more than one. **Data source:** Kantar Worldpanel, a longitudinal panel of ~30,000	To explore, by descriptive analysis of survey data, consumer's choices after changes in product availability associated with implementation of plain packaging. Cross-sectional survey without an experimental design Bespoke survey of Kantar Worldpanel panel members March to May 2018	**Consumer response** Participants were asked: • what would they do if the product they usually purchase was not available when going to a store; and • what factors determined their decision to purchase a different product or a different variant in that case.

	households recruited using stratified sampling to represent GB by region, household size, age of main shopper and socioeconomic status.		
Evans-Reeves 2019 (BMJOpen) **Relevance:** High **Quality (sales data):** None (sales data), Some minor concerns (pack purchase, advertisements, commercial literature) **Aims clearly stated:** Yes (sales data), Yes (pack purchase, advertisements, commercial literature **Funder:** Cancer Research UK **COIs**: none	United Kingdom **Pack purchases:** monthly purchase of eight top-selling cigarette and RYO products, across price segments and multinationals, between March 2016 and May 2017 **Retail/wholesale trade press ads:** 195 ads in 3 magazines published between January 2015 and December 2017 **Commercial literature:** 396 articles and reports by retailer magazines, industry analysts and tobacco companies published between January 2015 and December 2017 **Sales data:** monthly Nielsen electronic point of sale (EPOS) data, July 2014 to November 2017. Tobacco sales from nearly 90% of UK supermarkets and a stratified sample of 15% of convenience stores. 71 brands, 97 families, 241	"To use mixed methods to combine data from four different data sources up to 7 months after full-implementation [of standardised packaging in the UK] to systematically and rigorously examine how compliant tobacco companies were with the legislation, and to explore any attempts they made to circumvent it." Methods included monthly pack purchases and observation of price lists and multipacks 'outers'; a content analysis of tobacco ads in retail press; qualitative coding of commercial literature for evidence of circumvention of the legislation; and an analysis of EPOS sales data for compliance with the legislation (standardised packs and name changes). Natural experiment: observational prospective study to monitor multiple data sources Content analysis July 2014 to December 2017	**Change in retail environment** Data were analysed: • for compliance with legislation, • for name changes, and • whether product innovations were targeted at particular price segments of tobacco products. Results were presented by 4 key strategies used by tobacco companies identified to circumvent the legislation: 1. keep branded packets on the market as long as possible; 2. maintaining brand variant differentiation through name changes 3. focus on lower price segments and 4. innovating exemptions to the legislation. Compliance with the legislation (removal of branding, name changes, pricemarking and small pack sizes) was assessed using the monthly Nielsen sales data. For each product, Nielsen records hierarchically the tobacco brand, brand family, brand variant and then specific features of the pack denoted by a unique serial (SKU). For FM, Nielsen data identifies which packs are standardised and which are branded but not for RYO. As 30g packs of RYO were negligible prior to the legislation, ≥30g packs of RYO were treated as standardised. Innovation targeting: compared the distribution of name changes and new variants in November 2017 Nielsen sales data with the distribution of price segments prior to the decision to implement legislation in July 2014.

	variants and 1022 SKUs in November 2017.		Tobacco price segments: FM (factory made cigarettes) – Premium, Midprice, Value and Subvalue; RYO (roll-your-own tobacco) – Premium, Midprice and Value. Time periods: May 2016 – May 2017 "sell-off" or "sell-through" period May 2017 – onwards "full implementation" period
Hiscock 2020 (PLoSOne) **Relevance:** High **Quality:** No concerns **Aims clearly stated:** Yes **Funders:** Cancer Research UK and the British Heart Foundation **COIs**: none	United Kingdom (11 geographical areas, including all four countries) **Sample size:** Tobacco sales from nearly 90% of UK supermarkets (including a census of sales from stores owned by the largest four UK supermarket chains) and a stratified sample of 15% of convenience stores. **Products:** 107,571 monthly observations Monthly data were available on volume of sales, sales prices, and distribution of sales for each product (or stock keeping unit (SKU)) **Data:** Nielsen electronic point of sale (EPOS) data	Arm 1: To evaluate the impact of standardised packaging in the UK, the Minimum Excise Tax (MET) for factory made (FM) products and the roll your own (RYO) tobacco focussed tax changes on price and tobacco industry profitability. Natural experiment: descriptive analysis using line graphs to compare estimated monthly trends and forest plots from GAMM (generalized additive mixed model) multivariable modelling May 2015 to April 2018 (36 months)	**Change in retail environment** In addition to standardised packaging, 2016 and 2017 "also saw a number of changes to tobacco taxation which will have also impacted tobacco prices. Most notable were the introduction of a minimum excise tax (MET) on FM cigarettes in May 2017 and two increases in specific taxes on RYO products in addition to the usual tax escalator (that applied to both FM and RYO taxes)." **Research questions:** 1. Is there is any evidence that commoditisation happened after the introduction of standardised packaging as suggested by the tobacco industry: a. Did overall tobacco prices fall following implementation of standardised packaging? b. Was there a decline in FM prices leading to a decline in the price gap between FM (premium, midprice, value and subvalue) and RYO tobacco (premium, midprice and value) types? c. Was there a decline in FM premium prices leading to a decline in the price gap between the most expensive and cheapest FM cigarettes? 2. Was the MET associated with a rise in the price of the cheapest FM cigarettes and a narrowing of the price gap between these and other FM cigarettes? 3. Were the RYO focussed tax rises associated with a rise in price of RYO tobacco and a narrowing of the price gap between RYO and FM?

