Review of: "Tobacco endgame intervention impacts on health gains and Māori:non-Māori health inequity: a simulation study of the Aotearoa-New Zealand Tobacco Action Plan"

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Potential competing interests: No potential competing interests to declare.

Summary

Building on recent progress towards the New Zealand Smokefree 2025 goal, the Government plans to introduce tobacco control legislation giving ministers powers to implement three significant new policies:

- a steep reduction in the number of retail outlets that can sell tobacco;
- a 'smokefree generation' proposal that would make it illegal to sell tobacco to anyone born after a certain date, and;
- regulations to remove most of the nicotine from tobacco to reduce its appeal and addictive effects.

In preparation for this legislation, the Ministry of Health funded academics from Australia and New Zealand to model estimates of the likely impact of these measures, especially their contribution to achieving the Smokefree 2025 goal. The modelling, published as a preprint, Ouakrim et al. (2022)[1], is the subject of this review. It focuses on the modelling of the denicotinisation of tobacco because, according to the authors, it has the greatest impact.

A number of significant flaws have been identified. The modelling is based on a fundamental and incorrect assumption that denicotinisation would reduce smoking by 85% over five years compared to business-as-usual. This draws on an earlier modelling paper, Wilson et al. (2022),[2] supplemented by other literature and expert opinion.

The assumption, used as a key input to the model, is derived from a misinterpretation of a well-conducted randomised controlled trial of smoking cessation interventions that included very low nicotine content (VLNC) cigarettes in New Zealand in 2009-10, Walker et al. (2012).[3]

The problem is that the trial design bears little relation to a population-wide denicotinisation regulatory intervention and its findings are not at all transferable to a model of the legislation.

- Volunteers who had already called the Quitline were given pharmacological and behavioural support;
- The intervention group were also given free VLNC cigarettes and instructed to smoke them if they wanted to;
- The trial intervention lasted only eight weeks and its impact assessed at six months.
- The trial does not include the most likely responses to the denicotinisation measure: switching to vaping, accessing an expanded illicit market, or workarounds by consumers or producers.

The results of the trial indicate that the 7-day abstinence quit rate at six months increased to 33% in the group with access to VLNC cigarettes, compared to 28% in the "usual care" control group, a 5% increment. The modelling, however, implicitly assumes that:

- All people who smoke - including people with no interest in quitting or who are unable or unwilling to access pharmacological and behavioural support - would achieve this rate of quitting;

- The same quit rate would apply if people had to purchase denicotinised cigarettes, rather than receive them free of charge.

- All of the quit rate, 33%, could be attributed to the introduction of a population-wide denicotinisation policy and this quit rate would compound over five years, deriving, erroneously, an 85% reduction in smoking prevalence; the trial provides no basis for assuming a regulatory intervention will have this smoking cessation effect after one year or that it will repeat year after year.

Finally, the modelling makes unrealistic estimates of the implementation timetable, transitional arrangements, and the effects of stocks and hoarding. In doing so, it greatly exaggerates any likely impact on the 2025 targets.

In conclusion, the modelling on which the proposed legislation is based is seriously flawed:

- It makes ill-founded assumptions based on a misinterpretation of a smoking cessation trial in which denicotinised cigarettes were provided as an enhancement to standard smoking cessation interventions to people who were already making a quit attempt.

- It does not reflect the real-world dynamics of the population-wide regulatory intervention it is supposed to represent.

- It fails to take into account illicit trade in regular tobacco and other "workarounds". This could be substantial and must be incorporated into any modelling of the denicotinisation measure.

- Modelling the legislation for policymaking purposes should more accurately reflect the real-world processes involved (e.g. illicit trade, workarounds, switching to vapes) and place greater emphasis on transparency of the assumptions used, sensitivity testing and scenario analyses.

Recommendations

We recommend that the government reconsiders its confidence in the policy assessment and impact analysis that underpins Cabinet support for denicotinisation. We note that further forecasts of impact will not be reliable or informative at this stage.

We recommend that the Government should require that:

- Future modelling should focus on testing a range of scenarios in relation to quitting behaviours, switching to smokefree products, and access to illicit tobacco products;

- A more focussed examination be undertaken of plausible unintended consequences of the legislation and the impact of trying to impose abrupt non-voluntary smoking cessation on the whole population;

- Further analyses examine the optimum timing for introducing these measures, for example, once smoke-free alternatives are more widely accepted and used voluntarily as alternatives to smoking

- Such analyses build on recent progress towards the Smokefree 2025 goal by strengthening existing measures which seem to be working including a broader and more concerted push to encourage people who smoke to change to

smoke-free alternatives.

