

**A GLOBAL RAPID REVIEW OF INTERVENTIONS TO TACKLE THE HARMS OF
ILLICIT TOBACCO**

Nathan Davies, School of Medicine, University of Nottingham, Nottingham City Hospital,
Hucknall Road, Nottingham NG5 1PB, UK (Corresponding author,

Nathan.davies@nottingham.ac.uk)

Ize Bogdanovica, School of Medicine, University of Nottingham, Nottingham City
Hospital, Hucknall Road, Nottingham NG5 1PB and SPECTRUM consortium, Edinburgh,
UK

Manpreet Bains, School of Medicine, University of Nottingham, Nottingham City Hospital,
Hucknall Road, Nottingham NG5 1PB, UK

Leah Jayes, Institute of Health and Allied Professions, Nottingham Trent University, Clifton
Campus, Nottingham NG11 8NS, UK

Tessa Elisabeth Langley, School of Medicine, University of Nottingham, Nottingham City
Hospital, Hucknall Road, Nottingham NG5 1PB and SPECTRUM consortium, Edinburgh,
UK

ABSTRACT

Objective

This review aimed to assess interventions designed to reduce harm from illicit tobacco (IT). We evaluated health outcomes, cost-effectiveness, the advantages and disadvantages of interventions, and contextual factors affecting implementation.

Data sources

We searched MEDLINE and Embase databases from January 2002 – June 2024, the grey literature, and undertook backward and forward citation searches of included studies, without geographic restrictions.

Study selection

Eligible study types included non-randomised trials, interrupted time series, before-after studies, economic simulations, and mixed-methods studies. Case studies providing outcome data linked to specific interventions were also included. Studies were screened by multiple reviewers for eligibility.

Data extraction

Data was extracted on geographical location and dates of interventions, descriptions of the interventions, contexts, and outcome data relevant to review objectives, which were checked by a second reviewer. Quality assessment was conducted using the JBI critical appraisal tools appropriate for each study design.

Data synthesis

Five studies and 16 case studies were included. These reported on a range of interventions (including track-and-trace systems, anti-counterfeit measures and communications campaigns) and outcome (including tax revenue and population attitudes toward IT). There was some evidence for the effectiveness of track-and-trace systems. Case studies,

predominantly on national-level interventions, reported decreases in IT market share and increases in tax revenue, suggesting potential benefits of multi-component strategies.

Conclusions

There is promising limited evidence for interventions to tackle IT, but they are seldom systematically evaluated. Comprehensive, independent evaluations are required to support policymaking and avoid tobacco industry influence in IT research.

KEY MESSAGES

What is already known on this topic

Illicit tobacco trade (IT) undermines public health policies by providing cheap, accessible alternatives to duty-paid tobacco, driving consumption among younger and more deprived populations. Interventions involving the tobacco industry have been shown to be counterproductive, but there is limited systematic evaluation of independent interventions.

What this study adds

This global review identifies significant gaps in the evaluation of IT interventions, especially in understanding the effectiveness of individual intervention components and contextual factors influencing success. There is some evidence for positive impact of independent, government-financed track-and-trace systems on health and economic outcomes related to IT.

How this study might affect research, practice, or policy

The findings emphasise the need for comprehensive, independent evaluations of IT interventions, including both supply and demand-side measures. Policymakers and researchers should consider evaluation mechanisms when designing IT interventions to measure effectiveness and avoid reliance on industry-provided data.

INTRODUCTION

In the context of tobacco, illicit trade is defined by the World Health Organization (WHO) as “any practice or conduct prohibited by law and which relates to production, shipment, receipt, possession, distribution, sale or purchase including any practice or conduct intended to facilitate such activity”.^[1] It is widespread; a recent review of 36 countries estimated that illicit tobacco (IT) makes up 11% of the global cigarette market.^[2] This availability of IT undermines the effectiveness of evidence-based measures to reduce smoking prevalence, particularly tax increases, by increasing availability of a cheap, easily accessible alternative to duty-paid tobacco.^[3] In this way, IT is a particular driver of tobacco consumption in more deprived and younger age groups, increasing health inequalities.^[4,5] Purchase of tobacco from illicit sources is also associated with reduced smoking cessation.^[6,7]

Tackling IT requires partnership working between several agencies. This may include health authorities, trading standards bodies, customs bodies and other enforcement agencies such as the police. Programmes can take place at international, national, regional and local level^[8–10] and include interventions such as licensing conditions, compulsory record-keeping and monitoring for those in each stage of the product journey, markers such as tax stamps, tracking and tracing tobacco products, and public campaigns to reduce demand and increase reporting.^[9] Tobacco companies seek to position themselves as legitimate partners in reducing IT, but have been shown to profit from IT trade.^[11] Although there are case studies and guidance on reliable ways to collect data on the size of the IT market, ^[12–14] reliance on methodologically-flawed industry estimates remains common.^[15]

Involving the tobacco industry in partnerships provides them a platform for advocating commercial interests over health interests, for making and funding arguments against tobacco

tax rises,[16,17] and for drawing focus away from other tobacco control issues.[11,18–20] Voluntary Memoranda of Understanding (MOU) agreements have been a key tool for the tobacco trade to work towards these aims.[21]

There has been detailed work setting out the rationale for avoiding partnering with the tobacco industry when tackling IT, but the range, intensity and geographical reach of activities that could have positive outcomes has not been systematically reported. It is very important for tobacco control practitioners and policymakers to understand what it is they can do to tackle IT as well as what they should avoid doing. In this context, we undertook a global rapid review of research that had assessed outcomes from interventions aimed at reducing harm from IT.

