Scoping of Policy Impacts for Regulating E-cigarettes (SPIRE): a data and decision-analytic model mapping project

# PROTOCOL VERSION NUMBER 1 20/09/24

This protocol has regard for the HRA guidance.

# **RESEARCH REFERENCE NUMBERS**

IRAS Number:	The unique identifier generated by Integrated Research Application System (IRAS) for the project. This will be the primary reference number used by Research Ethics Committee, Health Research Authority and sites to identify the project and should be quoted in all project related correspondence as well as on all participant literature.

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## **KEY STUDY CONTACTS**

Project co-leads	Prof Lion Shahab, lion.shahab@ucl.ac.uk
	Dr Hazel Squires, h.squires@sheffield.ac.uk
Funder	The National Institute for Health and Care
Key Protocol Contributors	Dr Duncan Gillespie, duncan.gillespie@sheffield.ac.uk
	Dr Filippos Filippidis, f.filippidis@imperial.ac.uk
	Dr Rosemary Hiscock, R.Hiscock@bath.ac.uk
	Dr Deborah Robson, deborah.j.robson@kcl.ac.uk
	Dr Tessa Langley, tessa.langley@nottingham.ac.uk
	Dr Ilze Bogdanovica, Ilze.Bogdanovica@nottingham.ac.uk
	Dr Sarah Jackson, s.e.jackson@ucl.ac.uk

**KEY WORDS:** 

Electronic Nicotine Delivery Systems

Smoking cessation

Decision Support Techniques

Data science

Behavioural medicine

## **STUDY SUMMARY**

## Background

E-cigarettes (EC) deliver nicotine efficiently without combustion, and thus are less harmful than standard cigarettes while aiding smoking cessation. Yet, EC are not risk-free, particularly for people who have never smoked, and their use has been rising recently, especially among young people. Decision modelling can be used to synthesise data and understand and predict the impact of EC policies on consumption and health outcomes. To date, limited modelling of EC use and policy effects has been undertaken in the UK and little is known about the data needed to do so.

# Aims and objectives

We aim to identify a) data sources that can inform modelling of priority policies and b) gaps in data that are required to undertake appropriate modelling by:

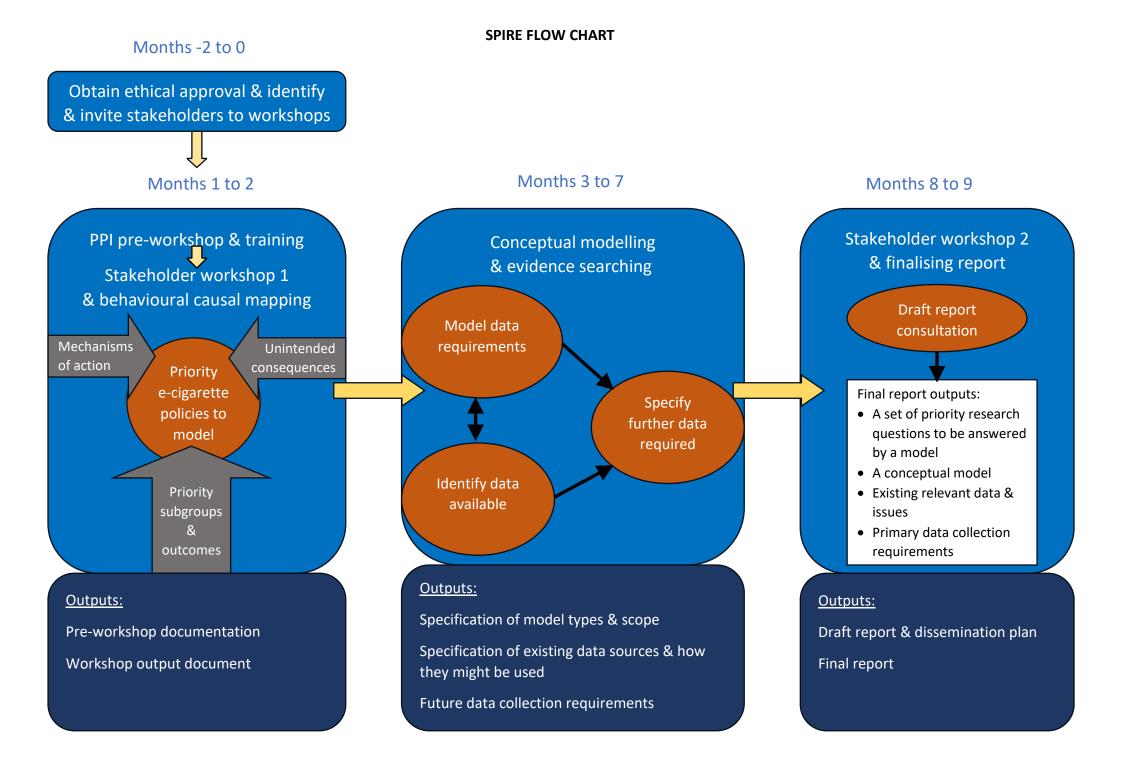
- 1. Engaging with stakeholders to identify priority EC policy options, mechanisms of action, unintended consequences, key subgroups and outcomes of interest;
- 2. Providing recommendations for the types of modelling that could be constructed to assess the impact of key EC policies;
- 3. Establishing which categories of data would be most valuable and at what level of detail;
- 4. Identifying data currently available and describing any potential issues including data accessibility and access costs;
- 5. Suggesting new types of data that would need to be collected to allow accurate modelling of EC policies and how future research efforts could be coordinated.