Introduction

To help New Zealand come closer to meeting its *Smokefree Aotearoa 2025* target to reduce adult daily smoking prevalence to below 5 per cent by 2025,.[4][5] the Smokefree Environments and Regulated Products (Smoked Tobacco) Amendment Bill now before Parliament proposes three major tobacco policy interventions with the following aims:[6]

1. To significantly limit the number of retailers legally able to sell smoked tobacco products.
2. To prevent young people from taking up smoking by prohibiting the sale of smoked tobacco products to anyone born on or after 1 January 2009.
3. To make smoked tobacco products less appealing and addictive, primarily by reducing nicotine levels in tobacco on sale in New Zealand ("denicotinisation").

With funding from the New Zealand Ministry of Health, Ouakrim and colleagues[1] have modelled the effect of these measures on smoking prevalence and ultimately on health outcomes and health disparities. This modelling has been promoted in support of a political decision to implement the measures.

For example, a commentary, *New Zealand's 'tobacco endgame' law will be a world first for health – here's what the modelling shows us,* enthusiastically backs the measures and assert that the modelling was used as part of New Zealand Cabinet deliberations on the proposals.[7]

> Our findings underpinned the regulatory impact statement that set out the options to regulate tobacco products as part of the action plan, which Cabinet considered in early 2022.

The relevant Cabinet paper confirms the modelling was a material consideration in the government's decision to proceed with these measures:[8]

> The University of Melbourne undertook modelling to inform the proposed actions. This provides confidence that the bold actions proposed are required to meet the goal.

While the intentions of the Bill are laudable, measures with a coercive restrictive element often give rise to perverse unintended consequences.[9] Further, over-reliance on the apparent sophistication and precision of models may lead decision-makers into complacency about unwanted harmful effects arising from such policies, and to dismiss the need to mitigate these risks.

The credibility of the modelled results, and the claims made about them, clearly depend on the credibility of the assumptions entered into the model. The critical assumption in the main modelling paper, Ouakrim et al. 2022[1] is based on two earlier papers: Wilson et al. 2022,,[2] which is an effort to model the effects of tobacco denicotinisation in New Zealand, and Walker et al. 2012[3] which is a randomised controlled trial conducted in New Zealand in 2009-10 and used as the source for the major assumptions in the Wilson et al. modelling paper. The data from the earlier papers is

supplemented by other literature and expert opinion, including opinions of the authors.

Analysis

This analysis reviews the three papers in turn and highlights major concerns with the ultimate findings of the Ouakrim et al. modelling. Ten specific problems are identified.

Are the critical assumption made in Ouakrim et al. 2022[1] credible and evidence-based?

This paper reports on modelling of combinations of the three "endgame" strategies incorporated in the legislation, making assumptions about their timing and scale:

> *1. Denicotinisation of all retail tobacco in 2023,*
>
> *2. 1 plus media promotion,*
>
> *3. 95% reduction in tobacco retail outlets in 2023,*
>
> *4. a tobacco free-generation whereby people born in 2006 and later are never legally able to purchase tobacco,*
>
> *5. combined package of 2, 3 and 4.*

This review focuses only on the denicotinisation measure because it dominates the benefits generated by the model both individually and when the interventions were combined. According to Ouakrim et al.:

> *The denicotinisation strategy alone achieved 97% of these HALYs [health-adjusted life-years], the retail strategy 19%, and tobacco-free generation 12%.*
> **Conclusion** *A tobacco endgame strategy, especially denicotinisation, could dramatically reduce health inequities.*

To reach this finding, Ouakrim et al. make a bold input assumption that in five years, smoking prevalence will fall to approximately 15% of business-as-usual (BAU) as a result of the denicotinisation measure and adjusted their smoking cessation rates to align with this assumption.

> *Denicotinisation: initiation was estimated to reduce to 10% (95% UI 2.6% to 21.5%) of that in BAU by five years after implementation;* **cessation transition probabilities were increased so that over five years the smoking prevalence in CS [current smoker] and DU [dual use] states was 15.2%** *(95% UI 3.7% to 32.9%)* **of that in BAU***, and from the sixth-year onward cessation transition probabilities were doubled. (bold emphasis added)*

