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Plain Packaging of Waterpipe Tobacco? A Qualitative Analysis Exploring Waterpipe Smokers' and Non-smokers' Responses to Enhanced versus Existing Pictorial Health Warnings in Egypt

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RESEARCH ARTICLE**Plain Packaging of Waterpipe Tobacco? A Qualitative Analysis Exploring Waterpipe Smokers' and Non-smokers' Responses to Enhanced versus Existing Pictorial Health Warnings in Egypt**

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ABBREVIATIONS

FCTC — Framework Convention on Tobacco Control

PHWs — Pictorial Health Warnings

WHO — World Health Organization

WT — Waterpipe Tobacco

WTS — Waterpipe Tobacco Smoking

WTPs — Waterpipe Tobacco Packs

ABSTRACT

Objectives Despite the global increase in waterpipe tobacco smoking (WTS), few studies have assessed the effectiveness of waterpipe tobacco (WT) health warnings. Although Egypt has used four generic pictorial health warnings (PHWs) on waterpipe tobacco packs (WTPs) and has rotated these every two years since 2008, WTS rates have continued to rise. We explored in this qualitative study how participants perceived existing PHWs on WTPs, assessed how they interpreted novel plain packaging of WT featuring enhanced PHWs, and probed perceptions of how existing and novel sets would affect uptake or cessation of WTS.

Design We conducted ten qualitative focus groups and ten in-depth interviews. We explored participants' views of the four existing PHWs (occupied 50% of the front and back of WTPs, displayed cancers, and featured colourful fruits and flavors) and four novel PHWs (occupied 80% of the front and back of WTPs, displayed different topical content, with plain packaging). Transcripts were analyzed using thematic analysis.

Setting Rural Menoufia, urban and semi-urban Cairo, Egypt.

Participants 90 waterpipe smokers and non-smokers, males and females, aged 18 years or older.

Outcomes Perceived potential effect on WTS uptake or cessation, probing factors related to PHW content and WTP design.

Results Participants in focus groups and in-depth interviews thought existing WT PHWs elicited affective responses, but found them unclear or unrealistic and thought the colourful packaging detracted from the warnings. In contrast, they thought novel and larger WT PHWs presented in plain packaging might prevent WTS initiation or trigger quit attempts. Participants regarded warnings featuring proximal health risks as most likely to be acceptable.

Conclusions Our exploratory study suggests larger WT PHWs featuring proximal risks and

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3 presented on plain WTPs could potentially deter experimentation with WT products among non-
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5 users and promote cessation among existing users.
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9 The abstract of this study has been presented at the World Conference on Tobacco and Health,
10
11 2018 in South Africa: <https://doi.org/10.18332/tid/84640>.
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ARTICLE SUMMARY

Strengths and limitations of this study

- This is the first qualitative study to explore plain packaging of waterpipe tobacco products in a country that has existing waterpipe tobacco pictorial health warnings.
- We provide novel insights from both non-smokers and smokers into potential policy-relevant outcomes, particularly uptake and cessation of waterpipe tobacco smoking.
- Use of combined focus groups and in-depth interviews as qualitative methods offered rich understanding of perceptions related to waterpipe tobacco labelling, with respect to which contents pictorial health warnings might feature, and how design of waterpipe tobacco packs might be improved.
- Our sample of 90 individuals means we cannot generalize our findings, however we included a variety of participants, and achieved data saturation.
- While we explored projected rather than actual responses to existing and novel waterpipe tobacco pictorial health warnings with plain packaging, our findings could guide future experimental studies and assist policy-makers to improve waterpipe tobacco regulations.

KEY WORDS

Plain packaging, Health warnings, Waterpipe tobacco, Uptake, Cessation, Qualitative research

INTRODUCTION

The introduction of flavoured tobacco and the lack of regulatory policies have seen waterpipe tobacco smoking (WTS) increase globally.¹ Misperceptions that WTS is a safe alternative to cigarette smoking may also have contributed to rising waterpipe tobacco (WT) use,² even though WTS causes respiratory illnesses, cardiovascular diseases and adverse perinatal outcomes.³ These factors have helped WTS become more socially acceptable, especially among youth^{4,5} and women.^{6,7}

WT use has extended beyond the East, where it has been present for decades, and is increasingly popular in the West, where WTS rates have reached 10% among some young adult populations in the United States and the UK.^{8,9} The WHO Eastern Mediterranean Region (EMR) remains home to the highest WTS rates worldwide;^{1,10} in some EMR countries, WTS has surpassed cigarette smoking in females and adolescents.^{11,12} In Egypt, adolescent girls (3.4%)¹³ and university students (12.2%)¹⁴ report higher WTS rates than their older counterparts (0.3% in women¹³ and 6.2% in men¹⁵), and rurally-located Egyptian males smoke WT more (7.5%) than men living in urban regions (4.9%).¹⁵ This global surge in WTS makes examining the perceived effectiveness of existing WT control policies important to inform a much needed WT regulatory framework.¹⁶⁻¹⁸

Applying health warnings to tobacco products can cost-effectively increase public awareness of smoking's risks, increase the likelihood of quitting among smokers, and deter smoking initiation among non-smokers.¹⁹ These outcomes are mediated by several measures of effectiveness that have been organized, based on behavioural theories, within conceptual frameworks of health