## Methods

We will use an established conceptual modelling framework for developing the structure of public health models. We will hold stakeholder workshops to identify key EC policy options, mechanisms of action, potential unintended consequences, priority subgroups and outcomes of interest. Participants will include key national/local policy makers, non-governmental EC policy experts, lay members, experts in public health and behavioural science, commercial determinants of health, data collection/analysis and modelling methods. A behavioural systems map will be developed to set out hypothesised causal relationships between potential interventions, sociodemographics, psychological variables, EC and smoking behaviours and their interactions, macro-level drivers (e.g., norms, business interests), and health outcomes. We will use existing guidance for complex systems models and a new toolbox of methods for modelling the influences on behaviour to provide recommendations for the types of modelling that could be undertaken to assess key EC policies. Existing data to parameterise such a model will be identified via input from collaborators, stakeholders and targeted literature reviews. We will describe any potential data issues, including missingness, data accessibility and costs. Areas with data missing from the conceptual model will be identified and possible ways of collecting or calibrating data will be described. We will hold a second stakeholder workshop to discuss and resolve any key issues arising from a review of the draft report. Public views will be given a strong emphasis by including lay members in the workshops and as advisors to the project team.

## Anticipated impact and dissemination

The project will enable commissioners to fund appropriate research for data collection and modelling to assess potential EC policy options. This future research could help improve societal health, reduce inequalities and costs to the health service. We will disseminate findings via the NIHR Journals Library, stakeholder events, conferences, journal articles and webinars.



#### **BACKGROUND AND RATIONALE**

E-cigarettes (EC) deliver nicotine efficiently without combustion and thus are less harmful than conventional cigarettes,<sup>1</sup> while aiding smoking cessation.<sup>2</sup> However, EC are not risk-free,<sup>1</sup> and their use is rising, especially among UK youth and young adults,<sup>3</sup> likely driven by new "disposable" EC.<sup>4</sup> Countries that have not prohibited EC therefore face a challenge on how to regulate EC so they are accessible and appealing to people who smoke as a cessation tool, while minimising uptake among those who would not have otherwise smoked.

In response, the UK government recently consulted on various policy options to address this issue.<sup>5</sup> While the government has already announced its commitment to two policies (banning disposable EC and applying an excise tax on EC),<sup>6</sup> other options (e.g., flavour restrictions) are still being assessed, and legislation has yet to be adopted. The government also has a parallel set of policies to make EC more accessible to people who smoke to support quit attempts, such as the "Swap to Stop" scheme,<sup>7</sup> which may particularly benefit less advantaged people who find it harder to stop smoking (e.g., people with mental health conditions).

