

Electronic cigarettes Priority Setting Partnership

PROTOCOL 16.10.18 Version 2

1. Purpose of the PSP and background

The purpose of this protocol is to openly and transparently set out the aims, objectives and commitments of the electronic cigarettes JLA Priority Setting Partnership (PSP). The Protocol is a JLA requirement and will be published on the PSP's page of the JLA website. The Protocol will be regularly reviewed by the Steering Group and any updated version will be sent to the JLA.

The James Lind Alliance (JLA) is a non-profit making initiative, established in 2004. It brings patients, carers and clinicians together in Priority Setting Partnerships (PSPs). These partnerships identify and prioritise the evidence uncertainties, or 'unanswered questions', that they agree are the most important for research in their topic area. Traditionally PSPs have focused on uncertainties about the effects of treatments, but some PSPs have chosen to broaden their scope beyond that. The aim of a PSP is to help ensure that those who fund health research are aware of what really matters to both patients and clinicians. The National Institute for Health Research (NIHR – www.nihr.ac.uk) funds the infrastructure of the JLA to oversee the processes for priority setting partnerships, based at the NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC), University of Southampton.

The Electronic cigarettes PSP is supported by the JLA and funded by Nottingham Hospitals Charity. In the UK, 16% of the population smoke. Smoking is the leading cause of preventable death and is a recognised cause of a wide range of diseases. Intervening to help all smokers quit has major potential to improve current and future health of all patients who use NHS services. Smoking cessation interventions are amongst the most clinically and cost-effective interventions available. Available NHS treatment includes Nicotine Replacement Therapy (patches, gum, spray, tablets, or lozenges), varenicline, and bupropion. Electronic cigarettes (EC) are another form of treatment, although not yet available on the NHS. Despite this, they have been increasing in popularity, and are now the most popular aid to smoking cessation, with 37% of smokers using them for quit attempts, and approximately 2.6 million adults currently using them. Most individuals who use ECs report doing so because they want to quit or reduce their use of traditional cigarettes, or consider them less harmful. Recently, Public Health England estimated they are likely to be 95% safer than cigarettes. In the UK, the government recommends that where someone finds it difficult to quit cigarettes, they should be encouraged to use ECs. However, the current evidence base is small and only just emerging. There is much we do not know, including the long-term effects. As the popularity of EC have increased, so has the controversy associated with using them, and media scare stories may deter their use. Concerns relate to the unknown impact of the long-term use of EC, the possibility that they may result in increased levels of nicotine dependence, the fact that some smokers become dual users and EC may delay or deter quitting, and the potential hazards that have been reported, e.g. devices exploding, burn injuries or poisonings. The controversy surrounding EC may have a negative effect on the attitudes that healthcare professionals (HCP) have towards them as a smoking cessation or harm reduction tool, which in turn may have an effect on whether they are likely to recommend them to their smoking patients.

The new PHE report (McNeil et al., 2018) contains lots of research questions that need addressing, relating to policy, nicotine, use in young people, use in adults, the use on smoking cessation and harm reduction, risks, safety and health risks, and pricing. Thus there is a need to ensure that there is consensus among academics,

clinicians, patients and the public, over what the priorities are. It is of paramount importance that research is informed and guided by the needs of patients to avoid waste in terms of inadequate focus and outcomes. The James Lind Alliance (JLA) Priority Setting Partnerships (PSPs) were established so that patients and clinicians can work together to prioritise uncertainties in research. All top ten priorities for the PSPs will be published on the JLA website, thus ensuring wide availability to government, academics, clinicians, research commissioners and funders to inform policy and practice.

2. Aims, objectives and scope of the (health problem) PSP

The aim of the electronic cigarettes PSP is to identify the unanswered questions about the use of electronic cigarettes for smoking cessation and harm reduction from patient and clinical perspectives and then prioritise those that patients and clinicians agree are the most important.

The objectives of the electronic cigarettes PSP are to:

- work with patients and clinicians to identify uncertainties about the use of electronic cigarettes for smoking cessation and harm reduction
- to agree by consensus a prioritised list of those uncertainties, for research
- to publicise the results of the PSP and process
- to take the results to research commissioning bodies to be considered for funding.

The electronic cigarettes PSP will include in its **scope** questions about:

- Pregnant smokers
- Young people
- Smokers with different health conditions, e.g. COPD, lung cancer
- Prisoners
- Mental health patients
- Homeless population
- Routine and manual workers
- Any age
- Non-smokers
- UK population only

No restrictions on who can answer the survey online but include a question about where they found the survey and which population group(s) they fall into.

The PSP will exclude from its **scope** questions about:

- Non-UK population

The Steering Group is responsible for discussing what implications the scope of the PSP will have for the evidence-checking stage of the process. It is important that resource and expertise are in place to operationalise this.

3. The Steering Group

The Steering Group includes membership of patients and carers and clinicians¹, as individuals or representatives from a relevant group.

