BMJ Open

Selecting an e-cigarette for use in smoking cessation interventions and healthcare services: findings from patient and public consultation for the COSTED trial

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To cite: Belderson P, Ward E, Pope I, *et al*. Selecting an e-cigarette for use in smoking cessation interventions and healthcare services: findings from patient and public consultation for the COSTED trial. *BMJ Open* 2024;**14**:e078677. doi:10.1136/bmjopen-2023-078677

► Prepublication history for this paper is available online. To view these files, please visit the journal online (https://doi.org/10.1136/bmjopen-2023-078677).

Received 08 August 2023
Accepted 25 January 2024

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ABSTRACT

Objectives The Cessation of Smoking Trial in the Emergency Department (COSTED) trial aims to ascertain whether brief advice, the provision of an e-cigarette starter kit and referral to stop smoking services (SSS), increases smoking cessation in people attending the emergency department. Patient and public involvement (PPI) and scoping work were undertaken to select an appropriate e-cigarette for the trial.

Design and setting PPI consultation and feasibility scoping about potential devices with a professional and lay panel, all based in England. Consultation was via email, telephone or video interview. This work took place between April and July 2021, prior to recruitment commencing for the COSTED trial.

Participants A professional panel (n=7) including representatives from academia, SSS and the independent vaping industry, and a PPI lay panel (n=3) who smoke or vape.

Results The professional panel recommended a shortlist of devices which were tested by the PPI lay panel. Key criteria for selecting an appropriate e-cigarette for smoking cessation intervention include satisfaction, usability, affordability and availability. Simplicity of use was highlighted by the PPI lay panel, who found refillable devices complex, and availability of consumables was highlighted as more important than price by both panels. The pod device selected for inclusion was rated highly for satisfaction and usability and had mid-price range and consumables which were widely available.

Conclusions To select the most appropriate device for the COSTED trial, each criterion required assessment to ensure the best fit to the intervention context and needs of the target population. There is a need for guidance to help enable decision-making about choice of vape products, tailored to service users' needs. We propose a bespoke checklist template, based on our findings, to assist with this process. This has applicability to the recent government announcement of a 'Swap to Stop' programme, offering a vaping starter kit to smokers across England, allowing services flexibility to shape their own programmes and models of delivery.

Trial registration number Clinical trial number NCT04854616; pre-results.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This was a systematic, robust patient and public involvement (PPI) consultation undertaken for selecting an e-cigarette for use in cessation interventions.
⇒ The consultation incorporated a range of perspectives, including experts from academia, stop smoking services and the independent vaping industry, and people who smoke and/or vape.
⇒ This paper provides timely guidance to aid the selection process for e-cigarettes for other interventions, given the recent implementation of the Swap to Stop scheme in the UK.
⇒ The work was not designed as a formal research study—in keeping with PPI consultation, information gathering was adaptable and informal, to suit individuals involved, and the number of participants was modest.

INTRODUCTION

Evidence reviews have consistently shown that e-cigarettes are substantially less harmful than smoking tobacco and are now the most popular method of smoking cessation in England.[1 2] When combined with behavioural support, people who use e-cigarettes to quit smoking are twice as likely to succeed as people who use other nicotine replacement products.[3] There is increasing need for research to establish the most effective methods to support people in switching from tobacco to e-cigarettes. Stop-smoking services and health trusts are increasingly incorporating e-cigarettes into their smoking cessation support.[4 5]

The recent independent Khan Review[6] recommended that, to help the government meet its ambition of making England smoke-free by 2030, vaping is offered as a substitute for smoking. Following this, in April 2023, the Department of Health and Social Care (DHSC) announced a 'Swap to Stop'

programme, offering a vaping starter kit to one million smokers across England.[7] A central procurement point has been set up allowing local stop smoking services (SSS) to access a catalogue of approved vaping products. The initiative allows services flexibility to shape their own programmes and models of delivery, including decisions about which populations to prioritise. In light of this, there is a need for guidance to help enable decision-making about choice of vape products to suit the requirements of localised programmes, tailored to service users' needs.