			4. Did the tobacco industry pricing strategy and the extent of over- and under-shifting of taxes change with introduction of standardised packaging and linked tax changes? Nielsen sales data were used to calculate real (inflation adjusted) monthly price per stick overall, by tobacco type (FM and RYO) and by seven market segments. "Trend estimation, using additive mixed models, assessed by dependent variables: weighted average price (weighted by volume of sales) and tobacco industry net revenue changes. The beginning and end of the data series were compared in terms of: (a) average monthly price growth, (b) average monthly net revenue growth, and (c) undershifting and overshifting patterns after tax changes. Tobacco price segments: FM (factory made cigarettes) – Premium, Midprice, Value and Subvalue; RYO (roll-your-own tobacco) – Premium, Midprice and Value.
Hiscock 2020 (TobControl) **Relevance:** High **Quality:** Some minor concerns **Aims clearly stated:** Yes **Funders:** Cancer Research UK and the British Heart Foundation **COIs**: JRB 10 shares in Imperial Tobacco for public health research purposes		Arm 2: To examine market segment sales volumes and company revenues surrounding the implementation of standardised packaging and a Minimum Excise Tax (MET) in the UK. Natural experiment: descriptive analysis using line graphs to compare trends and GAMM (generalized additive mixed model) multivariable modelling May 2015 to April 2018	**Change in retail environment** From above: *In addition to standardised packaging, 2016 and 2017 "also saw a number of changes to tobacco taxation which will have also impacted tobacco prices. Most notable were the introduction of a minimum excise tax (MET) on FM cigarettes in May 2017 and two increases in specific taxes on RYO products in addition to the usual tax escalator (that applied to both FM and RYO taxes)."* Analysis: To take account of tobacco industry market segments and non-linear effects of predictor variables including time, and to create confidence intervals in order to understand whether patterns in the data are noise or evidence of a significant change in outcome variables, we estimated additive mixed models (AMM), which is a special case of Generalised Additive Mixed Models. … The dependent variable for the first model was [tobacco sales] volume and for the second, tobacco industry revenue."

			Time periods: Period 1: preimplementation June 2015–March 2016 (the 10 months before the sell through period) Period 2: post full implementation June 2017–March 2018 (the same 10 calendar months after the introduction of standardised packaging and MET) (Excluded the month immediately before the implementation or the month of implementation because changes might already have been underway.) Market segments Overall – FM and RYO FM – 4 segments by 'value' (Premium, Midprice, Value and Subvalue) RYO – 3 segments (Premium, Midprice and Value) Tobacco industry revenues refer to net revenues after tobacco taxes have been paid (ie, net price per stick – minus taxes due per stick – multiplied by volume of sticks sold), and hence cover the manufacturing, packaging, retailing, and distribution costs with the remainder accruing as industry profit.
Breton 2019 (TobControl) **Relevance:** High **Quality:** Some minor concerns **Aims clearly stated:** Yes **Funder:** Cancer Research UK **COIs**: none	United Kingdom **Sample size**: >75,000 stores **Stores:** megastores, superstores, high street stores and convenience stores in the UK **Products:** 5972 observed RYO products (1713 of legislated pack size) and 18,062 observed cigarette products (8246 of legislated pack size).	To describe RYO price and sales trends in relation to pack sizes before, during and after the UK transition to plain packaging, and in relation to cigarette sales volume and prices. Natural experiment: descriptive analysis using line graphs to compare monthly trends and a linear regression model March 2013 to June 2018 (Regression model May 2015 to May 2018 only)	**Change in retail environment** • RYO and cigarette products: each product defined as a combination of brand, brand variants, pack size and (if relevant) multi-pack size characteristics • Monthly volume of sales: the number of grams of RYO products and cigarette sticks sold each month • Sales in standardised packs: the percentage of volume of cigarettes sales in plain packs compared with total volume of sales and, the percentage of volume of sales of RYO packs containing ≥30g tobacco compared with total volume of sales. Three bandings after implementation: <50% standardised pack sales, 50-75% sales and >75% sales.