The electronic cigarettes PSP is led and managed by the following:

Patient and carer representative/s:

Andy Morrison (New Nicotine Alliance). Glasgow

Carmen Glover (Nottingham)

Julian Lewis (Nottingham)

Carrie Stimson (Nottingham)

Clinical representative/s:

Sanjay Agrawal (Consultant respiratory and intensive care medicine). University Hospitals Leicester NHS Trust

Lisa Adams (Community midwife). Derby Teaching Hospitals NHS Trust

Jane Jobarteh (Health and Wellbeing Programme Manager). Public Health England East Midlands

Louise Ross (Stop Smoking Advisor). Leicester.

The Partnership and the priority setting process will be supported and guided by:

- The James Lind Alliance (JLA)
 - Toto Anne Gronlund
- PSP Lead
 - Dr Abby Hunter (University of Nottingham)
 - Dr Sue Cooper (University of Nottingham)
- PSP Coordinator and Information Specialist
 - Dr Abby Hunter (University of Nottingham)
 - Mr Chris Hill (University of Nottingham)
- PSP support
 - Professor Michael Ussher (St George's, London)

The Steering Group agrees the resources, including time and expertise that they are able to contribute to each stage of the process.

4. Partners

Organisations and individuals will be invited to be involved with the PSP as partners. Partners are groups or individuals who will commit to supporting the PSP by disseminating the PSP survey and helping the PSP to

¹ In some cases, it has been suggested that researchers are represented at this level, to advise on the shaping of research questions. However, researchers cannot participate in the prioritisation exercise. This is to ensure that the final prioritised research questions are those agreed by patients, carers and clinicians only, in line with the JLA's mission.
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gather questions and uncertainties of practical clinical importance relating to the treatment and management of the health problem in question. Partners represent the following groups:

- people who smoke or vape
- non-smokers
- medical doctors, nurses and professionals allied to medicine with clinical experience of smoking cessation advice and support or treating smoking related illnesses.

List of potential partners (groups that will actively promote the survey and support it)

- Cancer Research UK
- British Heart Foundation
- British Lung Foundation
- New Nicotine Alliance
- AD Action
- Public Health England
- Action on Smoking and Health
- Smoke free leads (trusts)
- National Centre for Smoking Cessation Training
- Smoking in Pregnancy Challenge Group
- Department of Health
- UK Centre for Tobacco and Alcohol Studies
- MIND
- National Housing Federation
- Framework (homeless charity)
- Opportunity Nottingham (homeless organisation)
- Fenix (Carrie knows someone)
- East Midlands Recovery Forum
- Glasgow school of Vape?
- Live Life Better, Derbyshire, (LA)

List of potential stakeholders (groups that will complete the survey)

- Smokers/vapers
 - Maternity
 - Homeless population
 - Mental health patients
 - Routine and manual workers
 - Young people
 - Prisoners
 - Smokers with other health conditions, e.g. COPD, heart disease, lung cancer
- Non-smokers
- Royal College of Physicians
- Royal College of Nursing and Midwifery
- Royal College of General Practitioners
- Primary care
- Stop smoking advisors

It is important that all organisations which can reach and advocate for these groups should be invited to become involved in the PSP. The JLA Adviser will take responsibility for ensuring the various stakeholder groups are able to contribute equally to the process.

Exclusion criteria

Some organisations may be judged by the JLA or the Steering Group to have conflicts of interest. These may be perceived to adversely affect those organisations' views, causing unacceptable bias. As this is likely to affect the ultimate findings of the PSP, those organisations will not be invited to participate. It is possible, however, that interested parties may participate in a purely observational capacity when the Steering Group considers it may be helpful.

5. The methods the PSP will use

This section describes a schedule of proposed stages through which the PSP aims to fulfil its objectives. The process is iterative and dependent on the active participation and contribution of different groups. The methods adopted in any stage will be agreed through consultation between the Steering Group members, guided by the PSP's aims and objectives. More details can be found in the Guidebook section of the JLA website at www.jla.nihr.ac.uk where examples of the work of other JLA PSPs can also be seen.

Step 1: Identification and invitation of potential partners

Potential partner organisations will be identified through a process of peer knowledge and consultation, and through the Steering Group members' networks. Potential partners will be contacted and invited to be involved with the PSP as partners, and informed of the establishment and aims of the electronic cigarettes PSP.

Partners represent the following groups:

- people who smoke(d) or vape(d)
- non-smokers who may live with a smoker/vaper
- clinicians and other professionals - with experience of treating smoking cessation

Step 2: Awareness raising

Awareness raising has several key objectives:

- to present the proposed plan for the PSP
- to generate support for the process
- to encourage participation in the process
- to initiate discussion, answer questions and address concerns
- to identify those potential partner organisations which will commit to the PSP and identify individuals who will be those organisations' representatives and the PSP's principal contacts
- to establish principles upon which an open, inclusive and transparent mechanism can be based for contributing to, reporting and recording the work and progress of the PSP.