METHODS

Search strategy and selection criteria

Studies were included if they reported one or more interventions to reduce the health-related harms of IT, defined as “any activity that aims to reduce the burden caused by IT by tackling the supply of and demand for IT.” Our five broad research questions were as follows:

- 1) What are interventions that have been used to reduce the size of the IT market and IT use in different settings?
- 2) What are the qualitative advantages and disadvantages of the different interventions?
- 3) What are the contextual factors which may facilitate or hinder interventions to tackle the IT trade?
- 4) What are the health-related outcomes as a result of different interventions including differential effects by socio-economic group?

5) Which interventions are cost-effective?

Study designs included in our primary analysis were non-randomised trials, interrupted time series, before-after studies, modelling of specific IT policies on outcomes of interest (IT use, IT availability, population smoking prevalence, intervention delivery, behavioural outcomes or cost-effectiveness) and formal mixed-methods studies. Where reports included specific interventions and quantitative outcome data or qualitative data that supported answering our research questions, but did not use an aforementioned study design to assess associations or to collect or analyse qualitative data, we included this as a “case study” and summarised the data from these case studies separately. Case studies which did not provide descriptions of both interventions and outcomes, purely reported on punitive criminal justice measures (e.g. fines), or summarised pre-existing peer-reviewed literature were excluded. There were no restrictions by location or population. There were no restrictions on geographic location, study type or language.

We searched the electronic databases MEDLINE and Embase through OVID from 2002 – June 2024. We used a broad search approach to identify all relevant papers (illicit* OR illegal* OR smuggl* OR "contraband" OR counterfeit*).mp. AND ("tobacco" OR cigar*).mp. In addition, the grey literature was searched by using adaptations of the search string on the first 100 hits for Google and the websites of the World Bank, WHO , Tobacconomics, Tobacco-Free Kids, the Centers for Communicable Disease Control and Action on Smoking and Health.

Studies were extracted into Rayyan[22] and de-duplicated before screening. Pairs of reviewers screened all titles and abstracts, and then full texts, to identify eligible studies. Any disagreements between reviewers were resolved through discussion or by adjudication from a

third reviewer. A backwards and forwards citation search of included peer-reviewed studies was conducted to identify any additional papers.

Data extraction

Data extraction forms were piloted and standardised (fields provided in Supplementary File 1). ND extracted information including dates and geographical location of interventions, a description of the intervention, intervention context, and outcome data relevant to the study questions. All data extraction forms were independently cross-checked by IB.

Data analysis

As the included studies and reports were anticipated to be highly heterogeneous, two reviewers used the JBI critical appraisal tool for the relevant study design to make a quality assessment of each study meeting the full inclusion criteria. Again, due to the heterogeneous nature of the studies anticipated to be included, a narrative synthesis was planned and conducted. We used a simultaneous, convergent integrated approach to synthesis, exploring quantitative and qualitative together, because both methods help answer our research questions.[23] We synthesised and reported findings from studies with formal research study designs separately to case studies. Data was largely quantitative, and two researchers narratively summarised outcome data from quantitative studies. Narrative strengths and weaknesses from studies was also captured. There was only one formal qualitative study. For both formal studies and case studies, two researchers explored connections within and between case studies through tables and charts, visually organised intervention types (such as supply-side and demand-side), population characteristics (such as geographical region), timeframes, measures of impact, and contextual factors, such as underlying levels of IT.

The review protocol was pre-registered in PROSPERO (CRD42023452732) and a PRISMA checklist was completed. A PRISMA flow diagram is presented in Figure 1.

RESULTS

Table 1 presents the characteristics of studies which fully met the inclusion criteria from both peer-reviewed reports and the grey literature i.e. studies that outlined specific outcomes that were formally assessed against interventions. Table 2 presents a quality assessment of included formal studies. Table 3 presents the contextual factors and outcomes recorded in included formal studies. Table 4 presents included case studies where both interventions and associated outcomes were described, but the relationship between the two was not formally assessed. Supplementary File 2 presents excluded case studies which were identified in the grey literature search and provides the rationale for exclusion.