The rapidly evolving nature of the sector poses a challenge for selecting the right e-cigarette to include in both research and health service interventions. Speed of product development and user preference are major factors impacting effectiveness and therefore potential outcomes. Although e-cigarettes are diverse in attributes, the types are not always fully differentiated within published research, although there are possibly large differences in outcomes for interventions. More formalised definitions are being constructed as part of the E-cigarette Ontology covering all the types of entity that are referred to in reports of e-cigarette research.[8 9] The recent Cochrane review of over 60 e-cigarette trials reported only one trial to date which has used a newer prefilled pod-style device, with the majority of evidence currently available deriving from trials using older refillable style devices.[2] Previous studies tend not to outline their method of selecting the device used. A systematic approach to intervention development is recommended[10] and patient and public involvement (PPI) is increasingly recognised as essential at all stages of the research process. However, guidance on how to approach PPI is lacking. This paper aims to address this gap by offering a description of the PPI process applied to selecting an e-cigarette for a research intervention with a view to providing guidance for future trials and smoking cessation services.

The PPI process reported here was used to inform choice of an e-cigarette that was a component of the intervention for the Cessation of Smoking Trial in the Emergency Department (COSTED).[11] The trial is a two-group, multicentre, pragmatic, individually randomised, controlled trial of a smoking cessation intervention delivered to patients in the emergency department (ED). The trial aims to ascertain whether brief advice, the provision of an e-cigarette and referral to UK SSS, increases smoking cessation in people attending the ED compared with signposting to SSS.

METHODS

Ethical approval

The COSTED trial received ethical approval from the UK National Research Ethics Committee—Oxford B (reference 21/SC/0288). As a PPI consultation, the work presented here did not require formal ethical approval, in accordance with NIHR guidelines[12] whereby contributors are involved in the design, implementation and management of the research process itself, rather than being participants or subjects of the research. The ethics committee were aware of the PPI activities through the protocol.

Although no formal written consent procedures were undertaken, the purpose and nature of the activity were described prior to involvement. For interviews with the lay panel, verbal consent was obtained for audio recording. The final draft article was also shared with all panel members (lay and professional) prior to submission and where direct quotes from professional or lay panel members are included, explicit consent to use these was obtained via email.

Consultation process

In designing the PPI work, we specifically aimed to recruit a range of professional panel members representing the following categories: academic, smoking cessation service and independent vaping industry. For the lay panel, we sought to include current or recent tobacco smokers. We aimed for at least two representatives from each professional sector, and three 'experts by experience' to trial the devices. The total number of 10 was felt to be appropriate (in line with recommendations for focus group research), allowing for diversity of representation, while keeping the panel to a manageable size.

A three-phase approach was used in selecting the e-cigarette. This process is summarised next and represented in figure 1.

Phase 1: scoping and approaching professional panel

A professional panel was recruited through the research team's existing networks and included seven representatives from different sectors, including two academics with specialism in smoking cessation/e-cigarette intervention with disadvantaged groups, two senior SSS representatives with experience of implementing e-cigarette interventions, and three people from the independent vaping industry, including a trade body representative, the head of retail for a large retail chain and a frontline shop assistant. They were each asked via email, telephone or video interview to recommend potential devices, with follow-up questions to explore their reasoning.

Phase 2: testing by PPI panel

The PPI panel was recruited via the UEA Addiction Research Public Involvement Panel, which is an established group of people with lived experience of addiction who have volunteered to assist with PPI activity for addiction-related research studies. The panel receive remuneration for their time in shopping vouchers. The PPI panel comprised two current smokers (male and female) and a male experienced vaper with recent smoking experience. Seven devices were provided to the PPI panel to test over a 4-week period during May and June 2021. When requesting feedback, panel members were asked to consider both their personal preference and their views on the suitability of each device for the