This assumption, an 85% reduction in smoking prevalence compared to BAU, produces extremely abrupt declines in smoking in all groups, as shown in the graphic below extracted from Ouakrim et al. Figure 1. Findings of such abrupt changes in behaviours that have proven stubbornly resistant to policy over many years of tobacco control policy test the boundaries of plausibility. Perhaps, they are possible: but it should require convincing evidence for legislators and policymakers to rely on such changes.
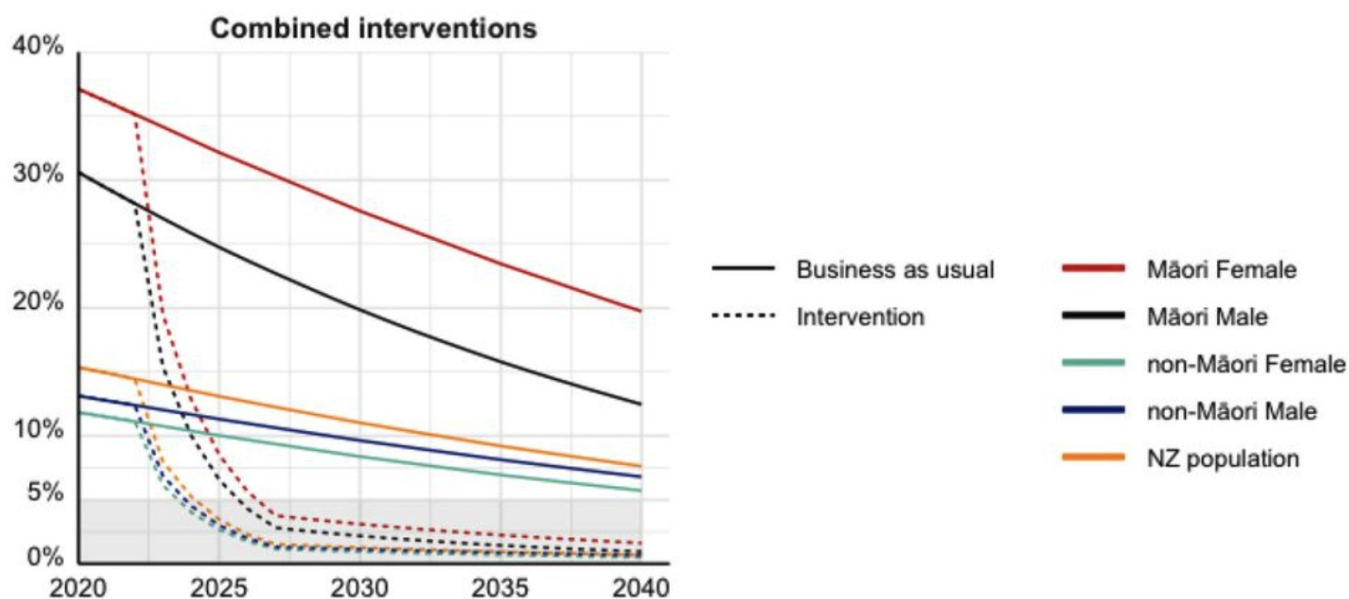
Problem 1. The authors have built a dramatic expected decline in smoking into their model *as an input*

Deep reductions in smoking prevalence are included as an *input* to the model. Unsurprisingly, dramatic declines in smoking emerge as an *output* of the model and account for the gains in health and health equity shown in the rest of the modelling. As this review will show, both the structure of the model and the basis for this critical assumption does not stand up to scrutiny of the sources on which it depends.

Ouakrim et al. support their input assumption of an 85% reduction in smoking prevalence compared to BAU with reference to Wilson et al. 2022 (which is cited as reference 28 in Ouakrim et al.) plus their own expert judgement and other opaque sources.

> *To parameterise the intervention scenarios we adapted initial estimates by **Wilson et al, (28)** which derived their potential effects based on A/NZ-specific literature (including a randomised trial of denicotinised cigarettes) and international literature; adaptation for this paper included incorporating additional research and **expert judgements by the authors**. (bold emphasis added)*

Problem 2. Critical assumptions and the literature used are not transparent, and authors rely on their own expert judgement, introducing risks of bias

The published preprint includes the disclaimer that "This article is a preprint and has not been peer-reviewed. It reports new medical research that has yet to be evaluated and so should not be used to guide clinical practice". It is important, therefore, to scrutinise the nature and provenance of critical assumptions made by the authors.

For the analysis to be credible as a basis for policymaking, there must be clarity about the assumptions made and why they were chosen. Given the Ouakrim et al. modelling results are largely determined by the input assumptions made about

smoking cessation, the statement above describing how the authors made their assumptions ("*parameterise the intervention scenarios*") is insufficient and too opaque. It raises several questions.

- Why was the modelling of Wilson et al., and the particular trial it relied on, deemed a reasonable proxy for characterising the impacts of population-wide denicotinisation legislation?
- How did Ouakrim et al. translate the trial data, literature and expert judgements into an assumption that around one-third of smokers would quit in the first year and this would repeat annually?
- Which international literature was selected, and how was this chosen?
- Was other trial data considered?
- What role did expert judgements play, how did they affect the assumptions, and on what experience and evidence were these judgements based?
- How were plausible unintended consequences, such as a rise in illicit trade, addressed and incorporated?