Studies meeting full inclusion criteria

All studies were in English. The five studies from five reports which fully met the inclusion criteria related to interventions conducted in Europe and Africa.[24–28] Four of the studies reported country-level interventions[25–28] and one reported on a subnational intervention.[24] Three of the five studies focused on track-and-trace systems,[25–27] one on implementing the Framework Convention on Tobacco Control Protocol to Eliminate Illicit Trade in Tobacco Products[28] and one on a subnational multiagency programme.[24] Two studies were health economic simulation studies[25,28] and three evaluated empirical interventions.[24,26,27] The duration for the empirical interventions ranged between 17

months and 42 months. The range of outcomes reported were heterogenous, with no overlapping outcomes across studies (Table 1).

Table 1: Overview of characteristics of included studies

First author (publication year)	Study type	Population	Intervention	Time covered	Outcomes measured
Liutkute-Gumarov 2023 [27]	Intervention fidelity assessment	Lithuania	European Union track-and-trace system	May 2019 - September 2020	Share of discarded cigarette packs with (1) a Lithuanian tax stamp (2) health warnings as per Lithuanian law (3) a unique identifier
Johnson 2009 [28]	Cost benefit economic simulation	United Kingdom	Implementing the FCTC protocol on IT in tobacco products	Projection from 2009 for 50 year span	Reduced healthcare costs Output gains due to reduced mortality Reduced absenteeism Years of life gained
McNeill 2014 [24]	Mixed methods (Repeated cross-sectional and qualitative)	North of England	Multiagency regional IT programme aiming to reduce the supply and availability of IT and reduce the demand for IT using marketing and communication	2009 – 2011	Awareness of, purchase of and attitudes towards IT Calls to hotlines to report IT Qualitative stakeholder perspectives on programme implementation
Munga 2023 [26]	Interrupted time series	Kenya	An excisable goods management system (a form of track-and-trace)	November 2013 - March 2017	Excise tax revenue changes
van der Zee 2024 [25]	Cost-consequence economic simulation	South Africa	Simulation of an independent, government-financed track-and-trace system	Projection beyond 2021	Cost-consequence model subtracting the cost of implementing a track-and-trace system from the additional revenue gained from tax

Quality assessment

All five studies that met the full inclusion criteria were quality assessed using the JBI critical appraisal tool for the relevant study design (Table 2). McNeill 2014 was assessed using two separate tools as it contained both qualitative and quasi-experimental data.[24] The two economic analyses were found to meet all relevant quality criteria.[25,28] All three quasi-experimental studies did not use a control group for at least some of their analyses.[24,26,27] Two of these studies met all other relevant criteria.[26,27] One study had two main quantitative outcomes for which design, sampling and measurement differed significantly.[24]

Table 2: Quality assessment of included studies

First author (publication year)	JBI checklist	Applicable criteria met	Applicable criteria not met	Overall appraisal
Liutkute-Gumarov 2023 [27]	Quasi-experimental	6/7	No: Control group	Include
Johnson 2009 [28]	Economic evaluation	11/11	None	Include
McNeill 2014 [24]	Qualitative	8/10	Unclear: congruity between philosophy and research methodology Unclear: statement locating researcher culturally/theoretically	Include
McNeill 2014 [24]	Quasi-experimental	5/8	Unclear: comparator participants were similar No: Comparator participants received similar treatment Yes and No: Control group Yes and No: Multiple measurements Unclear: Appropriate statistical analysis	Include
Munga 2023 [26]	Quasi-experimental	7/8	No: Control group	Include
van der Zee 2024 [25]	Economic evaluation	8/8	None	Include

Four of the five studies reported positive outcomes related to the interventions or modelled interventions (Table 3). One subnational English study (2009 – 2011) found an association between a co-ordinated multi-agency IT partnership strategy and social marketing campaign with the proportion of members of the public who disagreed that buying IT is 'no big deal', who disagreed that 'everyone buys IT' and would be likely to report someone suspected of selling IT. They also found increased calls to IT hotlines.[24] A Kenyan study found a statistically significant increase in the trend of excise tax revenue between 2013 and 2017, relative to the pre-intervention period, following an introduction of an electronic goods management system (EGMS).[26] A simulation study in England found that implementing the FCTC Protocol to Eliminate Illicit Trade in Tobacco Products in 2009 would be cost-effective across a range of scenarios, producing between £0.1 billion and £8.9 billion in net benefit.[28] A South African study simulated several scenarios for introducing a track-and-

trace system in 2021, finding that a cost-per-pack between US\$0.17-0.34 would break-even and reduce cigarette consumption between 5% – 11.5%, with comparable systems costing roughly US\$0.02 per pack.[25] A Lithuanian implementation study found that a European Union track-and-trace system was not implemented as planned in 2019, partially due to a lack of compliance from the tobacco industry. Post-track-and-trace implementation, 32% of all illicit and licit packs had no unique identifiers, and 5.8% of licit packs also did not have unique identifiers. [27]

Case studies

We identified 16 case studies from seven full reports within the published literature and grey literature, as some reports contained multiple case studies covering different geographies (Table 4). These reports did not use formal methods of assessment to assess the relationship between interventions with outcomes, nor conduct formal qualitative research. Rather, they provided a narrative description of approaches to tobacco control within a country or region and accompanying changes in the IT market or proxy measures. The highest number of case studies come from the United Kingdom (n = 3)[29–31] and United States (n = 3).[32,33] Nine of the 16 studies reported on multicomponent interventions delivered over a period of several years.[30–32,34]