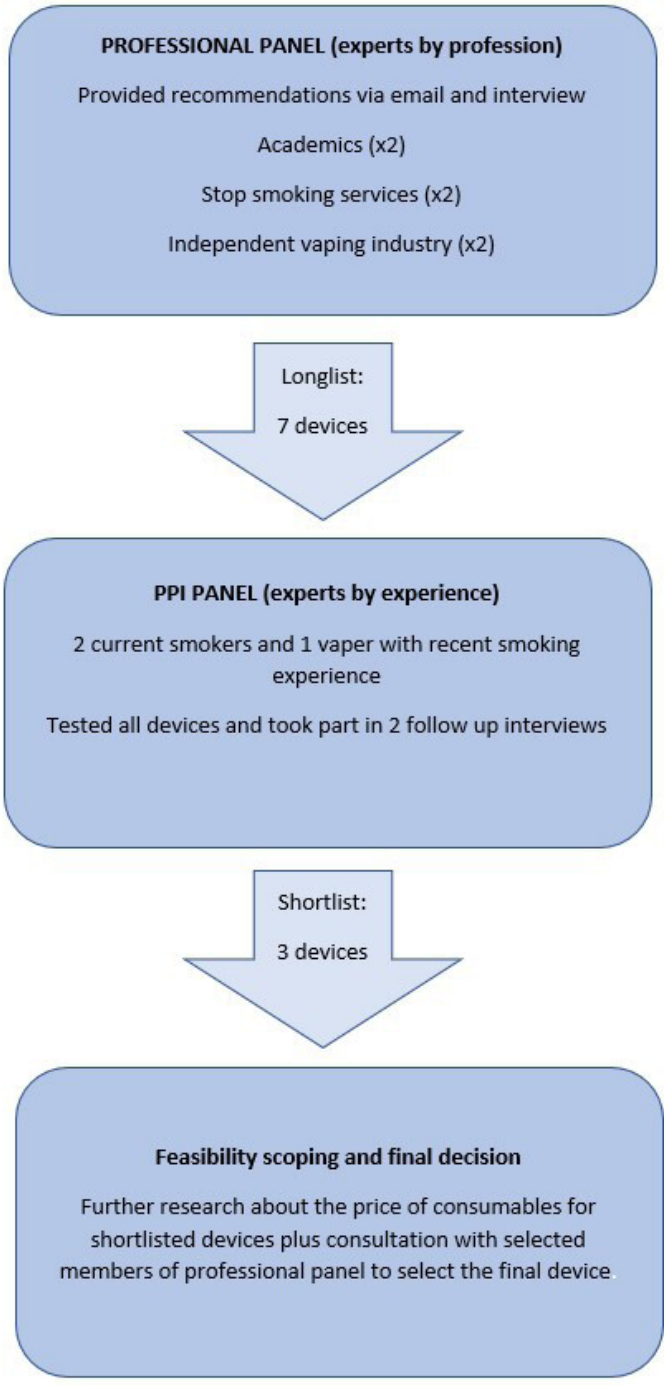

Figure 1 Patient and public involvement (PPI) process for selection of e-cigarette.

proposed intervention. The panel members were asked to rate devices for satisfaction and usability. These scores were used as a prompt for discussion in individual follow-up interviews. As well as device specifics, the interviews also explored the issues of availability, price of devices and their perceived appropriateness to the specific intervention context and population. Interviews were recorded with consent and autotranscribed for analysis, supplemented by researcher notes. A total of six interviews were undertaken, two with each panel member. The first set of interviews provided feedback on all devices included in the original longlist, and the second interview with each member focused on comparing the final shortlist of three.

Phase 3: feasibility scoping and final decision

Further detailed research, using internet and email enquiries, about the range and number of stockists and the price of consumables was conducted for the shortlisted devices. Further consultation with selected members of the professional panel was undertaken to enquire about their views on the relative importance of price and availability. The findings were brought to the wider researcher team for discussion and final decision-making.

Patient and public involvement

The present manuscript reports on a PPI-based consultation to inform the design of the COSTED trial.

RESULTS

Phase 1: scoping and professional panel suggestions

The professional panel's recommendations were based on suitability for beginners, popularity, degree of availability and a precedent of previous use by SSS or research interventions. Only brands independent of the tobacco industry were considered for inclusion, in order to avoid any perception of tobacco industry influence over the research. Consultation with the professional panel resulted in a longlist of devices which included five closed-pod systems (device codes: 1, 2, 3, 4, 5) and two refillable devices (device codes: 6, 7). Closed pods were suggested for their simplicity, facilitating ease of switch from smoking to vaping, and their increasing popularity and market share. Disposable e-cigarettes were discounted at the time of the scoping exercise as they were very new to the market, had higher ongoing use costs and did not have the longevity of pod-style devices. One refillable device (device 6) was suggested as an established, consistent best-selling starter kit used in other e-cigarette research; device 7 was suggested as offering a popular refillable alternative to pod devices.