Given the complex interplay between EC availability and, on the one hand, youth uptake and potential gateway effects to smoking and consequences of dual and long-term EC use, and, on the other, adult smoking cessation rates, the likely public health effects of various standalone or combined policy options are not immediately clear. Computational modelling can help policy makers assess intended and unintended consequences of policies, including on health equity and economic outcomes, to inform decision making.<sup>8</sup>

Computational modelling has been widely applied to tobacco control,<sup>9</sup> both to simulate pre- and postimplementation policy impacts.<sup>10</sup> These models can be broadly classified into those that work on the aggregate/macro (e.g., system-dynamics and cohort Markov models) or individual/micro level (e.g., agent-based and discrete event simulation models),<sup>8</sup> though hybrid models also exist.<sup>11</sup> These models have been used to evaluate the economic and health impact of single policy options (tax rises<sup>12</sup>, age<sup>13</sup> or location-based<sup>14</sup> sale restrictions) or comprehensive tobacco control policies,<sup>15</sup> including endgame strategies.<sup>16</sup>

Computational modelling to assess the effects of EC use is increasing. We undertook a PubMed search combining the MeSH term "Electronic Nicotine Delivery Systems" with policy ("Policy" OR "Policies" OR "Scenario\*" OR "Legislat\*") and modelling ("Model\*" OR "Simulat\*") free text terms, yielding >450 results. Models have been used to assess behavioural, economic and health consequences, including gateway effects in youth<sup>17</sup> and transitions among adults,<sup>18</sup> impact on health care costs<sup>19</sup> and smoking-related mortality.<sup>20</sup> Decision-analytic models have been developed to evaluate specific policy effects (e.g., EC flavour bans<sup>21</sup>, EC legalisation<sup>22</sup>), to assess the impact of cigarette policy changes on switching,<sup>23</sup> to simulate effects of combined EC and tobacco control policies<sup>24</sup> and the removal of existing (anti) EC policies.<sup>25</sup>

However, most models have been applied to the US, and we could identify only two specific to the UK.<sup>26, 27</sup> Further, the usefulness of policy modelling will depend on available data, appropriate model specification, parameter calibration, sensitivity analyses and validation.<sup>8</sup> These challenges are exacerbated when it comes to evaluating the policy impact of EC (compared with tobacco) regulation, given limited data on the mid-/ long-term effects of EC use, with greater uncertainty around key parameters. This has resulted in contradictory predictions of the impact of EC on possible transition gateways<sup>28, 29</sup> and population health.<sup>30, 31</sup>

Given the need to match the right modelling approach with the specific policy effect to be simulated and the necessary data to estimate parameters accurately, we propose a two-stage design: a) establish which policy options, outcomes and subgroups to prioritise via stakeholder input,<sup>32, 33</sup> and b) determine the most appropriate modelling approaches for assessing these policies, and the data required and available to parameterise them. The overall aim of this project is to identify data sources

(with UK focus) that can inform modelling of priority policies and to identify gaps in data that are required to undertake appropriate modelling.

# **RESEARCH QUESTIONS**

- 1. What are the priority EC policy options, their mechanisms of action and unintended consequences, and which key subgroups and outcomes are important to stakeholders?
- 2. Which types of decision-analytic models would be most suited to assess prioritised EC policies?
- 3. Which data sources currently exist to inform such decision-analytic models and what are the potential challenges in using them to produce the required model inputs?
- 4. What new types of data would need to be collected to enable modelling of EC policy effects on EC consumption, tobacco consumption, health and economic outcomes in priority subgroups?
- 5. How can we coordinate research efforts when collecting new data?