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3 warning impact.²⁰⁻²³ In line with this evidence, guidelines for implementing Article 11 of the
4 WHO's Framework Convention on Tobacco Control (WHO FCTC) call for on-pack pictorial
5 health warnings (PHWs), and recommend plain packaging and increasing warning size.²⁴ Egypt,
6 a signatory country to the WHO FCTC, has applied generic PHWs to waterpipe tobacco packs
7 (WTPs).²⁵ Since 2008, a set of four PHWs has appeared on the bottom half of the front and back
8 of WTPs; these warnings carry the quitline number and rotate every two years.²⁶ However,
9 WTPs still depict colourful fruits and flavours in brand imagery.²⁶

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12 Several observational²⁷ and experimental studies,²⁰ suggest plain packaging with larger PHWs²⁸
13 could more effectively reduce tobacco smoking through increasing warning salience, making the
14 packaging and smoking less appealing, and reducing misperceptions about product harm,^{29,30}
15 especially in non-smokers or non-established smokers.³¹ Yet, while this evidence is encouraging,
16 these studies have focussed largely on cigarettes and we know little about how PHWs could
17 reduce non-cigarette tobacco use, particularly WTS.³²

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20 To our knowledge, only a few studies have examined the impact of WT PHWs: two online
21 surveys from Canada and the United States,^{33,34} two qualitative studies from the UK³⁵ and the
22 EMR,³⁶ and one recent Egyptian survey.³⁷ The two online surveys tested hypothetical warnings
23 shown on computer screens rather than on WTPs and examined the effectiveness of text-only
24 versus PHWs.^{33,34} Both studies found that PHWs had a modest impact on established waterpipe
25 smokers.^{33,34} The UK qualitative study found that when warnings increased in size and packs
26 became less branded, participants felt WTPs were less attractive and warnings were more
27 impactful.³⁵ EMR study participants reported that PHWs improved respondents' knowledge

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3 about WTS health hazards.³⁶ These studies are important but were confined to waterpipe
4 smokers;³³⁻³⁶ while it is important to examine how WT PHWs might pertain to both smokers and
5 non-smokers. The Egyptian study reported that only half of 1048 waterpipe smoker and non-
6 smoker participants thought that existing PHWs on WTPs were visible; they expressed varying
7 views on the effectiveness of WT PHWs across several measures (such as salience, credibility,
8 perceived harm, affective reactions).³⁷ However, this survey did not examine whether
9 participants perceived existing WT PHWs effective in deterring uptake or quitting of WTS.
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21 Given rising WTS rates in Egypt, in 2015 the Tobacco Control Unit in the Egyptian Ministry of
22 Health proposed amending PHW regulations and introducing plain packaging. Specifically, it
23 recommended increasing PHW size to 80% of the pack surface, and removing colours and
24 flavour imagery from tobacco packs. Preliminary evidence on the potential effects of this
25 approach was required. Qualitative methods are particularly useful in exploring understudied
26 areas.^{38,39} To inform WT labelling policy, we conducted this qualitative study to explore how
27 participants perceived existing PHWs on WTPs, assessed how they interpreted plain packaging
28 of WT featuring enhanced PHWs, and probed perceptions of how existing and novel sets would
29 affect uptake or cessation of WTS.
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45 **METHODS**

46 **Design**

47 The study comprised ten focus group discussions and ten in-depth interviews that took place in
48 urban and semi-urban regions in Cairo, and a rural area in Menoufia governorate. We utilized
49 both focus groups and in-depth interviews as complementary approaches; focus groups explored
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3 participants' interactions and whether and how consensus views evolved while in-depth
4 interviews allowed detailed probing and deeper understanding of participants' views.^{38,39} Some
5 sessions were conducted in WTS usage settings, such as cafes, where we observed social and
6 cultural dynamics of WTS and assessed WT PHW's visibility to others.
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14 Our conceptual framework drew on the theory of planned behavior,⁴⁰ as outlined in IARC
15 Handbooks of Cancer Prevention, Tobacco Control, Methods for Evaluating Tobacco Control
16 Policies 2008.²³ We explored policy-relevant outcomes with respect to the perceived potential
17 effect on WTS uptake and cessation, and probed factors related to PHW content and WTP
18 design, including salience, affective reactions, perceived harm and credibility. This study was
19 approved by the Ethical Review Board of the Faculty of Medicine, Ain Shams University
20 (FMASU R 10/2015). We used SRQR guidelines for reporting qualitative research.⁴¹
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33 **Sample**

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35 Our sample comprised men and women, 18 years of age or older, who lived in rural, urban, and
36 semi-urban locations. We included self-identified waterpipe smokers (exclusive WT or dual
37 users of WT and cigarettes) and non-smokers (non-users of any tobacco product), as we were
38 interested in how warnings could influence WTS initiation as well as cessation. Participants were
39 recruited using snowball sampling;⁴² we explained the study purpose to people who made
40 contact, invited them to participate in a one-on-one interview or focus group, and then set a
41 meeting date and time. Participants did not discernibly differ by type of interview chosen.
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54 In total, 90 individuals participated, including 80 in homogenous focus groups (with respect to
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3 age, gender, smoking status) with 6–8 individuals per group, and 10 in in-depth interviews (**see**
4 **Supplementary Table 1**). As WT use in Egypt is generally higher among males,¹⁵ more males
5 participated in our sessions. **Supplementary Table 2** contains details of participants'
6 demographic characteristics.
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11 **Tools**