Phase 2: testing by PPI panel

Satisfaction, nicotine strength and flavours

There was variation in opinion among the panel about satisfaction. Some liked the flexibility, and button-activated adjustable airflow, that refillable devices offered. Another panel member particularly preferred the draw on pod device 4 which he felt had more 'resistance' and most closely resembled that required for a tobacco cigarette. Regardless of device type, nicotine salt e-liquid (contained in pod devices and an option for refillable devices) was preferred:

> There's something about this salt nicotine stuff, because this is a different sort of nicotine, isn't it. And you know what? I got on really well with it. [PPI2]

The panel were provided with a range of nicotine strength e-liquid to try (range 6–20 mg). The consensus among the panel was that stronger (18/20 mg) nicotine strengths should be provided to participants in order to satisfy cravings and maximise chances of a successful switch. However, panel members commented that providing a device that enabled use of lower strength liquids (eg, 10 mg pods) was a consideration, allowing scope for personal preference and potential for tapering down in the longer term:

> I do think [higher strength] is a good idea because you want to pre-empt the crave. [PPI1]

Not unexpectedly, preference for flavours also varied between panel members. Some, for example, discussed using a flavour that resembles cigarettes or alternately, a desire to move away from tobacco flavour. All felt, therefore, that providing a choice to participants was important, and that a range of flavours should be offered to accommodate personal preference.

> Trying out flavours that you might like is easier with the pods which you can just swap over—it's harder to empty out like the liquids for the vapes. [PPI1]

Usability and design

All PPI panel members commented on the relative difficulty with setting up refillable devices and felt that this was less appropriate for the context of an opportunistic trial in the ED:

> It's just the inconvenience of [refillables]…if it's someone you're giving it to out at A&E, they're not going to want to faff about with [a refillable e-cigarette], and they're gonna get really annoyed when they get covered in bloody vape juice. [PPI3]

None had previously tried a closed-pod e-cigarette, and all commented on simplicity and ease of use. Two panel members particularly struggled with operation of one of the refillable devices. Simplicity of use was viewed as a critical factor, with all feeling that a pod device would be better suited and more appropriate for the purposes of the intervention, providing an accessible introduction to vaping for trial participants, including those with limited dexterity:

> You take literally two different bits out of a packet and put them together…. Someone who hasn't got very good dexterity I think it's going to benefit …I think [a closed-pod device] for reaching people and trying to stop them smoking at that point in time. [PPI2]

An additional dimension of usability noted by panel members was the 'ready to use' nature of the precharged pod systems, compared with other devices provided that required charging prior to use. This was highlighted as a particular advantage in the context of this intervention with patients in the ED, who may be waiting some time for their care, and would have the opportunity to use a precharged device on/off site while waiting for their care:

> They all came with a bit of charge already in them, so for the purposes of trying to catch people at the A&E and get them on it there and then, you can literally unpack it, show them how easy it is and away they go. Whereas with the [refillables] both had to go on charge for a bit… the fact that you can take them straight out the box and get rolling with them is a massive advantage. [PPI2]

The PPI panel also spoke about the product look, messaging and packaging proposed intervention. Some pod devices were felt to have better aesthetic qualities in terms of 'look and feel', and as such were suggested as having more potential appeal to intervention participants. E-cigarettes packaged in 'presentation style' boxes were highlighted for similar reasons.