# **RESEARCH METHODS**

To understand data requirements for an EC model, we first need to understand the sorts of questions key stakeholders would like to answer with such a model and based upon this, the most appropriate modelling approaches and the data that will be needed. We will use an established conceptual modelling framework for developing the structure of public health models, developed by the co-lead applicant<sup>34</sup>, which sets out methods for involving stakeholders, understanding the problem and developing and justifying the model structure. This framework has been used to develop the structure of the Sheffield Tobacco and Alcohol Modelling platform, which is capable of modelling a range of policy options using systems to organise data and a code structure that can be deployed efficiently to new modelling problems.<sup>32, 35</sup> The current data mapping exercise could inform the creation of a similarly curated modelling platform to investigate the joint impact of tobacco and e-cigarette policies.

## Months 1 – 2: Stakeholder workshop and behavioural systems mapping

We will hold a stakeholder workshop in person to understand priority EC policy options, mechanisms of action, potential unintended consequences, and health inequity priority subgroups and outcomes of interest. Participants will include key national/local policymakers, non-governmental EC policy experts (e.g., ASH), lay members, and experts in public health and behavioural science, commercial determinants of health, data collection/analysis and modelling methods. Potential participants will be selected by the research team based on relevant research and policy experience. We will not involve people with conflicts of interest (e.g., tobacco or EC industry). At least one person from each institution in the research team will attend the workshop. The substantial existing knowledge and expertise about ECs within the research team, alongside existing logic models,<sup>36</sup> will be used to prepare pre-workshop documentation. Stakeholders will be asked to prioritise interventions, subgroups and outcomes. We will gain an understanding of inequalities in impact of policy and access to services. A behavioural systems map will be developed with stakeholders to set out hypothesised causal relationships between potential interventions, sociodemographics, psychological variables, EC and smoking behaviours and their interactions, industry behaviours, macro-level impacts upon behaviours (e.g., social norms), and health outcomes. We will share a workshop output document with stakeholders for review to agree priorities and the behavioural systems map. We will obtain ethical approval and invite stakeholders to be involved prior to the start of the project.

# Months 3 – 7: Identifying the model type, boundary, level of detail, data available and further data collection requirements in an iterative manner

We will use existing guidance on the use of complex systems models developed by the research team<sup>8</sup> and a new toolbox of methods for modelling influences on behaviour<sup>37</sup> to provide recommendations for the types of modelling that could be constructed to assess priority EC policies and to better

understand data requirements. The new toolbox of methods includes a decision algorithm for choosing (non-mutually exclusive) methods according to the characteristics of the behaviour of interest and the types of questions being assessed within the model. Methods include decision-analytic modelling techniques (agent-based models, differential equation models, discrete event simulation, macroeconomic modelling), quantitative methods to estimate parameter inputs (theory-informed statistical and econometric analyses, social network analysis, geographical information system analysis) and qualitative methods of data collection (qualitative research, process tracing, expert elicitation, industry document analysis and systematic reviewing).

Based upon the appropriate modelling approaches identified and the initial work with stakeholders, a proposed model boundary (i.e., which factors are important to include vs. those that might be excluded and why) and level of detail (i.e., the relationships between variables) will be described using the conceptual modelling framework. This includes an algorithm for helping to determine the model boundary and a set of questions for defining the level of detail. The model boundary will not be limited by what data are currently available and will be chosen to capture all of the important factors, including key sociodemographic characteristics, and potential unintended consequences of priority policy options including potential for industry attempts at circumvention. This will be an iterative, parallel process, defining the level of detail and identifying data sources (including datasets, existing models, academic literature and statistical reports).