	Data: Nielsen Scantrack cigarettes and RYO (including make-your-own) sales data		• Estimated average retail price for products scanned: average retail price (in pence) per gram of tobacco and per cigarette. Nielsen data set categorised prices as standard or promotional (when a ≥5% price reduction was observed compared with second highest price registered for the same product during the previous 6 weeks) • Model controlled for changes in tax levels over time, adjusted prices for inflation and used standard prices only, not promotional prices.

KEY: Relevance study's relevance to our review's aims (high or medium), as assessed by the reviewers; **Overall quality rating** "Overall, are there concerns about the soundness of the study?" (Yes, major concerns / Yes, some minor concerns / No); critical appraisal by independent research team; **Clear statement of aims** "Was there a clear statement of the aims of the study?" (Yes / No); critical appraisal by independent research team.

ABBREVIATIONS: COIs conflict of interests; NR not reported; SD standard deviation; IQR interquartile range; EPoS Electronic Point of Sale; UPC Universal Product Code; FMC factory-made cigarettes; RYO roll-your-own; RRP recommended retail price; CPIH Consumer Prices Index including owner occupiers' housing costs; TPD The Tobacco Products Directive.

Appendix 6 EPPI-Centre critical appraisal results

Quantitative studies − Human participants

	Aleyan 2020	Drovandi 2019	Haw 2020[19]	Breton 2020 (Addiction longitudinal)	Breton 2020 (Addiction cross-sectional)	Mitchell 2020	Moodie 2020
OVERALL							
AIMS: Was there a clear statement of the aims of the study?		Yes	Yes	Yes		Yes	
OVERALL, are there concerns about the soundness of the study?		Yes, major concerns	Yes, some minor concerns	No		Yes, some minor concerns	
DATA							
Was the sampling method appropriate to the question/inference being made?		Yes	Unclear/ partial	Yes		No	
Did the study report *a priori* power calculations (where appropriate)?		Unclear	No	No		No	
Was the data sample representative of intended population?		Unclear	Unclear	Yes		Unclear	
Was the measurement of the dependent variable(s) likely to be reliably assessed and validated?		Unclear	Yes	Yes		Unclear	
Was the measurement of the independent variable(s) likely to be reliably assessed and validated?		Unclear	Yes	Yes		Yes	
Was the response rate sufficient?		Unclear	Yes	Unclear		Unclear	
Were all variables of interest measured in the dataset?		Unclear	Yes	No		Yes	
Are the data adequately described?		No	No	Yes		Yes	
Overall, are there concerns about the soundness of the data for the purposes of the study?		Yes, concerns	Yes, concerns	No		Yes, concerns	

	Aleyan 2020	Drovandi 2019	Haw 2020[19]	Breton 2020 (Addiction longitudinal)	Breton 2020 (Addiction cross-sectional)	Mitchell 2020	Moodie 2020
ANALYSIS, INFERENCES AND CONCLUSIONS							
Were the analyses appropriate given the stated aims?		No	Unclear/ partial	Yes		Yes	
Was the size of the dataset sufficient for the analyses being conducted?		Yes	Yes	Yes		Yes	
Have the data been analysed appropriately?		Unclear/ partial	Unclear/ partial	Yes		Unclear/ partial	
Overall, are there concerns about the analyses?		Yes, concerns	No	No		Yes, concerns	
Are the inferences drawn from analyses appropriate given the sample relative to population?		Unclear	Unclear	Yes		Yes	
Are the inferences drawn appropriate given the analyses and results?		No	Unclear/ partial	Yes		Yes	
Is there an over-emphasis on statistical significance rather than magnitude/ direction of effect?		Unclear/ partial	No	No		Unclear/ partial	
ETHICS							
Have ethical issues been taken into consideration?		Yes	Yes	Unclear/ partial		Yes	

Quantitative studies − Structured observation of documents or places

	Evans-Reeves 2019 [Pack purchase, advertisements, commercial literature]
OVERALL	
AIMS: Was there a clear statement of the aims of the study?	Yes
OVERALL, are there concerns about the soundness of the study?	Yes, some minor concerns
DATA	
Were the parameters of the documents/websites/other data to be analysed made clear?	Yes
Were the data extracted/collected using a structured approach?	Unclear or Not Applicable
How were the data collected?	Manual recording and extraction of documents
Were any validity checks imposed around data collection?	No
Were measures taken to address any issues in validity?	Unclear
Were there gaps in the data in terms of range of observations?	No obvious gaps
Were there apparent, unintended restrictions in the dataset in terms of tobacco products or data sources?	Yes
Did the study provide an explanation of any sampling strategy imposed?	No
If sampling method employed, was it appropriate to the question/inference being made?	Unclear
Was the sample of structured observations representative of intended population?	Unclear
Was the period of data collection appropriate for the aims of the study?	Yes
Were all plausible data of interest extracted and measured in the dataset?	Unclear
Are the data (measured collected/extracted) adequately described or summarised?	No
Overall, are there concerns about the soundness of the data for the purposes of the study?	Yes, concerns
ANALYSES	
Were the analyses appropriate given the stated aims?	Yes
Was the size of the dataset sufficient for the analyses being conducted?	Yes
Have the data been analysed appropriately?	Unclear
Overall, are there concerns about the analyses?	Yes
INFERENCES AND CONCLUSIONS	
Are the inferences drawn from analyses appropriate given the sample relative to population?	Unclear/partial
Are the inferences drawn appropriate given the analyses and results?	Yes
Is there an over-emphasis on statistical significance rather than magnitude/ direction of effect	No
ETHICS	
Have ethical issues been taken into consideration?	Yes