There is no experience of a population denicotinisation intervention to draw upon and no expertise anywhere in the world in implementing and evaluating such a measure. It follows that any assumptions made about its effects will be speculative and vulnerable to confirmation bias and, therefore, must be highly transparent and open to challenge.

With this sort of modelling exercise, authors should convene independent experts other than themselves to advise on modelling assumptions in a transparent manner. This approach is to lend a measure of impartiality and to avoid bias arising from the policy preferences of the authors. This is important given some of the authors are committed advocates of the 'endgame proposals' having advocated for VLNCs for several years (see the Blakely, Waa, & Ouakrim Conversation commentary[7]).

> *If successful, this would be a monumental achievement for generations of tobacco-control advocates and researchers. The concept of a "tobacco endgame" will move beyond aspiration and into reality.*

This overt policy preference amounts to a significant and unacknowledged conflict for the authors. However, the more fundamental weaknesses arise from assumptions made by Wilson et al., which were then incorporated into Ouakrim et al., as discussed below.

Are the assumptions about smoking cessation made in Wilson et al. 2022[2] credible and evidence-based? Wilson et al. set out their assumptions on the modelling of the impact of denicotinisation:

> 4. **We assumed that 33% of smokers would quit in 2023** as per the New Zealand trial data for such products (more specifically, in a trial of 1,410 people, 33% had quit at six months with no reported difference in impact between Māori and non-Māori (31). The remaining 67% were assumed to continue smoking, using either denicotinised tobacco or regular tobacco (obtained via illicit supply or via home-grown tobacco for personal use, which is legal in New Zealand).
>
> 5. We assumed that there would be the **same impact in 2024 and 2025 as there would be in 2023** (ie, 33% of smokers using denicotinised tobacco would quit per year).

> *(bold emphasis added)*

Note: Reference 31 in Wilson et al. 2022 cites the Walker et al. 2012 RCT discussed below.

These assumptions form the basis for the extremely high and abrupt rate of smoking cessation assumed by Ouakrim et al. However, neither of these assumptions is justified by the findings of the Walker et al. trial, as we show in the discussion of that paper below.

Does the Walker et al. 2012[3] trial support the assumption of a 33% quit rate following a nationwide denicotinisation measure?

No criticism of the Walker et al. trial and paper is expressed or intended. Its findings are modest, and its conclusions are cautiously stated. The scientific concern is that Wilson et al. and, therefore, Ouakrim et al. have significantly misinterpreted the Walker et al. trial findings.

Problem 3. The Walker et al. smoking cessation trial bears no relation at all to the effect of imposing a population-wide nicotine regulation covering all smokers

There is no basis for incorporating this effect size of 33% smoking cessation rate into the Wilson et al. modelling and, therefore, into the Ouakrim et al. modelling.

In the Walker et al. trial, the trial population only included people already sufficiently motivated to quit that they had previously called the Quitline. The trial specifically examined what happened when denicotinised cigarettes were added to the relatively intensive smoking "usual care" cessation intervention offered by the Quitline. Walker et al. describe it as follows:

> *Aim: To determine the combined effect of very low nicotine content (VLNC) cigarettes and usual Quitline care [nicotine replacement therapy (NRT) and behavioural support] on smoking abstinence, **in smokers motivated to quit.** Design Single-blind, parallel randomized trial. Setting New Zealand. **Participants Smokers who called the Quitline for quitting support** were randomized to either VLNC cigarettes to use whenever they had an urge to smoke for up to 6 weeks after their quit date, in combination with usual Quitline care (8 weeks of NRT patches and/or gum or lozenges, plus behavioural support) or to usual Quitline care alone.*
> *(bold emphasis added)*

Most people who smoke in New Zealand are not this motivated to quit (i.e. to the point of taking action), most are not accessing these services or interventions, and most are not volunteering to participate in an experiment. Ouakrim et al. estimate a 'business as usual' quit rate of about 3% per annum.

Walker et al., *by design*, do not use a population that is remotely representative of New Zealand's smoker population. The enhanced smoking cessation intervention in Walker et al. is also not a credible proxy for the market-wide denicotinisation measure, which does not involve mass participation in smoking cessation treatment and counselling for all smokers, even if offered. Uptake of such services might increase to some extent following the legislation, but it cannot be assumed that

the quit rates found with this quite intensive short-term intervention can be generalised to the whole population in response to a denicotinisation mandate. The conditions, intervention, duration and affected populations are *completely different*.