Relevant datasets will be identified via input from collaborators, stakeholders, searches of trial registrations, ongoing projects and major metadata resources (e.g.; https://www.hdruk.ac.uk/, https://healthdata.gov/; https://www.who.int/data/collections). Datasets identified could be used to generate a synthetic population (e.g., Health Survey for England) and to undertake statistical analyses to explore the relationship between variables, for example predictors of behaviour and the relationship between ECs and smoking tobacco (e.g., the Smoking Toolkit Study). Independently available datasets of industry data and industry analyst data providing information on sales values/volumes (e.g., Nielsen data) will also be identified. In addition, we will undertake targeted literature reviews. Methods will follow the NICE Technical Support Document on Identifying and Reviewing Evidence to Inform the Conceptualisation and Population of Cost-Effectiveness Models.<sup>38</sup> Literature reviews will seek to identify EC market data, health effects of ECs, costs, uptake of policies and intervention impacts. Different sources of data are likely to be required for young people, adults and priority subgroups. We will give preference to UK data over international data, unless we are persuaded that international data have direct applicability to the UK context (e.g., by providing mechanistic, universal insights). We will describe any potential issues with the data including missing variables, geographical gaps in data coverage, data accessibility and access costs.

Based on the above, areas where data are missing will be identified. For example, data describing the relationships between people who vape and people who smoke are not expected to currently be available but may be important for modelling EC behaviour. We will review trial registrations and check key funding streams (e.g., NIHR, CRUK) to report ongoing relevant data collection. Where relevant data collection is not ongoing, possible ways of collecting the data will be described. We will present essential and desirable areas for further data collection described by likely impact upon model results and financial as well as logistical feasibility of collecting the data. We will also highlight where calibration approaches could be used to estimate unknown parameters using data that is available. There is typically a trade-off between which model types are most appropriate given the priority questions for policymakers and what is feasible given available data. We anticipate that we will make some short- and longer-term recommendations according to existing data availability and future data collection requirements. We expect that additional questions may need to be added to key datasets to investigate policy impacts on e-cigarette use. Our multi-institution project team has vast experience using these datasets. To maximise scientific value, we will discuss and make recommendations about how systems could be developed for public sharing and communication among research teams to ensure that new questions are necessary and consistent across different surveys.

### Months 8 - 9: Finalising the report

We will send a draft report setting out the previous work to our stakeholders for review, with a focus on evaluating whether the proposed approach and data collection would align with their current or anticipated information needs and capacity for local data collection. In addition to those stakeholders attending the first workshop, we will also send this to a group of international stakeholders to assess utility and generalisability to non-UK contexts and to provide external expert input into the modelling recommendations. We will hold a second (hybrid) stakeholder workshop to discuss and resolve any key issues arising from the review of the draft report. The final report will include a set of priority research questions to be answered by decision-analytic modelling, a behavioural systems map, recommended appropriate modelling approaches and scope, and a roadmap for a future model platform to flexibly assess comprehensive policy options. It will report on the data available to describe relationships between model variables, any issues with this data, and essential and desirable data requirements where there are missing data, with likely timeframes for *de novo* data collection. It will also detail recommendations for public sharing and communication among research teams working on EC data collection and analysis.

## Dissemination, outputs and anticipated impact

We will disseminate findings to participants through stakeholder events, to scientists via listservs of relevant learned societies (e.g., SRNT, ERS) and to policy makers via existing contacts in nongovernmental (e.g., ASH, RCP), health/health care (e.g., NHS, OHID), governmental (e.g., APPGs, CMO) and international (e.g., WHO, ENSP) organisations. Dissemination of work to the wider public will be achieved by drawing on advice on our existing PPI networks of collaborators (UCL, Sheffield, SPECTRUM, BR-UK, TANG, Addictions PRU) and media engagement (working closely with Science Media Centre/university and funder media teams to coordinate a press release of outputs) as well as contributing to podcasts, blog posts and research commentaries for outlets such as 'The Conversation'. Other outputs will include (1) publications in high-impact peer-reviewed journals on: *i*/ conceptual modelling for EC policies, and *ii*/ data mapping for EC, (2) a report in the NIHR library, (3) conference presentations to scientists and policy makers. Collated data from this project (e.g., meta-data on datasets, parameters) will be made available on https://osf.io/. Any example source code for potential modelling work will be made available on GitHub.

# What do you intend to produce from your research, how will your outputs enter our health and care system or society as a whole and what further funding will be required?