12 *Interview Guide*

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15 We developed the interview guide in Egyptian colloquial Arabic and incorporated qualitative
16 measures used to assess tobacco labelling policies.²³ We pilot tested the interview guide for
17 clarity and comprehensiveness, tested the appropriateness of our prompts and questions after the
18 pilot sessions, and made modifications following discussions with the research team. We used
19 the same guide with focus groups and in-depth interviews and probed participants' experiences
20 of WTS, their knowledge of WT PHWs, their views on the existing and novel PHWs on WTPs,
21 and their perceptions of placing PHWs on waterpipe devices (**see Supplementary for interview**
22 **guide**). In this article, we focus on discussing PHWs on WTPs.
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40 *Pictorial Health Warnings on Waterpipe Tobacco Packs*

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42 The existing PHWs depicted cancers of lung, throat, mouth, and face, covered 50% of the lower
43 surface of the front and back of the WTP against a colourful background depicting fruit and
44 flavour imagery. The warnings included pictures, generic text and the quitline number (**Figure**
45 **1A**).
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53 We adapted novel PHWs from a health warning database⁴³ and followed WHO FCTC
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3 recommendations for plain packaging^{24,44} building on the proposal of the Tobacco Control Unit
4 of the Egyptian Ministry of Health; the PHW thus covered 80% of the upper surface of the front
5 and back of the WTP against a dark uniform plain background not depicting any fruit or flavour
6 imagery, with the remaining 20% depicting only the brand name in standardised font. The novel
7 PHWs included pictures, text and the quitline number. We applied newly designed PHWs to
8 used WTPs to promote authenticity. We pilot tested health warnings messages with
9 corresponding images for clarity and comprehension: (“Smoking kills,” “Smoking causes lung
10 cancer”, “Smoking causes clotting of blood vessels”, “Smoking causes blindness”, “Smoking
11 during pregnancy harms fetus”, and “Don’t let your children inhale your smoke”). The warnings
12 used were selected following discussions amongst the research team and feedback from pilot
13 sessions, and reflected the best available evidence on WTS health outcomes.⁴⁵ WTS share
14 common harms with those caused by cigarette smoking.³ We sought topical content showing less
15 severe harms than those depicted in existing PHWs. The four novel warnings selected included
16 the effect of smoking during pregnancy on the fetus, effects of peripheral vascular diseases
17 affecting the feet and eye, and effects on teeth and gums (**Figure 1 B**). Although it was important
18 to adapt the textual message to be waterpipe-specific, we did not test this in the study reported
19 here; this was assessed separately in another study of our research project.
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44 **Data Collection**

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46 Data were collected from October 2015 to February 2016 at the Faculty of Medicine, Ain Shams
47 University in Cairo (five focus groups and five in-depth interviews), and at participants’ homes
48 or in cafés for those in rural and semi-urban areas (five focus groups and five in-depth
49 interviews). All participants received an information letter explaining the study and were asked
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3 to provide verbal consent prior to each discussion or interview commencing. Participants were
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5 advised their data and identity would be confidential, and told they could withdraw from the
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7 study at any time.
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10 Each focus group or interview was moderated by two of the co-authors (AM, WS, ME, and WM)
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12 and audio-recorded; each session was about one hour long. The facilitator and note taker
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14 regularly switched roles to promote reflection, and the wider team critically reflected on the
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16 interviews during team meetings. The facilitators followed standard procedures when discussing
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18 the interview guide topics and introduced the PHW stimuli when the relevant topic was opened
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20 for discussion. No further sessions were scheduled once data saturation had been reached, i.e. no
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22 new themes were being generated during the discussions.⁴⁶
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28 **Analysis**

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30 Two authors independently transcribed verbatim the recorded sessions and compared the two
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32 transcripts to ensure inclusivity and accuracy (WH, HM); a third author (AM) resolved any
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34 discrepancies. Considering the identical aims and topics explored, data from focus groups and
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36 interviews were analyzed together. We analysed the data using a thematic approach.^{47,48} We
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38 coded transcripts as the study progressed using a three-phase process that began by organizing
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40 ideas in relation to the research questions, then involved independent reviews of transcripts to
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42 identify preliminary themes and create an initial coding list.⁴⁹ We finally independently refined
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44 this list (AM, AA), added new codes where appropriate, and developed broader themes, that one
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46 author (HM) then reviewed across all cases. We resolved minor inconsistencies during
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48 discussion sessions and after extensive reviews of transcripts before we finalized the themes and
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50 subthemes (**see Supplementary Table 3**). In this article, we focus on policy-relevant outcomes
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3 relevant to PHWs on WTPs as described above in methods “design”.
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10 **RESULTS**