Problem 4. The results presented by Walker et al. show a small incremental effect from the denicotinised cigarettes, not the 33% used by Wilson et al.

A critical assumption in Wilson et al. is that the denicotinisation measure leads to a 33% smoking cessation rate. But the Walker et al. trial shows that offering denicotinised cigarettes made a small incremental increase in the smoking cessation rates in the intervention group compared to the "usual care" control group:

> *Participants in the intervention group were more likely to have quit smoking at 6 months compared to the usual care group [**7-day point-prevalence abstinence 33 versus 28%**, relative risk (RR)=1.18, 95% confidence interval (CI): 1.01, 1.39, P=0.037]*
> *(bold emphasis added)*

The impact made by offering denicotinised cigarettes alongside conventional smoking cessation treatments was to raise the quit rate from 28% to 33%, just five percentage points. This was only just statistically significant and only applies in this particularly motivated group alongside the "usual care" intervention. If most smokers were like that, then without denicotinisation, there would be an annual baseline smoking decline of compound 28% per year, applying the logic of Wilson et al.

Wilson et al. and Ouakrim et al. cannot assume that the intervention they are modelling ("banning nicotine-based tobacco for everyone in a country") has the same effect as the intervention used in the Walker et al. trial ("offering denicotinised cigarettes to smokers enrolled in a smoking cessation programme") yet that is what they have done. Even more concerning, most (28% of the 33%) of the smoking cessation effect used in subsequent modelling is not even attributable to denicotinised cigarettes but to the quitting behaviour of this motivated group accessing conventional smoking cessation services.

Problem 5. Denicotinised cigarettes were given free to smokers as part of a trial, but in real life, smokers would have to pay and are unlikely to use these products

The smokers calling the Quitline in the intervention group were given their denicotinised (referred to in Walker et al. as VLNC - very low nicotine content) cigarettes underline free-of-charge as part of the trial and instructed to use them when they wished to smoke.

> *Intervention group participants were delivered a carton of 200 VLNC [denicotinised] cigarettes (Quest 3 brand; Vector Tobacco Inc.) by courier, at no cost. Participants were instructed to stop smoking their regular cigarettes on their designated quit day (QD) and to smoke the VLNC cigarettes ad libitum whenever they had an urge to smoke during the subsequent 6 weeks.*

But under the proposed legislation, VLNCs are mandated for the entire smoking population, not provided to manage abstinence for motivated quitters as per the trial. The goal of the proposed policy is not the same as the goal of the trial on which assumed impact is based. The impact of forced abstinence will likely see very different outcomes.

Smokers would need to choose denicotinised cigarettes from the available alternatives, legal or illegal, and buy them with their own money. However, a vast literature characterises tobacco use as primarily a nicotine-seeking behaviour[10] and concludes that nicotine is the reason people smoke.[11] It is unlikely, therefore, that many smokers would choose to spend their money on tobacco with minimal nicotine content. In fact, the Walker et al. trial suggests that few users wanted these products, even if free. Only around one-fifth of those using VLNC cigarettes wanted any more of these free-of-charge cigarettes when offered at the three-week point in the trial:

> Overall, 94% (583) of the 619 participants in the intervention group who could be contacted at 6 weeks had smoked the VLNC cigarettes given to them, **with 21% (n = 132) asking for a second carton.**
> (bold emphasis added)

It is far more likely that smokers will seek out nicotine from other sources (illicit tobacco, vaping, renicotinisation) than purchase denicotinised tobacco. The Walker et al. trial does not try to reflect the real decisions smokers would likely make when faced with a range of choices following a denicotinisation regulatory intervention.

Does the Walker et al. 2012[3] trial support the assumption of continuing year-on-year smoking cessation rates of 33%?

The authors build on the inappropriate use of the 33% quit rate from the Walker et al. trial discussed above by making a further assumption that this rate if smoking cessation will continue and compound over multiple years.

> 5. We assumed that there would be the same impact in 2024 and 2025 as there would be in 2023 (ie, 33% of smokers using denicotinised tobacco would quit per year).

It is this compounding of the 33% smoking cessation rate that underpins the assumption of an 85% reduction in smoking prevalence in Ouakrim et al. Though the assumption is not made explicit, a compound annual 33% decline over five years (the timeframe of the assumption made in Ouakrim et al.) results in an approximately an 85% decrease used in Ouakrim et al. The effect size extracted from the Walker et al. trial and an assumed projection that this will continue and compound for several years is the critical underlying assumption in the Ouakrim et al. paper. There is no basis for making this assumption.