Our report will outline research needs for data collection and assessment of potential EC policy options and their impact on inequalities. A key objective of this research will be to set out key barriers to future research and how current data can be effectively used. We will link to the NIHR Public Health Knowledge Mobilisation team (KNOW-PH) based in Sheffield to disseminate our findings to local governments. Further funding will be required to develop a simulation model to assess the impact of alternative policy options. Further primary data collection may also be needed. Our research output should enable commissioners to fund appropriate research for data collection and assessing potential EC policy options, considering inequalities. This future research could help improve societal health and reduce inequalities, while reducing costs to the health service.

## What are the possible barriers for further research, development, adoption and implementation?

This is a fast-moving field where political decision making may supersede ongoing work (e.g., EC policies are implemented before these can be modelled). However, modelling, data collection and analyses are still needed to evaluate policy impacts and inform future decision making. Further, given vested commercial interests, industry interference may create potential barriers to policy adoption and implementation, even after evaluation, and seek to undermine this research and involved researchers. We will therefore ensure that we follow scientific principles throughout.

# What do you think the impact of your research will be and for whom?

The potential impact of this research project includes more effective use of existing resources and setting out a future research agenda, which can improve policy decisions about EC. Some of the key beneficiaries include *i*) UK and international government (to support design of effective policies); *ii*) Public health agencies (to undertake surveillance functions and policy analyses); *iii*) Funding organisations (to set funding priorities for future research); *iv*) Relevant charities (to inform health promotion activities and advocacy strategies) and *v*) Public health academics (to inform future research and build on the data, collaborations and policy models developed here). The longer-term benefits of this project include the potential to improve health and wellbeing of the general public, facilitate decisions about targeting specific populations to reduce inequalities and reduce costs to the NHS. It may also inform future international research.

How will you inform and engage patients/service users, carers, NHS, social care organisations and the wider population about your work? The two workshops with policy makers, experts and members of the public will provide a forum for stakeholders to engage directly with the research. We will gain advice from these stakeholders, including ASH, about methods for dissemination of the research.

*How will you share with study participants the progress and findings of your research?* We will share a pre-workshop document and a workshop output document with all stakeholders for each of the two workshops, written in an accessible form. We will allow time for stakeholders to review and ask questions.

# **PROJECT MANAGEMENT**

We will have fortnightly online meetings, and one mid-project in-person meeting to review progress, with all co-applicants and collaborators. For these, the project co-leads (Shahab and Squires) will produce meeting notes including clear actions for each co-applicant and collaborator as appropriate. The project co-leads will meet fortnightly between meetings to produce an agenda, assess progress and plan next steps of the research. Subcontracts will be set up between Sheffield, UCL and the collaborating institutions detailing the budget resources allocated, the responsibilities and expected contributions of each party.

# ETHICS

Given that the project mainly consists of secondary data review without access to patient data, NHS ethical approval will not be required. However, we have obtained University of Sheffield ethical approval to cover workshop-related activities. Any data collected will be handled in line with university information governance and ethical procedures.

## PATIENT AND PUBLIC INVOLVEMENT

It is crucial that the views of people with lived experiences inform this research. As this project is methodologically complex, we have taken an approach where we invite a group of PPI members and involve them throughout the project. We will provide training that gives them sufficient knowledge and confidence to participate in two stakeholder workshops and ensure that their voice is heard. Additionally, we have already sought involvement of established PPI groups and will do so again at the end of the project to ensure that broader views are included. We are keen to have a diverse PPI group, as we want to understand the perspective of people undertaking different behaviours relating to e-cigarette and tobacco use, the interaction between the two, and what might influence

their behaviour. It is also important to understand the perspective of members of the public for whom e-cigarette policy interventions may produce inequitable outcomes.

We will approach the Nottingham and UCL PPI groups to ask the members of these groups to express their interest in being involved in the project. We will select six PPI members to include smokers, vapers and young adult non-smokers or vapers, as well as ethnic minorities and a range of ages, if possible. If there are insufficient PPI participants from the above-mentioned groups we will approach other PPI groups, for example the Sheffield Centre for Health and Related Research PPI panel.