Thirteen of the 16 case studies reported positive outcomes for IT interventions or multicomponent strategies.[29–34] Outcomes largely related to falls in the overall size and share of the illicit market and rises in tax revenue from tobacco products. Three case studies reported on mixed outcomes from interventions.[31,32]

All seven case studies focusing on single interventions considered interventions focused on disrupting supply, rather than demand.[29,30,33] Of the nine case studies reporting on multi-component strategies, the focus of the strategies was largely on disruption of supply.[30,32,34]

Methods for linking interventions to data on IT measures or proxies was mixed. Some case studies used a range of data sources to track illicit market share over time rather than a single timeseries and triangulated possible links between interventions and outcomes. Nine of the 16 reports used quantified illicit market share as a measure for the impact of interventions.[29–32] Seven of the 16 reports include licit tobacco sales or increased tax take as a measure of impact.[29–34] Case studies were written in peer-reviewed journals,[29,34] for the World Bank Group[31] and for research organisations and consultancies.[30,32,33] Case study authors did not have any apparent conflicts of interest. No case studies attempted to formally consider confounders other than interventions that could have affected illicit market share or other outcomes over time in analysis, although causal language was sometimes used in reporting results.

The highest-quality recent evidence was for independent, government-financed track-and-trace-systems, all coming from 2010 onwards. Recent positive outcomes for cost-effectiveness and impact were formally reported across two African settings.[25,26] Case studies also suggested a link between track-and-trace systems from the 2010s and cigarette smoking prevalence in Turkey and the Philippines[30] although this was based on triangulation of data sources rather than being formally assessed. There were examples of paper tax stamps being effective in older case studies from the US (1998 and 2002-6)[32,33]

and Brazil (2007).[32] The studies suggested that track-and-trace technology and methods must keep pace with the methods employed by those in the IT trade.

The review found other evidence for action being taken against IT in low and middle-income countries, although the interventions are heterogenous, and possible outcomes mixed.

Significant reductions in IT in Georgia were linked to broader anti-corruption reforms[31] but focus on enforcement volume and performance and public communication in Indonesia was not described as having a clear effect on IT prevalence.[31]

Common themes for strengthening interventions included the need to continually update enforcement and tracking methods to overcome methods used by the illicit trade, the avoidance of tobacco industry input into IT interventions, a focus on reducing corruption and strengthening tax governance, increasing investment into enforcement agencies, targeting interventions at all parts of the tobacco supply chain, and combining supply-side activity with demand-side communication campaigns.

Excluded studies

Reports were excluded for a range of reasons, including not reporting on outcomes, solely focusing on criminal enforcement, or solely summarising data that was also published in peer-reviewed journals or other case studies.[9,32,33,35–46] These are summarised in Supplementary File 2.