Problem 6. The authors assume that the smoking cessation effects estimated in year 1 will continue and accumulate in subsequent years

There is no basis for assuming that the initial effect of the denicotinisation measure would be replicated and compounded

at the same rate over three years (or, it seems, for five years in Ouakrim et al 2022). It is not possible to support this assumption with the findings from the Walker et al. trial on which the estimate of Wilson et al. is based. The Walker et al. trial concentrated the availability of denicotinised cigarette intervention into just six weeks with a follow-up to look at the results after six months. Walker et al. have nothing to say about subsequent years or a longer intervention than six weeks. The Wilson et al. assumption of continuing cumulative smoking cessation rates equivalent to the initial effect seen in the Walker et al. trial is pure invention.

It is likely that there would be a lower quitting propensity among those that did not quit at the first opportunity. These smokers would tend to be more dependent, less motivated to quit or more committed to continued smoking, and more likely to access a black market.

Have Wilson et al. made reasonable assumptions to incorporate illicit trade into their modelling?

In the Wilson et al. model, two-thirds (67%) of smokers continue to smoke after the first year of the denicotinisation legislation.

> *4. We assumed that 33% of smokers would quit in 2023, as per the New Zealand trial data for such products (more specifically, in a trial of 1,410 people, 33% had quit at six months with no reported difference in impact between Māori and non-Māori (31).* **The remaining 67% were assumed to continue smoking, using either denicotinised tobacco or regular tobacco (obtained via illicit supply or via home-grown tobacco for personal use, which is legal in New Zealand).**
> *(bold emphasis added)*

The paper recognises that some of these may be accessing illicit trade in regular tobacco. But it does not provide an explicit assumption about the share.

Problem 7. The authors do not have a transparent approach to illicit trade and appear to have ignored it

Wilson et al. have made a hidden or implicit assumption about illicit trade. What if most of the 67% who continue to smoke in year 1 are actually using regular tobacco (e.g. illicit or homegrown), not denicotinised tobacco? Why would these users have an elevated quit rate in subsequent years, as stated in point 6? If there is an available illicit supply, it is possible that many of those in the initial wave of quitting would relapse to using illicit trade in regular tobacco as the illicit market develops. It matters, therefore, what sort of tobacco the 67% who do not quit immediately are using (denicotinised or regular). The approach to illicit trade taken by Wilson et al. is opaque and not articulated. Ouakrim et al. appear to dismiss it as irrelevant.

> *Homegrown tobacco for personal recreational use, and illicit supply, may provide some alternative tobacco source in A/NZ with denicotinisation or substantial reduction in retail access. However, homegrown tobacco is uncommon in A/NZ due to a non-ideal physical environment in most of A/NZ for growing, and tight border security in an island nation with no land borders reduces the potential of an illicit market.*

It is impossible to assess the impact of these measures without including an assessment of consumer and supplier reactions, some of which may be illegal under the proposed regime. Such reactions might include:

- Large-scale smuggling of regular cigarettes
- Cross-border trade in cigarettes via internet mail order
- Significant switching to regular hand-rolling tobacco because it is easier to smuggle
- Illicit domestic manufacture of cigarettes, cigars or rolling tobacco
- Counterfeiting denicotinised cigarettes with regular nicotine levels to avoid detection
- Use of tobacco grown on private land or in controlled environments in New Zealand
- Addition of liquid nicotine to denicotinised tobacco
- Other workarounds arising from unforeseen consumer, supplier or criminal ingenuity

Rather than ignore these possibilities, a model should include illicit market developments explicitly as a module to reflect the role of illicit markets in the real word they are modelling. This applies even if the modellers wish to argue that these effects will be small. Then at least, their assumptions will be visible and open to scrutiny, sensitivity testing and challenge.

How should policymakers and legislators think about these measures?

The problems listed above describe concerns about how the modellers choose assumptions to feed into their model. The second class of problems relates to what the modellers *did not do* and how a more rigorous policy assessment should be approached.

Problem 8. The modellers should treat the denicotinisation measure like a *de facto* ban of regular tobacco rather than a smoking cessation measure

Given smoking is well understood as a nicotine-seeking behaviour, it would be better to model denicotinisation as an outright ban on tobacco, rather than as an adjunct to a smoking cessation intervention, as in the Walker et al. trial. Similar to removing the alcohol from whiskey, removing the nicotine from a cigarette eliminates its*essence* and the main reason people buy cigarettes. These VLNC products have never been a commercial success and largely exist because of the research community's interest in them.[12] Illicit trade would increase (see Problem 7 above), but its scale and nature are difficult to anticipate.   There would be little practical difference between a denicotinisation regulation and a full ban of the *tobacco people wish to buy*, and it would bring clarity to model the legislation as a*de facto* ban on tobacco rather than as a smoking cessation intervention.