Affordability

One pod device (device 2), though liked by the panel, was felt to be excessively expensive. Interviews specifically explored views on the relative importance of prices of starter kits and pod refills versus availability. Although panel members viewed affordability as an important consideration, all felt that availability was more important than price, citing the comparatively higher cost of smoking. One panel member described how, in selecting a starter device to encourage smokers to make the switch, availability may be more critical:

> You don't think about six-month price…If you're choosing one for yourself you're going to look at what's going to be convenient. You want something that's easy to replace. [Device 5] is so much more easily available…every shop I've been in recently has [Device 5] pods. [PPI3]

Availability

Good availability, not only online but also in bricks and mortar retailers, was highlighted as an important factor for encouraging continued use. One PPI panel member commented that the advanced planning involved in online purchasing may prompt relapse due to comparative convenience and availability of cigarettes in multiple local outlets.

> You want ease of availability because when you smoke you can literally just go to a corner shop and buy cigarettes whenever you want. You don't want to have to plan to buy your vape stuff online and run out, or find yourself at a loss….for somebody that's literally gonna be freaking out if they've run out of vapes, they'll think "Oh my God, I'm just gonna go buy cigarettes", like that desperation when you've run out. [PPI1]

Views were also sought at this stage from the PPI panel on the possibility of offering a single device or choice of device to intervention participants. Panel members felt

it more appropriate to offer one device only. Given the opportunistic context of intervention delivery in the ED, they felt that offering a choice would be overwhelming for participants, some of whom may not have even considered vaping before:

> I think I'd prefer just to be offered one because it's quite overwhelming, and smokers infamously are really defensive as well. Giving them loads of options and overwhelming them when they're like "I'm not even sure if I wanna quit!". It's easier to make it really simple—"if you'd like to be part of the study then try this." [PPI1]

One PPI representative encouraged contact with the specialist expertise and informal support offered in vape shops. All felt that it was important that participants were encouraged, after receiving the starter kit, to also experiment and explore other options to find the device set-up which best suits them.

Phase 3: feasibility scoping and final decision

In response to the feedback from the PPI panel on the importance of simplicity of use, both refillable devices (devices 6, 7) were excluded from the shortlist. Two of the closed-pod devices were also excluded: one (device 2) because it was thought too expensive, and the other (device 3) because of uniformly poor feedback on satisfaction, look and feel. This left a remaining shortlist of three closed-pod devices (devices 1, 4, 5).

Further scoping was undertaken on the final shortlist, with the focus on affordability and availability. The estimated cost of continuing use, calculated based on a 20-a-day smoker switching to 2 mL/day, was found to range significantly, between £854 and £1424 per year. Researchers (PB and EW) contacted the manufacturers for details of current locations for outlets where products could be purchased. This information was reviewed for availability specifically at intervention site locations. This ranged from 7 outlets within intervention areas for device 1, 170 outlets for device 5 to over 700 for device 4.

We returned to selected professional panel members to elicit their views on considerations around availability and affordability. One professional panel member responsible for delivering an e-cigarette smoking cessation intervention reported that their participants had adapted well to online purchasing during the COVID-19 pandemic. However, another panel member felt that for disadvantaged groups ease of access remained critical, especially for those who had poor IT skills or could not travel to specialist shops:

> We've found with our mental health and substance use service users that access and availability is really important. People do get frustrated if you start them on a product, they spend ages getting used to it and then when you stop supplying it and they can't buy it from their local shop. Some are OK about ordering it online, but several of our participants have poor IT skills. [PP1 email correspondence]

Although affordability was noted as essential, the importance of availability as a key ingredient to the success of an intervention was similarly highlighted by another professional panel member, consistent with thoughts on the issue shared by the PPI panel:

> My feedback from services [working with vulnerable groups] has always been availability is essential, price too, but the price difference from smoking is already a benefit even with the more expensive pods. Over the covid period I sent some [e-cigarette brand] devices to a few centres and the feedback wasn't great, the service users could not source the pods and this annoyed the users. [PP2 email correspondence]

The core team met to discuss findings from all phases of the PPI process to reach consensus on selecting the final device for inclusion in the study. The team excluded device 4 due to contradictory feedback on usability and satisfaction from the PPI panel and higher price. Two devices (1 and 5) were uniformly liked by the panel, but device 1 was excluded due to limited current availability. The final selection of device 5 was based on a combination of good panel feedback for satisfaction and usability, with mid-price range consumables widely available online and in the convenience sector.