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12 The 90 participants in focus groups and interviews comprised more males (72.2%) than females
13 (27.8%) and participants’ mean age was 33.4 ±11.6 (see **Supplementary Table 2**). We
14 identified the overall themes: warning label content and pack design features, and discuss these
15 in relation to WTS uptake and cessation comparing throughout existing and novel sets. We
16 report below results from both focus groups and individual interviews. We cite exemplar
17 quotations below and provide a more detailed set of quotations in **Supplementary Table 4**,
18 where we also indicate the gender, age group, smoking status, and location of participants.
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31 Most participants were aware of warning labels on WTPs and reported seeing these when
32 purchasing or preparing their tobacco. However, those using waterpipes in cafes or were less
33 likely to see WTPs as WT was prepared out of their sight *“I was downtown and we saw smokers
34 in cafes but shisha is always served ready...I never saw the packs”* (Female non-smoker, >25y,
35 semi-urban).
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43 **Warning label content – perceived likely effect of existing and novel PHWs**

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45 Participants who were aware of existing WTP warnings recalled these as disturbing; however,
46 several felt these warnings had limited impact. Many recalled the lung cancer PHW and the text
47 “smoking is hazardous to health and causes death” as the most believable warning, yet also the
48 least impactful, because of wearout: *“...the other warnings like the lung cancer one...people got
49 used to them after a while”* (Male smoker, >25y, rural). Participants found the existing
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3 warnings, which all featured cancer-related harms, frightening and disgusting, and non-smokers,
4 particularly, avoided looking at them. Nonetheless, several questioned the harms existing PHWs
5 featured and saw these as exaggerated: *"I don't want to look at it from near or far...they want to*
6 *send us a message that it is harmful but in an awful and overstating way"* (Female, smoker,
7 <25y, urban).

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10 Some also found existing warnings difficult to understand: *"It looks like a bad thing but it is not*
11 *clear what it is"* (Female, non-smoker, >25y, semi-urban". These participants saw existing
12 PHWs as unconvincing and exaggerated as they had not seen such conditions in real life and
13 sometimes knew people who had smoked for many years with apparent impunity: *"I have seen*
14 *the warning on the packs but I have never seen anything such as that in real life...I know a*
15 *person who has been smoking since the eighties and nothing happened to him"* (Male smoker,
16 >25y, rural).

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19 Participants often denied risks associated with occasional smoking; one exempted himself from
20 harm on the grounds that he did not smoke heavily and had seen no direct evidence of the harms
21 presented in PHWs: *"I don't think I can be affected by smoking, because I don't smoke heavily;*
22 *only once a day, besides...we have never seen the conditions in the warnings in real life"* (Male
23 smoker, >25y, rural). Several thought harms would not occur until they were older, and believed
24 that, if and when they experienced these, they could quit.

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27 By contrast, most participants favoured the new PHWs, which they first viewed during the
28 interview sessions. They found these clearer, more understandable and realistic than existing
29 PHWs, and more likely to capture their attention. Participants also commented that the new

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3 PHWs were easily understood even without text and thus likely to be effective among people
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5 with varying literacy: *"This one is more realistic for its purpose and understandable; even*
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7 *without any text...it is a more convincing warning"* (Female non-smoker, >25y, semi-urban).
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11 Specifically, participants found the new warnings featuring more immediate, proximal risks had
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13 the strongest perceived impact, particularly those showing harmful effects on teeth. Female
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15 participants also felt strongly affected by the PHW illustrating harm to unborn babies, which
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17 forced them to confront the harm they imposed on others: *"The baby warning is effective*
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19 *because it is not about me anymore...This is something way more important than me...I fear for*
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21 *my kid more than I fear for myself"* (Female non-smoker >25y, semi-urban). However, some
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23 continued to see images showing potential harms they may experience still as overstated and
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25 unlikely to happen in the near future: *"This didn't happen before to anyone (foot*
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27 *warning)...we're still young...we won't get this"* (Female smoker, <25y, urban).
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34 Although participants saw the new PHWs as more effective, they suggested improvements to the
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36 warning content. In line with earlier comments about perceived exaggeration, they sought greater
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38 credibility: *"It is very important that you convince me...put something there that I'll believe"*
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40 *(Male smoker, >25y, semi-urban)*. They suggested presenting testimonials: *"Show smokers live*
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42 *people who were damaged because of shisha smoking and others who quit and improved"* (Male
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44 non-smoker, >25y, rural).
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51 Participants recommended illustrating the effects WTS has on women by featuring relevant
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53 cancers and congenital diseases: *"Direct warnings addressing women like cancer of the breast or*
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55 *the uterus or congenital anomalies to the fetus"* (Female, non-smoker, >25y, semi-urban". Some
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3 also thought PHWs targeting women could encourage them to persuade their partners to quit.
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8 Several participants thought PHWs should target youth before they start smoking and suggested
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10 warnings showing how WTS smokers' social relationships (e.g., sexual dysfunction warnings)
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12 would have high impact: *"We want a real effect that already happened...like for example the*
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14 *side effects on sexual functioning...that will definitely affect smokers"* (Male non-smoker, >25 y,
15
16 *rural*).
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19 In addition, participants also suggested printing text warnings including details of the hazardous
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21 ingredients of smoke, with more information on health risks and cessation options inserted on the
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23 inside or outside of the WTP, together with external PHWs would promote cessation behaviour,
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25 and would enhance the impact of novel warnings.
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28 29 30 31 **Design Features of WTPs – perceived likely effect of existing and novel PHWs**