We will develop material for a bespoke online training session for PPI members. The training session will be combined with a pre-workshop PPI discussion where pre-workshop documentation will be presented and PPI views on potential e-cigarette policies and required data will be collated. At this stage we will also ask PPI members their views on the best approach for any further PPI involvement throughout the research project. PPI feedback provided in the pre-workshop discussion will be incorporated into the first stakeholder workshop and our PPI group will participate in the workshop.

We will ask PPI members for individual comments on the draft report which will be incorporated into the second stakeholder workshop discussion. To fully capture, evaluate and report PPI input in the project we will include a short section in the report summarising PPI input through the project, how the comments have been addressed and explain the impact PPI involvement has had on the project development, findings and dissemination. Throughout the project all PPI members will be reimbursed for their time as per NIHR guidelines. Travel and subsistence costs for in-person events will be covered.

### SUCCESS CRITERIA AND BARRIERS TO PROPOSED WORK

We will assess progress against the project timeline and outputs outlined in the Flow Diagram to measure ongoing success over the project. Ultimately the success of the project will be measured by its usefulness in informing future research. The main risk to the research is identifying a volume of evidence which is too great to manage in the given time frame. We will utilise the expertise of all stakeholders to focus the scope of the work around key policy questions and draw upon the expertise of all co-applicants and collaborators to focus our searches for data. Due to the experience of the research team, we have already worked with many relevant data sources, which will improve the efficiency of assessing their strengths, limitations and availability. We recognise that this is a polarised research area, but the multiple disciplines and backgrounds of the research team can help us develop comprehensive and balanced research. In addition, the team have a track record of working with colleagues in the SPECTRUM consortium who have a range of differing views.

#### **PROTOCOL CONTRIBUTORS**

Lion Shahab is Professor of Health Psychology and co-Director of UTARG, specialising in tobacco use, having published >200 papers in this area. He has worked with national/international datasets (to analyse, e.g., EC gateway<sup>39</sup> and tobacco tax<sup>40</sup> effects) and across various methodologies (e.g., meta-analyses,<sup>41</sup> Delphi exercises<sup>42</sup>, modelling studies<sup>17</sup>). He will jointly lead the project, supervise the UCL RA, and contribute behavioural science, epidemiology/modelling and data synthesis expertise.

<u>Hazel Squires</u> is a Senior Research Fellow in health-related decision modelling with expertise in conceptual modelling of public health interventions,<sup>34</sup> including running multidisciplinary stakeholder workshops. She has recently led the conceptual element of an existing collaboration between the University of Sheffield and UCL to assess smoking cessation policy options, incorporating the influences on smoking behaviours. Hazel will jointly lead the project, contribute conceptual modelling expertise and supervise the Sheffield RA.

<u>Duncan Gillespie</u> is a Senior Research Fellow in public health economics, with a focus on decisionanalytic model development for tobacco and alcohol policy. Following a similar stakeholder mapping exercise,<sup>32</sup> he led the development of the <u>Sheffield Tobacco and Alcohol Modelling platform</u>, which has has informed government policymaking on tobacco<sup>43</sup> and alcohol<sup>44</sup>. He will provide tobacco modelling expertise.

<u>Sarah Jackson</u> is a Principal Research Fellow with extensive experience of large population survey analysis on EC and policy.<sup>45, 46</sup> She sits on ASH's advisory council and regularly provides modelling to inform regional tobacco control strategy. She will contribute behavioural science, epidemiological, and modelling expertise.

<u>Filippos Filippidis</u> is a Reader in Public Health, focusing on nicotine use epidemiology and the evaluation of tobacco control policies in multiple countries. He has expertise in analysing national/international datasets using diverse methods (e.g., interrupted time series, difference-indifference, synthetic controls, meta-analyses).<sup>47, 48</sup> He is Chair of the ERS Tobacco Control Committee and will contribute data analysis expertise.