Quantitative studies − Sales data

	Evans-Reeves 2019 [Nielsen data]	Hiscock 2020 (PLoS One pricing)	Hiscock 2020 (Tob Control sales volume)	Breton 2020 (Tobacco Control)
OVERALL				
AIMS: Was there a clear statement of the aims of the study?	Yes	Yes	Yes	Yes
OVERALL, are there concerns about the soundness of the study?	No	No	Yes, some minor concerns	Yes, some minor concerns
DATA				
Was a commercial data set used?	Yes	Yes	Yes	Yes
What was the data collection method?	Unclear	Unclear	Unclear	Scanner
Was the dataset complete?	No, gaps were obvious and unclear how this was addressed	No, gaps were obvious but data company or researchers described modelling	No, gaps were obvious and unclear how this was addressed	Yes, no gaps obvious
Were there apparent, unintended restrictions in the dataset in terms of tobacco products or sales points?	Yes	Yes	Yes	Unclear
Was the sampling method appropriate to the question/inference being made?	Yes	Yes	Yes	Yes
Was the data sample representative of intended population?	No	Yes	Yes	Unclear
Did the study report *a priori* power calculations (where appropriate)?	No	No	No	No
Was the timing of the data collection appropriate for the aims of the study?	Yes	Yes	Yes	Yes
Duration of study: Were the data collected over a sufficient time period for the intended analysis?	Yes, sufficient	Yes, sufficient	Yes, sufficient	Yes, sufficient
Were all plausible variables of interest measured in the dataset?	No	Yes	Yes	No
Are the measures/ variables adequately described?	No	Yes	Yes	Yes
Overall, are there concerns about the soundness of the data for the purposes of the study?	Yes, concerns	No	No	No

	Evans-Reeves 2019 [Nielsen data]	Hiscock 2020 (PLoS One pricing)	Hiscock 2020 (Tob Control sales volume)	Breton 2020 (Tobacco Control)
ANALYSES				
Were the analyses appropriate given the stated aims?	Unclear	Yes	Yes	Yes
Was the size of the dataset sufficient for the analyses being conducted?	Yes	Yes	Yes	Yes
Have the data been analysed appropriately?	Yes	Yes	Yes	Unclear
Overall, are there concerns about the analyses?	No	No	No	Yes
INFERENCES AND CONCLUSIONS				
Are the inferences drawn from analyses appropriate given the sample relative to population?	Yes	Yes	Yes	Yes
Are the inferences drawn appropriate given the analyses and results?	Yes	Yes	No	Unclear
Is there an over-emphasis on statistical significance rather than magnitude/ direction of effect?	No	No	No	No
Is there an appropriate emphasis of the real-world importance of the statistical results?	Yes	Yes	Yes	Unclear
Overall, are there concerns about the inferences and conclusions drawn?	No	No	Yes	Yes
ETHICS				
Have ethical issues been taken into consideration?	Yes	Yes	Yes	No

Qualitative studies

	MacGregor 2020	Mitchell 2019
OVERALL		
AIMS: Was there a clear statement of the aims of the research?	Yes	Yes
OVERALL, are there concerns about the soundness of the study?	Yes, some minor concerns	Yes, some minor concerns
DATA COLLECTION		
Was the recruitment strategy appropriate to the aims of the research?	Yes	Yes
Were the data collected in a way that addressed the research issue?	Yes	Yes
ANALYSIS		
Was the data analysis sufficiently described?	Yes	Yes
Was the data analysis sufficiently rigorous?	Yes	Yes
CONTRIBUTIONS AND CONCLUSIONS		
Was the research design appropriate to address the aims of the research?	Unclear/partial	Yes
Has the relationship between researcher and participants been adequately considered?	No	No
Have ethical issues been taken into consideration?	Yes	Yes
Is there a clear statement of findings?	Yes	Yes
Are the conclusions appropriate given the analyses and results?	No	Unclear