Key recommendations for the COSTED trial

Figure 2 presents the key specific recommendations derived from the PPI consultation which ultimately informed the choice of e-cigarette for use in the COSTED trial. The priority recommendations were providing a device rated highly for nicotine satisfaction, simplicity of use, affordability and good availability (online and in bricks and mortar retailers).

DISCUSSION

The recommendations in figure 2 derived from our PPI consultation were considered against and set within a context of wider literature.

A pod starter kit was selected for the intervention primarily because of PPI feedback about its simplicity. The absence of complex features or requirements for maintenance meant that this was considered most appropriate for an intervention population who may not have considered switching away from smoking or trying vaping before. The choice of a draw-activated pod device was also felt more applicable to an intervention setting in ED waiting rooms where there was only limited consultation time to instruct on use. Similar reasoning was applied to the decision to provide one device rather than a choice. The PPI feedback was reflective of broader consumer trends which indicate a growing preference for closed systems, including disposable and pod e-cigarettes. E-cigarette users commonly start with a simple product before

Satisfaction

- Provide a range of flavours to encourage experimentation and accommodate personal preference
- Provide nicotine salt liquid for smoother throat hit and satisfaction
- Provide higher nicotine strength liquid (20mg) but also inform participants that lower strengths are available

Usability and Design

- A simple starter device is best suited to the opportunistic intervention with smokers who may not have previously considered or tried vaping. Provision of a closed-pod e-cigarette was recommended due to:
  - Simplicity of set up and lack of need for maintenance
  - Pre-charged ready for immediate use
  - Draw activated, rather than button activated
- Aesthetic appeal - visual and tactile appeal of the device, alongside product packaging should be a consideration

Affordability

- The device should be affordable, and consideration given to ongoing costs of consumables that will be acceptable to the client group.

Availability

- Availability of the device and consumables in local convenience stores as well as online is essential to help enable all participants to engage with the intervention.

Applicability (to intervention context)

- Product packaging and messaging should be compatible with the research intervention
- Provide a device that is simple to explain and instruct on use within the limited consultation time allocated for the intervention
- Provide a single device rather than a choice to avoid overwhelming participants who may not have previously considered vaping
- The device and accompanying information should appeal and be relevant to a potentially broad demographic range of people attending the ED
- The device and accompanying information should appeal to smokers who may have low motivation to quit, as well as those with or without previous experience of vaping
- Choice and personal preferences should be acknowledged and advice about alternatives provided to encourage participants, after receiving the starter kit, to find the device and flavours that best suits them. Suggest vape shop support for further specialist advice.
- Care should be taken around scoping and choice of commercial partner to explore factors such as independence from tobacco industry, company market share, availability of customer support, experience of being involved with stop smoking services or research.

Figure 2 Key recommendations for Cessation of Smoking Trial in the Emergency Department trial derived from patient and public involvement consultation. ED, emergency department.

progressing to more advanced devices.[13] Based on our PPI feedback, we were mindful that participants in the current study may potentially wish to transition to use of a different system. Therefore, intervention materials were designed to suggest to participants to be open to exploring other possibilities in order to find the device that best suits them, and to encourage use of vape shops for specialist advice.[14]

The PPI panel varied in their preference for flavours and felt that it was important to provide a range, as participants may be new to or have limited experience of vaping. Multiple studies show flavour as a key attribute of e-cigarette satisfaction, and that this preference can vary among subpopulations, for example, according to gender and age.[15–17] On the advice of the panel, we included refill pods for the three most popular generic flavour types, tobacco, menthol and fruit, and ensured further information was provided to participants about other available flavours. The inclusion of tobacco flavour was important for an intervention with current smokers who may initially prefer this,[18] but choice of flavour is

not fixed and that 'flavour migration', in particular from tobacco to other flavours, has been reported.[19]

Panel recommendation to provide a higher strength nicotine liquid (18–20 mg) echoes literature which indicates higher strengths better facilitate successful switch away from tobacco cigarettes.[20] However, the PPI panel did raise the issue of potential use of lower strengths, particularly with a longer-term view, and so our accompanying information for intervention participants included details on this, to allow scope for individual preference. Panel feedback on nicotine salt e-liquid was positive. Although to date, there has been little smoking cessation research conducted using vaping products containing nicotine salts,[21] recent evidence indicates that smokers who switched to nicotine salt pod system e-cigarette were able to maintain their nicotine levels and transferred their dependence, suggesting their potential for supporting switching.[22]