Table 3: Summary of findings of included studies

First author (publication year)	Contextual factors	Health and intervention-related outcomes	Cost-related outcomes	Intervention advantages and disadvantages
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<p>Liutkute-Gumarov 2023[27]</p>	<p>Illicit cigarettes comprised a high share of the market in Lithuania (20% in 2020, industry estimate).</p> <p>Lithuania had been using Codentify, an industry-developed system, since 2014, which did not appear to reduce IT market share.</p>	<p>No packs with EU unique identifiers (as required by EU track-and-trace system) were identified during track-and-trace transitional period.</p> <p>Post-EU track-and-trace implementation (June-Sept 2020) of 4259 packs, 32% had no unique identifiers. Most packs were illicit, but 5.8% of licit packs also did not have unique identifiers. Most duty-free packs did not have a unique identifier (84.7%).</p>	<p>Not assessed.</p>	<p>There is evidence that the industry did not start to phase in packs with unique identifiers until after the full compliance deadline.</p>
<p>Johnson 2009[28]</p>	<p>The FCTC Illicit Tobacco Protocol was still being negotiated at the time of publication.</p>	<p>Several effectiveness scenarios are modelled, ranging from 5% to 80% reductions in IT. To take one scenario, if the illicit market is reduced by 50% (an assumption of the authors based on EU and other countries adopting the FCTC protocol), averted smoking-related deaths are estimated to range between 311 and 660, with a central estimate of 488. Healthcare savings are estimated to range between £0.7 billion and £2.2 billion, with a central estimate of £1.5 billion. Output gains due to reduced mortality - £0.7 billion - £1.6 billion (central estimate - £1.1 billion). Output gains due to reduced absenteeism are estimated between £0.8 billion - £1.9 billion (central estimate - £1.3 billion).</p>	<p>The costs of implementation are estimated as being between £9 million and £53 million annually (equivalent to £0.2 billion and £1.1 billion Net Present Value (NPV) over 50 years).</p> <p>Using three scenarios, dependant on which other countries also introduce FCTC, NPV values are calculated.</p> <p>The 'EU only' scenario leads to small positive net benefits, with the central estimates varying between £0.1 billion (\$0.16 billion) for 5% reduction and £0.9 billion (\$1.4 billion) for 15% reduction in the size of the illicit market.</p> <p>For the 'EU and other countries' scenario the central estimates of the net benefits vary between £1.6 billion (\$2.5 billion) and £3.4 billion (\$5.3 billion) for 25% and 50% reduction in the size of illicit market respectively.</p> <p>The 'worldwide' scenario always produces large net benefits. The central estimate is between £4.1 billion and £5.7 billion (\$6.4 billion - £8.9 billion).</p>	<p>Authors did not consider benefits from additional increased tax collection, which would be considerable, or reduced organised crime activity.</p>
<p>McNeill 2014[24]</p>	<p>The North of England had a higher illicit share of the market than elsewhere in England. It was difficult to maintain funding for the regional IT programme as it was not viewed by commissioners as a core issue during a time of recession. There was a clear plan not to allow industry to get involved and mislabel IT as key issue.</p>	<p>There were significant increases in the awareness of IT (54% to 69%, $p < 0.01$), in those who disagree that buying IT is 'no big deal' (65% to 58%, $p < 0.05$), in those who disagree that 'everyone buys IT' (69% to 59%, $p < 0.01$) and in those who would be likely to report someone if you suspected them of selling IT (26% to 29%, $p < 0.05$).</p> <p>There were non-significant findings for 8 measures, including a non-significant reduction in purchase of IT from 20% to 18%) and in IT as proportion of total consumption for those who use IT (36% to 33%).</p> <p>There was a 261% increase in calls to Crimestoppers and a 126% increase in calls to Customs Hotline. The greatest increase observed in calls to Crimestoppers was in the</p>	<p>Not assessed.</p>	<p>Bringing together health and enforcement was described by interviewees as extremely helpful. An intelligence sharing agreement was crucial in ensuring all partners could access information from reporting.</p> <p>Social marketing campaign changed perspectives on IT and avoided legitimising legal tobacco by avoiding "low quality IT" lines of communication.</p> <p>Training local health workers received mixed opinions; some did not want to jeopardise relationships by discussing IT, others wanted to keep using "IT</p>

		year in which the social marketing campaign was run (328%).		has greater health harm" message rather than focus on organised crime.
Munga 2023 [26]	Past measures had proved relatively successful, including introduction of paper tax stamps in 2003 followed by enhanced security paper stamps in 2010, annual renewal of manufacturer license, and requirement for detailed provision of information on tobacco products. However, there was a lack of a single data sharing platform, which is described as a motivation for introducing an electronic goods management system.	Not assessed.	<p>The coefficient for overall change in level of excise tax revenue (immediate treatment effect) was 10 (95% CI -68.6 to 88.7, p = 0.798). The coefficient for change in trend was 13.5 (95% CI 3.4 - 23.5, p = 0.010). The post-intervention slope coefficient was 1.33 (95% CI -1.95 to 4.61, p = 0.419).</p> <p>The coefficient of the interaction term (Pre-intervention trend*-Level change) measuring difference between the pre-intervention and post-intervention slopes of the real excise tax revenue suggests a statistically significant increase in the trend of excise tax revenue relative to the pre-intervention period [P =0.010, 95 % CI =3.4,23.5]. There was a trend effect of the policy intervention, with difference in slopes of Ksh. 13.5 million per month.</p>	Authors speculate that weak evidence for an immediate effect may have been related to the teething problems installing the electronic goods management system and ensuring compatibility. They suggest that the statistically significant trend but statistically insignificant postintervention slope suggested that the intervention "arrested" a previous downward trend over time.
van der Zee 2024 [25]	IT is estimated to have a cigarette market share of 35% in South Africa, which is extremely high by international standards.	The primary break-even model makes the assumption that track-and-trace is 60% effective, leading a total decrease in consumption of 99 million cigarette packs (between 5% and 11.5% in 9 scenarios modelled) increased government revenue of 3.82 million R, illicit consumption to reduce by 43 - 377 million packs. It assumes that of 170 million illicit packs that are redirected to the licit market, 56 million packs will be forgone as they have become too expensive.	In the primary break-even scenario, the cost-per-pack for the T&T system is between R2.68 (US\$0.17) - R5.24 (US\$0.34). The lowest cost estimate is far more expensive than real world track-and-trace systems (US\$0.016 in Brazil, US\$ 0.023 in Kenya). If a system was implemented that costs the same as the Kenya system, there would be net additional revenue of R3.49 billion per annum at 0.6 effectiveness.	As a modelling study, it does not go into the advantages and disadvantages of various track-and-trace systems.