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33 As well as responding to the different warning content, participants also noted that the different
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35 design elements used in the novel PHWs had improved the impact these had. Several commented
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37 on how bright colours and fruit imagery deflected attention away from PHWs and promoted
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39 experimentation: *"The peach drawing is appetizing... [and] drawing attention away from the*
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41 *warning...better put the warning on the top! The pack should be dark...this colour is very*
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43 *bright... just like bonbon packs"* (Female non-smoker, >25y, semi-urban). They found it difficult
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45 to associate fruit flavours with harm and thought the images invited trial: *"The pictures and the*
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47 *smell of fruits make a passerby want to try them all"* (Female non-smoker, >25y, semi-urban).
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54 By contrast, participants thought the plain background, contrasting colours, absence of fruit and
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3 flavour images, and larger warning images shown on the proposed new PHWs increased impact,
4 reduced distraction, and encouraged participants to look more closely at the pack. One noted:
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8 *“Here the picture is bigger and the text has a clear message...together with this dark colour...it*
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10 *makes me focus only on the warning...all this makes it more effective”* (Male smoker, <25y,
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12 *urban*). Together, the altered content and enhanced design attributes increased participants’
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14 perceptions of the impact the novel PHWs would have.
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19 Overall, most waterpipe smoker and non-smoker participants thought PHWs would deter non-
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21 smokers from trying WTS but were less optimistic about the effects on smokers. One noted: *“If*
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23 *we (non-smokers) lusted to smoke it and saw pictures like these...we won’t smoke, but those who*
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25 *do actually smoke already would be indifferent”* (Male non-smoker, >25, urban). Smokers
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27 themselves also felt PHWs had less effect because they had become accustomed to seeing the
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29 images: *“I used to think about the hazards a lot when the pictures first appeared...then I got*
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31 *used to them...I don’t pay them attention anymore”* (Male smoker, <25y, semi-urban). Others
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33 reported using stickers to obscure PHWs or avoiding packs with PHWs they found particularly
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35 confronting: *“I avoid buying the picture of the tongue in particular* (referring to the mouth cancer
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37 warning)*”* (Male smoker, <25y, semi-urban)
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45 As with the current PHWs, most waterpipe smoker and non-smoker participants thought the
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47 proposed PHWs would have a stronger effect on non-smokers than on long-term smokers,
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49 though some indicated they would avoid some warnings and may reduce their WTS: *“If I go to*
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51 *buy moassel (waterpipe tobacco) and found this pack, I’ll go to another shop to buy another*
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53 *one...if I don’t find a picture that makes me comfortable...I won’t smoke that day...but if they’re*
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3 *all like this...I guess I'll try to quit...or... at least decrease my habit” (Male smoker, >25 y,*
4 *rural). In general, participants thought that the new PHW set had greater potential to deter WTS,*
5 *especially among new smokers: “If I'll smoke and saw it... for sure I won't smoke at the*
6 *moment...it's disgusting” (Male non-smoker, <25y, rural).*
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14 **DISCUSSION**

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17 Our qualitative study found that participants privileged the short-term benefits they received over
18 the longer-term risks they faced. They saw existing PHWs as less likely to influence long-term
19 smokers, whose prolonged and repetitive exposure to PHWs appeared to have diminished their
20 response to these aversive stimuli.⁵⁰ Older adult waterpipe users typically dismissed risks
21 associated with WTS, especially if they had not experienced any health effects. This finding is
22 consistent with other studies that found age is negatively associated with perceived risks of
23 smoking and with attention to either graphic or text warnings on tobacco packages.⁵¹
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35 However, the existing PHWs and the novel PHWs tested appeared more likely to influence non-
36 smokers and less-experienced smokers by creating awareness of the health risks WTS presents.
37 These findings are in line with previous research³¹ and address McNeill et al.'s call in their
38 recent review on plain packaging for further research into the effects of tobacco packaging on
39 smoking uptake,⁵² and we provide preliminary evidence that presenting WT in plain packaging
40 could deter non-smokers from experimenting with WTS.
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51 Our findings that novel warnings with clear and large visual elements could challenge perceived
52 immediate benefits and enhance risk perception and acceptance is consistent with earlier work
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3 and suggest presenting PHWs on WTS products featuring plain packaging could cue cessation.³⁵
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5 More generally, our findings suggest a warning evaluation and regular refreshment programme
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7 may be important to ensure warning salience and avoid wearout.
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12 Although existing PHWs induced strong negative emotional reactions, several participants
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14 viewed these warnings as exaggerated and felt the health risk depicted was unlikely to occur.
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16 While PHWs that arouse fear may increase risk perceptions, they did not necessarily promote
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18 greater message acceptance; our findings are thus consistent with earlier studies that reported
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20 highly confronting PHWs could have little effect on behaviour or even elicit adverse
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22 responses,^{53,54} although other studies suggest that the higher negative affect aroused, the stronger
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24 the response elicited.⁵⁵ Our findings also show a complex relationship between the emotional
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26 response elicited and the salience and perceived impact of a message. The PHW depicting oral
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28 harm was minimally disturbing, yet participants saw it as the strongest and the most salient
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30 warning; by contrast, participants regarded the confronting vascular harm PHW as less effective
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32 because the condition was less salient and seen as more distal. As well as the image salience and
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34 affect aroused, the temporal framing is important and PHWs illustrating short-term harms were
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36 thought more effective. Our findings thus support earlier studies analysing the relationship
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38 between risk perception, believability, and temporal distance.⁵⁶
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47 Young adults and women found gender- and age-specific messages more persuasive. Evidence
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49 that WTS could be predicted by age and gender-related indicators,⁵⁷ suggests strategies targeting
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51 young adults and women are crucially important, particularly as these demographics perceive
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53 messages differently from older adults.⁵⁸ For example, messages about negative health effects
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3 from passive smoking, sexual dysfunction and intimacy, miscarriages, and harmful effects on
4 infants and children were considered more persuasive among younger adults and women than
5 other messages.
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12 Another plausible approach suggested by participants in our study was to develop a visible and
13 sensible message in both text and graphic formats that target waterpipe smokers with detailed
14 cessation information inserted on the WTP. This recommendation is consistent with that of an
15 earlier study that found that combined text and graphic warnings elicit adverse reactions to
16 smoking among non-smokers and smokers,⁵⁹ especially on the sustainability of quit behaviour.⁶⁰
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18 In line with these suggestions, the design of novel warnings helped make the cessation quit line
19 more prominent by the contrasting dark plain background.
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31 We also found specific design elements that could inform future PHW development. Some
32 participants thought plain packs increased the salience and effectiveness of the warnings, and
33 reduced the appeal of the packaging and misperceptions of harm. These findings are consistent
34 with the literature on plain packaging.^{44,52} Evidence that flavoured cigarettes reduce harm
35 perceptions appears relevant to WT^{61,62} as participants noted that images of fruits or appealing
36 flavours attracted them to WTS and deflected their attention from warning information. The
37 novel warnings tested were presented as vivid images with a contrasting dark plain background
38 and had no association with fruits or flavours. These PHWs had a stronger visual impact and
39 were considered more salient than the PHWs currently used in Egypt. Some recommended that
40 attractive imagery and flavour attributes should be banned. Furthermore, clarity of the pictures
41 and presenting them in larger sizes played a role in enhancing acceptance and risk perception
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3 among participants, a finding also reported by Jawad and colleagues.³⁵
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8 See **Strengths and Limitations** in **Supplementary file (page 8)**.
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10 11 12 *Conclusions*