Problem 9. The modellers do not use a realistic approach to timing and transition

The modelling shows full intervention effects starting in 2023. However, the legislation is still going through the Parliament of New Zealand, and the Health Committee will not deliver its report until 1 December 2022.[13] Once the legislation is passed, it will have a commencement date that will allow time for all the procedural machinery to be put in place. Once the primary legislation comes into force, the Minister will need to draft and consult on detailed implementing regulations for the measure. For example, the amending legislation inserts a new Part 3A into the Act. This new Part will require

regulations for a product approval process, a testing regime, a schedule of prohibited or limited constituents, and a temporary approval regime for non-cigarette tobacco products.

For the nicotine measure, Section 57H of the new Part 3A allows a 21-month period for introducing rules related to denicotinisation following the commencement of amended legislation:[14]

> *The Minister must,* **within 21 months of the commencement of section 31** *of the Smokefree Environments and Regulated Products (Smoked Tobacco) Amendment Act 2022, recommend that regulations be made prescribing the limits for the quantity of nicotine in any smoked tobacco product, and a method of determining whether those limits have been exceeded.*
>
> *(bold emphasis added)*

Such regulations could not take effect immediately but would require the Minister to consult and to allow a transitional period for the commencement of the regulations to permit suppliers to make the necessary applications and to manage inventories. It is unlikely that a legally watertight regime enforcing denico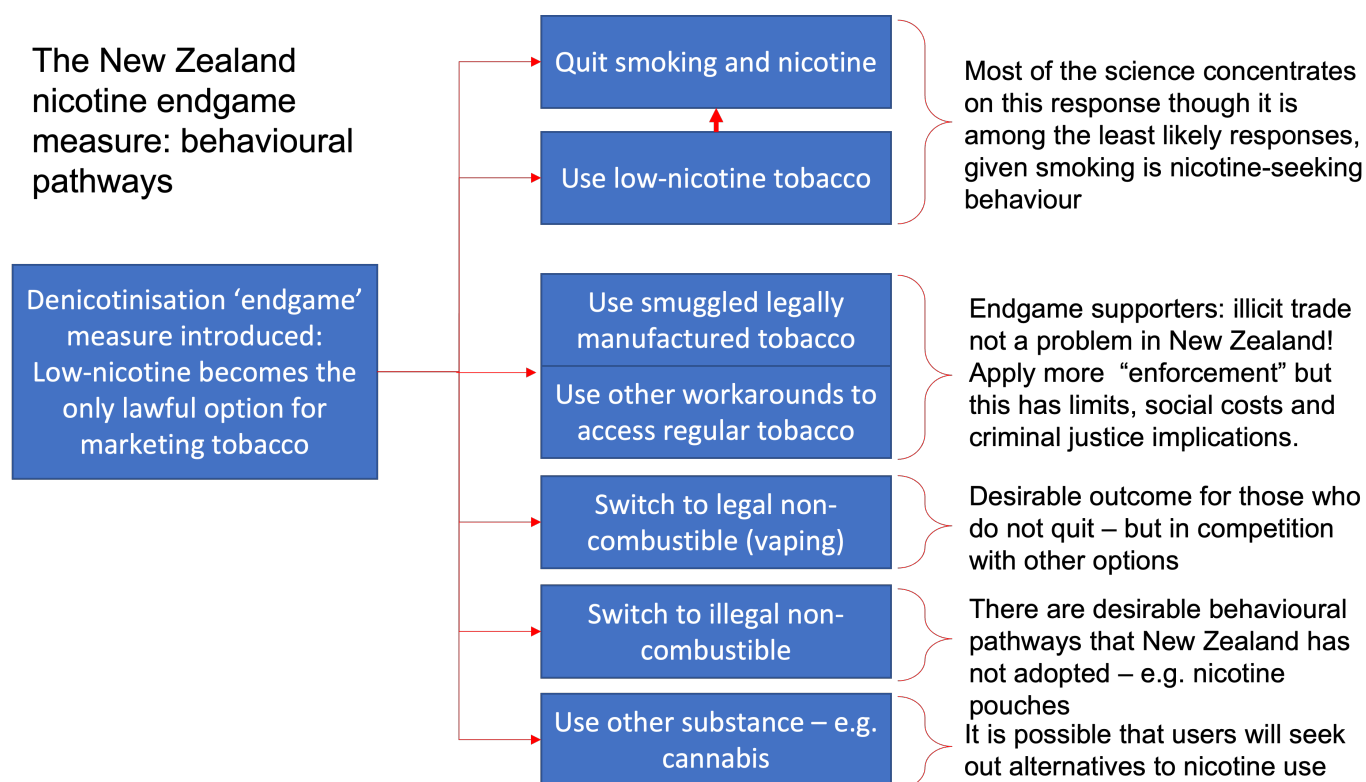tinisation will be in place before 2025. Further lags will arise from the management of inventories (regular nicotine tobacco products held in stock) through the length of the supply chain. Legislators would normally allow time for lawfully purchased stock to be sold off rather than destroyed. But inventories will also build up in the informal or illicit market as new suppliers hope to capitalise on scarcity once supply dries up in the legal market. Individual consumers may also build up stocks to the extent they can afford to purchase in advance.