Affordability was shown to be an important consideration, and any calculation should factor in ongoing costs for consumables as well as starter kit costs. Generally, closed-pod systems and disposable e-cigarettes require lower initial outlay, but ongoing costs can be higher than for open systems. Pod systems are often sold at a loss, with profits made on subsequent purchase of refill pods.[23] Research indicates that although consumers are likely to choose lower-priced e-cigarettes where other features are held equal, trade-offs are made against other factors, such as availability, flavour and nicotine strength.[15 18] These trade-offs were raised by both the professional and PPI panel, who noted the relatively higher cost of tobacco smoking, and the importance of local availability in both convenience stores as well as online. This emphasis is reflected in UK sales data over the last 5 years which shows that non-specialist and online purchases have risen while simultaneously purchases at specialist vape shops have declined.[24] Given that the COSTED trial aims to recruit attendees in the ED, with a broad demographic reach, it was felt important to offer a device which could be obtained via different points of purchase.

In terms of all dimensions, including price, style of device, complexity of operation, flavour and strength of e-liquids, e-cigarettes are a hugely diverse rather than 'one size fits all' product. Qualitative research shows that choice in vaping is important,[14 25] and this was reflected in the PPI panel having different personal preferences. Therefore, the intervention script and accompanying materials framed the provision of the device as an introduction to vaping, to encourage experimentation and provide advice about seeking support and alternatives.

Development of a generic tool for device selection for e-cigarette interventions for smoking cessation

PPI work identified a number of key criteria for consideration when selecting an appropriate device for smoking cessation services, health trusts and research interventions