<u>Rosemary Hiscock</u> is a Research Associate, has experience in quantitative and documentary data analysis (e.g., revealing industry circumvention of menthol/flavour bans).<sup>49</sup> She has long-standing expertise in health inequalities, commercial determinants of health and tobacco supply chains.<sup>50</sup> She will bring together the quantitative and qualitative expertise of the Bath team, which will feed into the wider project.

<u>Debbie Robson</u> is a Senior Lecturer and mental health nurse. She is a co-author of five evidence reviews on EC commissioned by the government, with the most recent being an extensive systematic review on the health risks of vaping.<sup>1</sup> Her research includes tobacco harm reduction amongst people from disadvantaged groups.<sup>51</sup> She is an ASH Trustee and will contribute data synthesis, inequalities and harm reduction expertise.

<u>Tessa Langley</u> is an Associate Professor in Health Economics, specialising in the economics of health behaviours and publishing widely on the evaluation of tobacco and EC policies and interventions<sup>52</sup>. She is Deputy Editor for <u>Nicotine and Tobacco Research</u>, member of the RCP Tobacco Advisory group, and has worked on tobacco policy for the World Bank, CRUK, ASH and will provide policy modelling expertise.

<u>Ilze Bogdanovica</u> is an Associate Professor in Public Health, with extensive experience in tobacco control policy evaluation, including work on EC.<sup>53</sup> She has experience developing and running bespoke

surveys and working with large national surveys and commercial datasets (e.g., Nielsen and Kantar Worldpanel). She co-leads TANG, one of the <u>SPECTRUM consortium</u> PPI groups and will provide policy, PPI and survey expertise.

This project also involves several senior multidisciplinary collaborators who have contributed to the development of this protocol. These include <u>Prof. Jamie Brown</u>, <u>Prof. Robin Purshouse</u>, <u>Prof. Alan</u> <u>Brennan</u>, <u>Dr. Anthony Laverty</u>, <u>Prof. Ann McNeill</u>, <u>Dr. Rob Branston</u>, <u>Dr. Iona Fitzpatrick</u> and <u>Dr. John Mehegan</u>.

PPI contributed to the development of this protocol. We held an online meeting with the existing University of Nottingham PPI Tobacco and Nicotine Discussion Group (TANG). The group consists of current or recent ex-smokers and vapers, and has been running since 2015. We presented our draft research proposal to the group and discussed the involvement of PPI members throughout the project, focusing on understanding the best approaches to PPI participation in the workshops, dissemination of the findings and how the research could benefit members of the public. TANG members emphasised the importance of including diverse participants to ensure that a range of views and lived experiences are represented and heard, and our participant selection will be in line with this suggestion. We also sought written input from the existing UCL PPI group on the plain English summary. The main comments were about making sure the summary recognised both the harms and benefits of e-cigarettes and the need to explain more about who the policy makers are.

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#### **GLOSSARY OF TERMS**

APPG — All-Party Parliamentary Group

ASH — Action on Smoking and Health

BR-UK — Behavioural Research-UK

 $\mathsf{CMO}-\mathsf{Chief}\,\mathsf{Medical}\,\mathsf{Officer}$ 

CRUK — Cancer Research UK

ENSP — European Network for Smoking and Tobacco Prevention

ERS — European Respiratory Society

NHS — National Health Service

NICE — National Institute for Health and Care Excellence

NIHR — National Institute for Health and Care Research

OHID — Office for Health Improvement and Disparities

PPI — Patient and Public Involvement

PRU — Policy Research Unit

RA — Research Associate

RCP — Royal College of Physicians

SPECTRUM — 'Shaping Public Health Policies to Reduce Harm' consortium

SRNT — Society for Research on Nicotine and Tobacco

TANG — Tobacco and Nicotine Discussion Group

UCL — University College London

UTARG — UCL Tobacco and Alcohol Research Group

WHO — World Health Organization

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