Table 4: Case studies identified

First author (publication year)	Population	Intervention	Time period	Major outcomes measured
Joossens (2008)[29]	United Kingdom	Anti-smuggling action plan	2000	Fall in illicit cigarette market share from 21% in 2000/1 to 13% in 2005/6.
Joossens (2008)[29]	Italy	Lawsuit and out-of-court settlement against Philip Morris	2000	Fall in seizures from 1673 tonnes in 1999 to 333 tonnes in 2000. Rise in legitimate sales from 96 thousand tonnes in 1999 to 103 thousand tonnes in 2002.
Joossens (2008)[29]	Spain	International efforts to combat cigarette smuggling	1993 - 2000	Increase in tax revenue from 2292 million euro in 1995 to 5232 euro in 2002. Decrease in illicit cigarette market share from 16% in 1995 to 2% in 2002.
National Research Council (2015)[33]	Michigan, USA	Tax stamp introduction	1998	14% rise in tax revenues, from \$531 million in 1998 to \$605 million in 1999.
National Research Council (2015)[33]	California, USA	Licensing requirements and digital tax stamp	2004/5	Tax revenue remained constant from 02/03 to 05/06, and then declined slower than projections, despite a past trend of sharply dropping revenue.
Ross (2017)[34]	Kenya	Multicomponent, including: <ul style="list-style-type: none"> • Paper tax stamps (2003) • Tax stamp verification, improved licensing controls, importer registration, cigarette production accounting reform and tax enforcement units • Electronic cargo tracking system (ECTS) to track cigarettes produced for export and cigarettes in transit (2010) • Track-and-trace system covering tobacco and other products (2014) 	2003 – 2015	<p>Paper stamps associated with 52% rise in legal sales from 2003 to 2004.</p> <p>Temporary measures in 2010 association with increase of legal and cigar sales by 67% between 2009 and 2010.</p> <p>Electronic Cargo Tracking System associated with up to 30% increase in legal cigarette sales near Western border of Kenya and industry-reported declines in illicit market.</p> <p>Excisable Goods Management System associated with 49% rise in legal sales between 2013 and 2015, 45% increase in tax compliance in 2014, and cigarette and cigar excise tax revenue increased by 20% (7% in real terms) from 2013 to 2015.</p>
Ross (2019)[30]	United Kingdom	Multicomponent, including: <ul style="list-style-type: none"> • Implemented enhanced enforcement and supply chain controls. • Mandated manufacturers to report product history. • Required all imported tobacco to have "UK DUTY PAID" labels. • Collaborated with postal services to tackle smuggling from Poland. • Introduced penalties for cross-border shopping. • Reduced duty-free allowances for EU travellers. • Increased the number of overseas intelligence officers 	2003 – 2016/17	<p>Market share dropped from a high of 20% in 2002/2003 to 8% in 2014/15. It then rose to 15% in 2016/17 against a backdrop of reduced smoking in general.</p> <p>Illicit trade dropped from 17 billion cigarettes in 2000/2001 to 6 billion in 2016/17.</p>
Ross (2019)[30]	Turkey	Digital stamp track-and-trace	2007 - 2011	Tobacco tax revenue increased by 83% between 2006 to 2011 despite daily adult smoking prevalence declining from 33.4% to 25.4%, suggesting proportionally lower illicit tobacco use.
Ross (2019)[30]	Philippines	Internal Revenue Stamps Integrated System	2013	Illicit cigarette consumption down to 5% in 2014 (industry predicted 19.4%). From 2013 – 2016, higher than projected tobacco tax intake, despite prevalence of

				cigarette use dropping from 28.3% in 2009 to 22.7% in 2015. In 2016, 99.6% of packs in retail space had tax stamps.
Sweeting (2009)[32]	Canada	Multicomponent, including: <ul style="list-style-type: none"> Export tax of \$8 a carton in combination with reduced excise tax Voluntary agreement with tobacco industry to reduce exports Anti-counterfeit tear-tapes 	2007 – uncertain	An unquantified decrease (described as significant) in counterfeit cigarette market in British Columbia was observed after the introduction of anti-counterfeit tear-tapes.
Sweeting (2009)[32]	California, USA	Multicomponent including: <ul style="list-style-type: none"> Licensing of entire supply-chain, from manufacturers to distributors to retailers Machine-readable tax stamp with unique identification number Quadrupling number of investigators with spot-citation powers 	2003 – 2007	\$292 million (26% market share) tax evasion losses in 2002 – dropped by \$56 million in 2006/7. Ratio of seizures per inspection fell from 27% prior to 2003 to less than 3% in 2006/7.
Sweeting (2009)[32]	Brazil	Multicomponent, including: <ul style="list-style-type: none"> 150% cigarette export tax (1998). Expanded to machinery and filters (2000) but ruled incompatible by MERCOSUR free-trade agreement Licensing, record-keeping and control stamp (1999) Enhanced taxation stamp required on the production line (2007) 	1998 - 2007	Illicit market share stayed high - from 37% in 1998 to 30% in 2006.
Sweeting (2009)[32]	United Kingdom	Multicomponent, including: <ul style="list-style-type: none"> National network of x-ray scanners Stronger penalties for smugglers and sellers Over £5 million in media campaigns aimed at smugglers Memoranda of Understanding with three major cigarette manufacturers Investigations by Health Select and Public Accounts Committees Supply chain legislation meaning manufacturers can be fined up to £5million (2006) "Counterfeit Kills" public awareness campaign (2008) 	2000 - 2007	Illicit cigarette market decreased from 21% in 2000 to between 8-18% in 2006-2007. Reduction in genuine UK brands in illicit market, from 31% in 2002 to 17% in 2006-2007.
World Bank Group (2019)[31]	Georgia	Corruption and tax administration reforms	2004 – 2017	Decrease in illicit market share from 51.63% in 2002 to 0.44% in 2016 (Euromonitor data, 2017). Largest drop from 2005 (48.08%) to 2009 (2.41%). Trend reported by Euromonitor corroborated by other reports (e.g. in 2017, Healthcare Committee of Georgian Parliament estimated <3% illicit share of consumption, Ministry of Finance estimated 2%).
World Bank Group (2019)[31]	United Kingdom	Multicomponent, including: <ul style="list-style-type: none"> £209 million for frontline and investigative personnel (2000 - 2002) Fiscal marks on UK duty-paid products (2000) 200 additional staff to focus on hand-rolled tobacco (2006) Memoranda of Understanding with tobacco manufacturers (2006) Supply chain legislation, where manufacturers can be fined up to £5million (2006) Adopting advanced technology, improving intelligence and detection capabilities, pursuing 	2000-01 to 2016-17	During first ten years of the IT strategy, from 2000-01 to 2009-10, the illicit market share for cigarettes was nearly halved, dropping from 22 percent to 12 percent (central estimates). The illicit market share for hand rolled tobacco dropped from 61 percent to 44 percent (central estimates) during the same period. The illicit market share of cigarettes increased between 2010-11 and 2016-17. Due to a decline in smoking prevalence, the size of the illicit market remained stable during this period at around 5 billion cigarettes per year. Hand rolled tobacco decreased in terms of both market