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14 PHWs on WTPs have the potential to reduce uptake and cue quit attempts but might be more
15 effective if PHWs used more impactful designs. Specifically, PHWs using contrasting
16 background colours and plain packaging, offering no association to fruits or flavours, targeting
17 age and gender, displaying proximal health risks, might enhance both warning impact and risk
18 perception. Our exploratory study provides preliminary evidence of the potential effectiveness of
19 WT products that carry enhanced warnings with plain packaging and suggests alternative designs
20 and contents that could be further developed and tested in other studies. Policymakers designing
21 and implementing health warnings on WT products now have clearer evidence on which to base
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9

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11
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13 AM, ME, WS, WM carried out the study. SL and AM sought necessary approvals for using the
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17

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25

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31
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34

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37 **CHECKLIST FOR REPORTING GUIDELINES** We used SRQR guidelines for reporting
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39

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For peer review only

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3 **Figure 1. Pictorial Health Warnings used in this study**
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A. Current PHW set used in the qualitative study
 (1)Face cancer, (2) Lung cancer, (3) Mouth cancer, and (4) Throat cancer



B. Alternative PHW set used in the qualitative study
 (1)Fetal harm, (2) Blindness, (3) Blood vessel clotting, (4) Tooth and gum decay

Figure 1. PHWs used in the study

Figure 1. Pictorial Health Warnings used in this study

297x300mm (300 x 300 DPI)

Supplementary

Table 1. Total number of interviews and focus group discussions conducted by demographic profile of participants

	FGDs (10, total participants=80)				IDIs (10)			
	Males (7)		Females (3)		Males (7)		Females (3)	
Age	S	NS	S	NS	S	NS	S	NS
	(5)	(2)	(2)	(1)	(6)	(1)	(2)	(1)
18-24	2	1	1		3	1	1	
25+	3	1	1	1	3		1	1

FGDs=Focus group discussions, IDIs=In-depth interviews, S=Waterpipe smoker, NS=Non-smoker

Table 2. Sociodemographic characteristics and waterpipe smoking status of participants

	N=90	%
Gender		
Male	65	72.2
Female	25	27.8
Age (range 18-73)		
Mean age ± standard deviation	33.4 ± 11.6	
Age group, years		
18-24	21	23.3
25+	69	76.7
Education level		
Primary or lower	16	17.7
Secondary	32	35.6
Tertiary	42	46.7
Occupation		
Employed professional	42	46.7
Employed non-professional	34	37.8
In further study or seeking employment	14	15.5
Residence		
Rural	20	22.2
Semi-urban	51	56.7
Urban	19	21.2
Smoking status		
Waterpipe smoker	62	68.9
Non-smoker	28	31.1
Ever noticed PHWs on WTPs		
Yes	53	58.9
Where		
At cafés	17	32.1
At home	11	20.8
Buying tobacco	25	47.2