Step 3: Identifying uncertainties

The electronic cigarettes PSP will carry out a consultation to gather uncertainties from patients, carers and clinicians. A period of 2 months will be given to complete this exercise (which may be revised by the Steering Group if required).

The electronic cigarettes PSP recognises that the following groups may require additional consideration:

- People with mental health problems
- People from low SES
- Pregnant smokers
- Prison communities

The Steering Group will use the following methods to reach the target groups. Andy Morrison has access to the prison population in Glasgow and can distribute surveys there. Sue Cooper has set up a 'smoking in pregnancy' PPI group and can distribute the survey through this group and through other contacts. Paper surveys will be available. Carrie Stimpson has access to homeless population through connections with a homeless charity. ▸

Existing sources of information about treatment uncertainties for patients and clinicians will be searched. These can include question-answering services for patients and carers and for clinicians; research recommendations in systematic reviews and clinical guidelines; protocols for systematic reviews being prepared and registers of ongoing research.

The starting point for identifying sources of uncertainties and research recommendations is NHS Evidence: www.evidence.nhs.uk.

Step 4: Refining questions and uncertainties

The consultation process will produce "raw" questions and comments indicating patients', carers' and clinicians' areas of uncertainty. These raw questions will be categorised and refined by Abby Hunter into summary questions which are clear, addressable by research and understandable to all. Similar or duplicate questions will be combined where appropriate. Out-of-scope submissions will be compiled separately. The Steering Group will have oversight of this process to ensure that the raw data is being interpreted appropriately and that the summary questions are being worded accessibly.

This will result in a long list of in-scope summary questions. It should be noted that these are not research questions and to try and word them as such may render them too technical for a non-research audience. They should be framed as researchable questions that capture the themes and topics that people have suggested.

The summary questions will then be checked against evidence to determine whether or not they have already been answered by research. This will be done by Abby Hunter. The PSP will complete the JLA Question Verification Protocol which clearly describes the process employed to verify the uncertainty of the questions, before commencing prioritisation. The Question Verification Protocol includes details of the types and sources of evidence used to ascertain uncertainty.

Questions that are not adequately addressed by previous research will be collated and recorded on a standard JLA template by Abby Hunter. This will demonstrate the checking undertaken to make sure that the uncertainties have not already been answered. The data should be submitted to the JLA for publication on its website on completion of the priority setting exercise, taking into account any changes made at the final workshop, in order to ensure that PSP results are publicly available. The Question Verification Protocol should be submitted at this point too, to be published alongside the questions to enable researchers and other stakeholders to understand how the PSP has decided that its questions are unanswered, and any limitations therein.

The Steering Group will also consider how it will deal with submitted questions that have been answered, and questions that are out of scope.

Step 5: Prioritisation – interim and final stages

The aim of the final stage of the priority setting process is to prioritise through consensus the identified uncertainties about electronic cigarettes. This will involve input from patients, carers and clinicians. The JLA encourages PSPs to involve as wide a range of people as possible, including those who did and did not contribute to the first consultation. There are usually two stages of prioritisation.

1. Interim prioritisation is the stage where the long list of questions is reduced to a shorter list that can be taken to the final priority setting workshop. This is also aimed at a wide audience, and is done using similar methods to the first consultation. With the JLA's guidance, the Steering Group will agree the method and consider how best to reach and engage patients, carers and clinicians in the process. The most highly ranked questions (around 25) will be taken to a final priority setting workshop. Where the interim prioritisation does not produce a clear ranking or cut off point, the Steering Group will decide which questions are taken forwards to the final prioritisation.

2. The final priority setting stage is generally a one day workshop facilitated by the JLA. With guidance from the JLA and input from the Steering Group, up to 30 patients, carers and clinicians will be recruited to participate in a day of discussion and ranking, to determine the top 10 questions for research. All participants will declare their interests. The Steering Group will advise on any adaptations required to ensure that the process is inclusive and accessible.

6. Dissemination of results

The Steering Group will identify audiences with which it wants to engage when disseminating the results of the priority setting process, such as researchers, funders and the patient and clinical communities. They will need to determine how best to communicate the results and who will take responsibility for this. Previous PSPs' outputs have included academic papers, lay reports, infographics, conference presentations and videos for social media.

It should also be noted that the priorities are not worded as research questions. The Steering Group should discuss how they will work with researchers and funders to establish how to address the priorities and to work out what the research questions are that will address the issues that people have prioritised. The dissemination of the results of the PSP will be led by Abby Hunter.

The JLA encourages PSPs to report back about any activities which have come about as a result of the PSP, including funded research. Please send any details to jla@soton.ac.uk.

7. Agreement of the Steering Group

The electronic cigarettes PSP Steering Group agreed the content and direction of this Protocol on October 2018.