		proceeds of crime, and reducing personal import limits (2011)		share and volume (4.2 million kg in 2010-11 to 2.7 million kg in 2016-17).
World Bank Group (2019) [31]	Indonesia	Multicomponent, including: <ul style="list-style-type: none"> • New performance contract for tax delivery multi-agency action plan. • The STOP Illegal Cigarette media campaign. • Enforcement and post-enforcement activities (~1000 in 2014 rising to ~4,000 in 2017) 	2014 - 2018	Mixed data sources show illicit share of cigarette market to rise from 6.14% in 2010 to 14.19% in 2016 then fall to 7.04% in 2018.

DISCUSSION

Summary of findings

Our review identified only a small number of formal studies which assessed the effectiveness of interventions to tackle IT, including track-and-trace systems, a sub-national multi-agency IT programme and the FCTC Illicit Tobacco Protocol. Four of the five included studies found positive associations between health-related and economic outcomes. However, significant heterogeneity between the studies means that it is not possible to draw conclusions as to the most effective and cost-effective interventions. A series of narrative case studies also generally reported positive changes following the implementation of interventions to tackle IT, including falls in the illicit market share and rises in tax revenue from tobacco products.

Interpretation of findings

IT continues to undermine tobacco control policies, even in countries such as the United Kingdom where a long-running IT strategy is widely reported as successful.[31]

Understanding which interventions to tackle IT are most effective and why is essential to addressing the problem; however, there are few formal studies which have evaluated such interventions. We identified only three empirical studies, indicating that interventions to tackle IT are not systematically evaluated. We also identified two modelling studies; such studies are valuable in demonstrating the potential benefits of investing in IT interventions, but are likely to be more robust when underpinned by empirical evidence. These studies

found both economic and health benefits associated with IT interventions, indicating the value of IT interventions to a range of policy sectors. Most of the evidence on IT interventions was found in case studies; while these are useful in providing insights into experiences of IT interventions – mostly at the national level - and possible outcomes, they are not designed to assess causal associations and may be subject to bias.

Despite the limited evidence, our review gives an indication of the range of interventions that can be used to tackle IT, including both supply and demand-side interventions. IT is a problem which crosses borders but also affects local communities and therefore needs to be addressed at the local level as well as through national and international approaches. Only one of the studies included in the review focussed on sub-national interventions. There is a need for better understanding of the effectiveness of interventions and approaches at different geographical levels and how they interrelate. Most interventions assessed focussed on supply side interventions; however, particularly at the local level, demand-side interventions, such as awareness campaigns, may also be important, and therefore evaluation of both supply and demand-side interventions is warranted.