Interview guide *

Interview guide questions	Parts relevant to this article
<p>Introductory questions</p> <p><i>In general, what do you think of waterpipe smoking?</i></p> <p>Personal experiences of waterpipe smoking</p> <p><i>Tell me about your waterpipe smoking, habits, duration, etc...Tell us more on how did you start smoking?</i></p> <p><i>Could you describe the setting in which you smoked waterpipe last time?</i></p>	
<p>Awareness of pictorial health warnings</p> <p><i>Have you ever noticed the pictorial health warnings on waterpipe tobacco packs?</i></p> <p><i>Where did you see them? Can you tell us more about the setting?</i></p> <p><i>How do they look like?</i></p>	√
<p>Positive and negative characteristics of the current/alternative set of PHW</p> <p><i>Have you ever come across the warning on this pack before? What is your first impression about it?</i></p> <p><i>What do you think/feel when you see it?</i></p> <p><i>In your opinion, what is good and is bad about it? Why do you think so?</i></p> <p><i>Do you think it is/would be effective? Why and how do you think so?</i></p>	√
<p>Reactions to placing PHW on the waterpipe device</p> <p><i>What is your first impression about putting the warning in this spot?</i></p> <p><i>What do you think/feel when you see there?</i></p> <p><i>In your opinion, what is good and is bad about this spot? Why do you think so?</i></p> <p><i>Do you think people will notice the PHW on this spot?</i></p> <p><i>Would it be effective? Why and how do you think so?</i></p>	

***This guide contains core questions. Probing questions were used when necessary (examples include questions on salience, affective reactions, perceived harm, credibility)**

Table 3. Themes and subthemes identified from focus groups and in-depth interviews*

Themes	Subthemes	Themes covered in this article
General perceptions of waterpipe smoking	Factors contributing to WTS Factors affecting WTS initiation and continuation WTS setting Patterns of WTS consumption Social and cultural context of WTS WTS compared to cigarette smoking Tobacco product characteristics Perceived health consequences Reasons for quitting	
Views on pictorial health warning labels on waterpipe tobacco packs	General knowledge /awareness of PHWs on WTPs Sources of awareness Most salient/recalled labels, reasons Cessation helpline Perception of PHWs on WTPs motivating and discouraging factors related to viewing PHW labels	Partly
Perceptions of existing waterpipe tobacco warnings	General impressions, attitude (appeal, affective reactions, avoidance, wear out) Positive and negative characteristics of design and content Participants views of the most effective one in general Possible effects on quitting and/or initiating WTS	√
Insights into novel waterpipe tobacco warnings	General impressions, attitude (appeal, affective reactions, avoidance) Positive and negative characteristics of design and content Participants views of the most effective one in general Possible effects on quitting and/or initiating WTS	√
Avenues for development	Participant suggestions of improved label characteristics regarding content, design, location Participant suggestions for other placement locations	Partly
Best location for inserting labels on the waterpipe device and accessories	Views behind choosing each location Concerns about each location Possible effects on quitting and/or initiating WTS	
Participant suggestions for reducing tobacco use in general and WTS in particular	Further strategies for improved regulations Enforcing existing laws Posting warnings in public and other places Associate warnings with mass-media anti-tobacco campaigns, increase taxation and other suggestions	

*** Themes presented in this article were synthesized in respect to warning content and pack design and their perceived likely effect on uptake or cessation of waterpipe smoking, comparing existing versus novel warnings.**

Table 4. Selected participants' quotes representing views of the current and alternative pictorial health warning labels on waterpipe packs. Quotes are presented by gender, age group*, smoking status, and region of participants

<i>Warning label content – perceived likely effect of existing and novel PHWs</i>	
"The picture of a bent cigarette (i.e. representing sexual dysfunction) caught people's attention considerably...but the other warning...people got used to them after a while"	<i>(Male smoker, >25y, rural)</i>
"The most commonly known warning is that of the lungs"	<i>(Male smoker, >25y, semi-urban)</i>
"The picture is disgusting and frightening..."	<i>(Male non-smoker, <25y, rural)</i>
"Pictures are scary and unpleasant"	<i>(Male smoker, >25y, semi-urban)</i>
"The pictures make me sick..."	<i>(Male smoker, >25y, urban)</i>
"The warning shouldn't be that it causes cancer and that's it...that is just routine talk"	<i>(Male non-smoker, >25y, urban)</i>
"I just don't believe it...nobody reaches this stage"	<i>(Female smoker, <25y, urban)</i>
"I don't believe the warnings...I know smoking is harmful but not to that extent. This is unrealistic"	<i>(Male smoker, <25y, rural)</i>
"We want to see the normal lung beside the diseased one...but this one straight is not clear"	<i>(Male non-smoker, >25y, urban)</i>
"The pictures are not realistic, we never see such things in real life"	<i>(Male non-smoker, >25y, semi-urban)</i>
"The pictures are extremely exaggerated"	<i>(Male smoker, <25y, urban)</i>
"Is this a burnt piece of pizza? (face cancer warning)...this one won't be clear to illiterates...I didn't get it before reading the text beneath"	<i>(Male non-smoker, >25y, urban)</i>
"The picture is frightening and is very disgusting"	<i>(Male smoker, >25y, urban)</i>
"It can make me want to look closely to see what the illness shown is"	<i>(Female non-smoker, >25y, semi-urban)</i>
"For me, the most effective one is picture of teeth affection...it's very scary and upsetting. I see that content of the warning is much more important than size"	<i>(Male smoker, >25y, semi-urban)</i>
"With this shape (deformed teeth and gums) I may disturb my son when I come close to kiss him...now that will hurt me"	<i>(Male smoker, >25y, semi-urban)</i>
"The baby's picture may affect women more than me"	<i>(Male smoker, >25y, semi-urban)</i>
"If a pregnant woman saw this picture...she would fear for her unborn child to have anomalies"	<i>(Female smoker, >25y, semi-urban)</i>
"Explain the components of tobacco as glycerin and the hazards of each of them...tell them: try to smoke each component by itself and see what happens to you"	<i>(Male non-smoker, >25y, semi-urban)</i>
"Simplify the matter of quitting to people...especially those who have been smoking for a long time..."	<i>(Male nonsmoker, >25 y, rural)</i>
"If you talk to a smoker about their health...they wouldn't pay attention but there are other aspects as hazards to their children"	<i>(Male non-smoker, >25y, semi-urban)</i>
"The most effective thing that makes a smoker quit is that they themselves get ill or they see someone get ill"	<i>(Male smoker, >25y, semi-urban)</i>
"I saw on the internet a pack of cigarettes with a picture of a mother and her child, and on opening it the mother is separated from him. This a new effective idea."	<i>(Female smoker, <25 y, urban)</i>