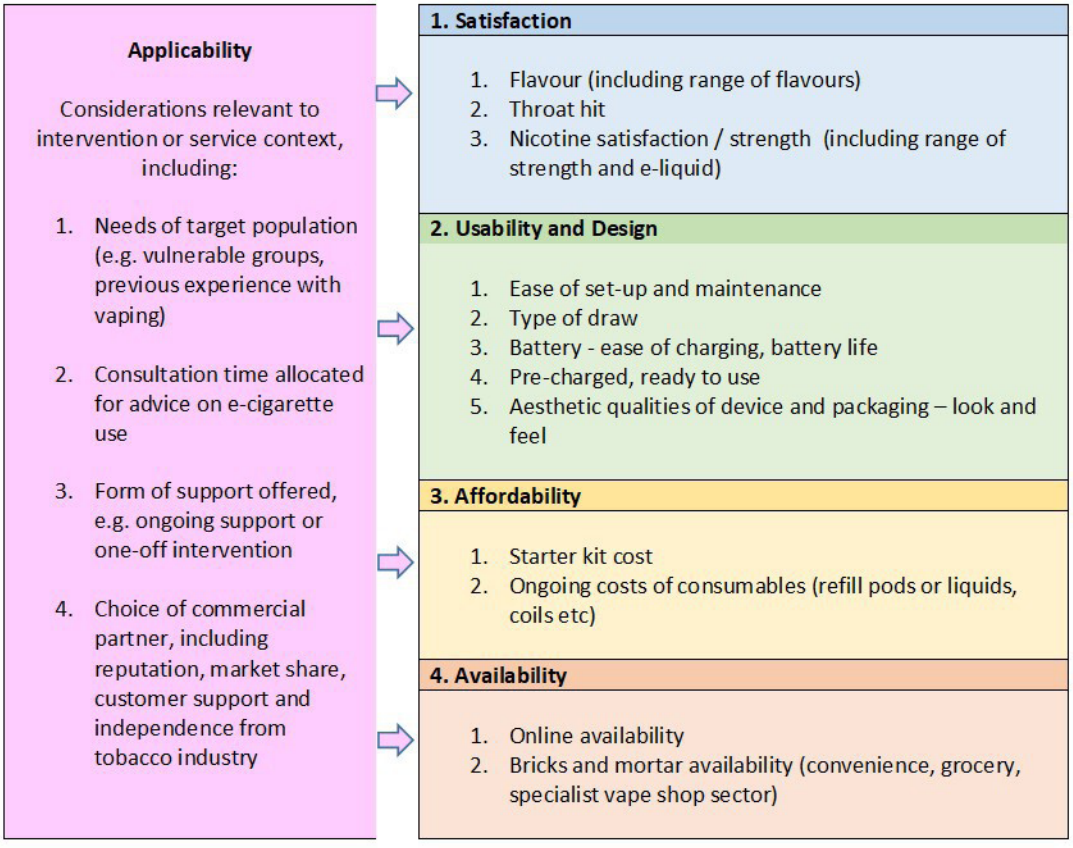

Figure 3 A checklist for device selection for e-cigarette smoking cessation interventions.

using e-cigarettes. Figure 3 summarises these as dimensions and subdimensions. This checklist has been developed for wider application, beyond the current study, to aid the selection process for e-cigarettes for other interventions. This is proposed as an adaptable tool, which can be applied in multiple ways, for example, questionnaire format (through application of a score or scale); as a prompt for discussion in interviews, focus groups or team discussion about intervention design. In England, this is timely, as guidance is needed for services to successfully implement the recently launched nationwide DHSC 'Stop to Swap' scheme.[7]

Barriers to e-cigarette interventions include fears around industry collusion. Farrimond and Abraham[26] describe tension over the profit/private nature of e-cigarette supplies and current lack of licenced e-cigarette product as a reasoning for hesitance from public health. A systematic process such as that used here may facilitate objective decision-making and go some way towards allaying these concerns.

Strengths and limitations

To our knowledge, this is the first systematic, robust PPI consultation undertaken for selecting an e-cigarette for use in cessation interventions. The consultation incorporated a range of perspectives, including experts from academia, SSS and the independent vaping industry, and experts by experience people who smoke and/or vape. The findings were critical for shaping our intervention design. For transparency however, we wish to emphasise that the work was not designed as a 'research study' and is not positioned as such. In keeping with PPI consultation, information gathering was adaptable and informal, to suit individuals involved, and the number of participants was modest.

CONCLUSION

The checklist presented here was derived from thorough PPI and scoping work, incorporating input from PPI and professional panel members to enable selection of an appropriate device for the COSTED trial. The process showed that key criteria for consideration when selecting an appropriate device for smoking cessation interventions using e-cigarettes include satisfaction, usability, affordability and availability. Each criterion required assessment to ensure the best fit to the intervention context and needs of the target population. This decision-making process may involve compromises to provide a device which represents the 'best fit' for purpose.

The emphasis of this paper is not to recommend a specific product to be included in all e-cigarette trials, but rather propose that a systematic evaluation should be undertaken before product selection to ensure appropriateness to a specific trial population, intervention or service. Input from smokers and ex-smokers is essential. To this end, we have produced a generic checklist to help inform these decisions. These considerations must be alert to current vaping market forces, where preference for type of device and point of purchase is rapidly evolving. Utilisation of this approach could contribute to the successful development and evaluation of cessation interventions.

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Acknowledgements We would also like to thank all our PPI contributors who have been critical in defining choice of e-cigarette starter kit and shaping the COSTED intervention.

Contributors PB and EW led the consultation design, data collection and synthesis. IP and CN led the main study (COSTED) and provided support on PPI consultation design and interpretation. PB led on reporting findings, with additional input from EW, IP and CN. IP and CN act as guarantors for the study.

Funding The COSTED trial is funded by the National Institute for Health Research (NIHR) HTA programme (project reference 129438).

Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Ethics approval The COSTED trial received ethical approval from the UK National Research Ethics Committee—Oxford B (reference 21/SC/0288). As a PPI consultation, the work presented here did not require formal ethical approval, in accordance with NIHR guidelines, whereby contributors are involved in the design, implementation and management of the research process itself, rather than being participants or subjects of the research. The ethics committee were aware of the PPI activities through the protocol. Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request. The data underlying this article will be shared on reasonable request to the corresponding author.

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