Our findings highlight possible tobacco industry strategies to hinder interventions to tackle IT. For example, Liutkute-Gumarov et al identified slow implementation of track-and-trace system-compliant packs in Lithuania,[27] in the Philippines the tobacco industry significantly underestimated the impact of a tax stamp system on the size of the illicit market[30] and Joossens outlined the weakness of MOUs on IT with the tobacco industry, which are not legally binding, rely on tobacco industry goodwill and include no penalties or seizure payments.[29] Other studies that did not meet our inclusion criteria set out narrative of tobacco industry involvement in IT policy, including assessments of the flawed tobacco-

industry backed track-and-trace system Codentify. In contrast to independent, government-financed systems, Codentify relies on changing information held by the tobacco industry to verify legitimacy,[47] is poorer at detecting IT than independent solutions,[48] and is in breach of the FCTC Illicit Trade Protocol.[49] Other articles highlight Philip Morris International (PMI) funding of illicit trade research,[50] PMI subsidiary donations to the Hellenic Coast Guard to “combat trade of illicit cigarettes”[51] and further assessment of the European Union’s ineffective MOU with the tobacco industry.[52] Tobacco industry behaviour and possible strategies to hinder IT interventions should be systematically monitored.

As highlighted by many of the included studies and case studies, IT interventions are typically complex interventions: they have multiple interacting components, which target different aspects and groups affected by and involved in illicit trade, and are implemented in different ways depending on the context.[53] For example, they might combine supply side components such as tax stamps, penalties for those involved in illicit trade, and tracking and tracing systems with demand side components such as awareness-raising campaigns. This complexity may partly explain the limited number of evaluation studies that have been conducted: the interventions involve overlapping components which develop and are implemented at varying levels of intensity over time. Furthermore, evaluation of the interventions is usually not planned prospectively, reducing the likelihood of suitable data being collected. Stakeholders who are involved in developing and implementing IT interventions, such as enforcement agencies, public health agencies and tax and revenue authorities, should seek to incorporate evaluation planning and engagement with independent researchers into the intervention development process, particularly as efforts to tackle IT

globally gather momentum.[54] The public, particularly those with experience of the harms of IT, should be involved in informing the design of this research.

IT interventions are not well suited to randomised controlled trials, and therefore evaluation of their outcomes relies on quasi-experimental analysis of high-quality data based on real-world implementation. While using seizure data to monitor the results of interventions is of value, changes to operational priorities, IT enforcement funding and recording procedures may also influence seizure data. Therefore, robust quantitative evaluation requires regular estimates of the scale of the illicit market and IT use, including population surveys. In many settings obtaining this type of data may be difficult.[55] Furthermore, comprehensive evaluation requires process evaluation, to “assess fidelity and quality of implementation, clarify causal mechanisms and identify contextual factors associated with variation in outcomes”.[56] Process evaluation, particularly using qualitative methods such as interviews with organisations involved in implementing and delivering interventions and assessment of public attitudes towards IT, may be particularly important in cases where quantitative evaluation indicates a lack of success, as it can shed light on barriers to success, such as limited enforcement. Understanding contextual factors which affect IT interventions is crucial for assessing how an intervention might be replicated in other settings. Future studies which evaluate IT interventions may also need to incorporate evaluation of measures implemented to tackle illicit e-cigarettes, such as those funded in England.[57]

Limitations

This review is the first to synthesise evidence on the impact of interventions to tackle IT, but it has some limitations. We searched a limited number of databases; however, our scope was health-related outcomes, rather than other outcomes such as tax policy and crime prevention,

and therefore we chose to search health-related databases. The main limitations of the review relate to the limited evidence that met the inclusion criteria and the predominance of case study designs, which meant our research questions were largely unanswered. We were not able to test for publication bias, which may mean more successful interventions are overrepresented. We did not exclude by language or geography, but some non-English language studies may not have been captured. As described above, we primarily identified case studies of interventions, rather than formal evaluations, which were not designed to establish cause and effect and have high risk of bias; we synthesised case studies separately from research studies to mitigate this. Among formal evaluations, only one study focused on demand-related outcomes such as attitudes towards IT and the remainder were focused on the supply-side.

CONCLUSIONS

Taken together, research evidence and national and international case studies demonstrate that up-to-date, independent, government-financed track-and-trace systems can have positive effects on health and economic outcomes. However, we find IT interventions are not systematically evaluated, and our review relies on case studies at high risk of bias, impacting the certainty of our findings. Little is known about the differential success of individual components or types of interventions. Furthermore, we find the exploration of barriers and facilitators which influence the effectiveness of interventions, including contextual factors, have generally not been incorporated into evaluation and modelling studies. The absence of independent research in this area risks the evidence gap being filled by other actors such as the tobacco industry, whose research may be unreliable and used to lobby against tobacco control interventions.[58,59] Comprehensive independent evaluation, comprising outcome and process evaluation and including impact on IT supply chains, prevalence and frequency

of IT use, and quantitative and qualitative measures of public attitudes towards IT should be planned prospectively when designing and implementing IT interventions.

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Data availability statement

Data available on request.

Contributorship statement

TL, IB, MB and LJ conceptualised the study. TL, IB, MB and LJ designed the protocol. TL, IB, MB, LJ and ND screened the data. ND and IB extracted the data. TL and ND conducted quality assessment. TL and ND conducted synthesis. ND and TL wrote the first draft of the paper. IB, MB, and LJ contributed to the final draft of the paper. All authors approved the final manuscript.

TL is the guarantor.

Ethics statements

Not required.

Patient consent for publication

Not applicable.

Conflicts of interest.

None declared.

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