For the reasons above, it is unlikely that the denicotinisation measure would have any material impact on the 2025 *Smokefree Aotearoa* targets. That does not, of course, invalidate any public health benefits that would emerge after 2025.

Problem 10. The modelling does not even try to reflect the real-world dynamics of a market intervention to denicotinise tobacco

Smokers facing the denicotinisation measure can adopt a range of responses and there would also be changes on the supply side. For example, smokers could conceivably access black-market tobacco, switch to vaping or quit. The proportions following "good" or "bad" pathways are partly a function of the communications, policy, fiscal and enforcement environment. If vapes are attractive, well-marketed, widely available and cheaper than illicit cigarettes, they will be relatively more successful. In practice, it is appropriate to conceptualise the various response options as in *competition* with each other for smokers responding to the denicotinisation measure.

The graphic below shows some possible pathways:

The New Zealand nicotine endgame measure: behavioural pathways

Denicotinisation 'endgame' measure introduced: Low-nicotine becomes the only lawful option for marketing tobacco	**Quit smoking and nicotine**
	Use low-nicotine tobacco

Most of the science concentrates on this response though it is among the least likely responses, given smoking is nicotine-seeking behaviour

Use smuggled legally manufactured tobacco

Use other workarounds to access regular tobacco

Endgame supporters: illicit trade not a problem in New Zealand! Apply more "enforcement" but this has limits, social costs and criminal justice implications.

Switch to legal non-combustible (vaping)

Desirable outcome for those who do not quit – but in competition with other options

Switch to illegal non-combustible

There are desirable behavioural pathways that New Zealand has not adopted – e.g. nicotine pouches

Use other substance – e.g. cannabis

It is possible that users will seek out alternatives to nicotine use

In taking such an approach, a model might have some of the following characteristics:

- Treat the denicotinisation measure as a *de facto* ban of tobacco, not a smoking cessation intervention
- Identify key response pathways that consumers and suppliers can adopt (see graphic above)
- Model different policy packages for each pathway - for example, "high enforcement" or "low enforcement" for illicit trade.
- Consider different responses in different communities.
- Consider the implications of increasing the available "harm reduction" pathways (heated tobacco, smokeless tobacco, nicotine pouches) to compete with the bad pathways.
- Assume initial 'announcement effects' but declining effectiveness over time
- Include the emergence of illicit trade or workarounds
- Allow for transitional timing, storage in the legal and illicit supply chain and hoarding

We do not argue that any of this would be straightforward. But a model purporting to inform policymakers about the effect of a denicotinisation would need to look more like this than the modelling presented in Ouakrim et al. and Wilson et al.

Conclusion

The statistician George Box coined the phrase "*All models are wrong, but some are useful*"[15] and followed this with the obvious corollary "*Remember that all models are wrong; the practical question is how wrong do they have to be to not be useful.*"[16]. The Ouakrim model is not useful, not because it is merely wrong, but because it does not even attempt to represent the underlying dynamics that would emerge following the implementation of the proposed legislation.

The input assumptions used in the model determine the positive outcomes presented by the authors. In particular, the modelling inappropriately uses an input assumption that smoking will decline by approximately 85% in five years following

a denicotinisation rule. The basis for this assumption is opaque and cannot be justified by the findings of the trial on which it is largely based.

Further, no information in provided for the evaluation of the expert judgements used in the modelling; how did they come to their conclusion that denicotinisation would lead to an approximate one-third quit rate in the first year after mandatory denicotinisation, which is then sustained for a total of five years?

The modelling is arbitrary and wholly unreliable as a guide to the policy impact. The measures will have consequences, both intended and unintended, but this modelling provides no useful information about what these could be.

We recommend that any modelling of this legislation should more faithfully reflect the real-world dynamics of the proposed population-wide measure and likely market response. We suggest that it is compared to a stronger intervention to encourage switching to smokefree products, rather than business-as-usual.

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