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"A pregnant woman or a mother may ask their smoker husband to stop"	(Female non-smoker, >25y, semi-urban)
"The only thing that can force me to stop smoking, even if I'm a heavy smoker is the baby affection"	(Female smoker, <25 y, urban)
"Warnings should target young people under 17 before they attempt smoking"	(Male non-smoker, >25y, semi-urban)
"Warnings concerning sexual dysfunction can affect young smokers"	(Male non-smoker, >25y, semi-urban)
"Focus on the damage that the family suffers...there are problems that can occur with the wife because of smoking...so smoking may endanger the family bonds"	(Male smoker, >25y, semi-urban)
"Pictures should be more realistic, and not only focus on severe side effects like cancers... like if warnings demonstrate just a fingernail affected due to smoking not all the hand, people will be more tempted to believe it"	(Male smoker, <25 year, rural)
Design Features of WTPs – perceived likely effect of existing and novel PHWs	
"The apples got my attention"	(Female smoker, >25y, semi-urban)
"After seeing this...(pointing to the fruit depicted on the pack)...it will be hard for me to link the idea with the damage in this picture"	(Male non-smoker, <25y, rural)
"Pictures of fruits are attractive and appetizing"	(Male smoker, >25y, semi-urban)
"If there is no flavored tobacco, I will quit"	(Male smoker, <25y, urban)
"I can't see any flavors on it...I want to hold it closely to know what did they put there instead...if shisha is served as it is...without any flavors?!...I'll quit"	(Male smoker, <25y, urban)
"If flavors were banned may be some will quit but warnings have no effect"	(Male smoker, <25y, urban)
"The pictures of fruits must be removed as they are appetizing"	(Male non-smoker, <2, rural)
"The dark background makes the writings clearer"	(Male non-smoker, >25y, semi-urban)
"The alternative pack is clearer regarding the color, the picture and the way of writing"	(Male non-smoker, < 25 y, rural)
"The black color makes the pack a lot chic"	(Male smoker, <25y, urban)
"The color of the package is dark and it conveys a sense of pessimism"	(Male smoker, >25y, rural)
"The bigger the picture, the better"	(Male smoker, <25y, semi-urban)
"The warning should be put on top because the pictures of fruits are drawing attention away from the warning"	(Female non-smoker, >25y, semi-urban)
"Oh! I didn't realize there was a quit line on the pack before...this dark background made some kind of contrast... the text now is way clearer for me to read"	(Female smoker, <25y, urban)
"I used to think about the hazards a lot when the pictures first appeared...then I got used to them...I don't pay them attention anymore"	(Male smoker, <25y, semi-urban)
"I have seen the warnings too often that they no longer frighten me"	(Male smoker, <25y, rural)
"The pictures are horrible but people got used to them, if a nonsmoker wished to try and saw the warnings they may change their mind but for those who are already smokers, the warnings make no difference"	" (Male non-smoker, >25y, semi-urban)
"Warnings influence the non-smokers much more than smokers, as non-smokers usually find the picture more disgusting"	(Female, non-smoker, >25y, semi-urban)

"I avoid buying the picture of the tongue in particular (referring to the mouth cancer warning)"	<i>(Male smoker, <25y, semi-urban)</i>
"People can go around all day looking for a certain picture (the lungs)"	<i>(Male smoker, >25y, rural)</i>
"Vendors used to sell the pack with free stickers to cover the warnings"	<i>(Male smoker, >25y, semi-urban)</i>
"No one would buy a pack with such warning (means warning picturing effect of smoking on children)"	<i>(Female smoker, >25y, semi-urban)</i>
"If the warning on the pack looks bad, we tend to throw the external package away and put tobacco in another package or may be order a certain warning"	<i>(Male smoker, >25y, rural)</i>
"The alternative pack may make some smokers reduce smoking"	<i>(Male non-smoker, <25y, rural)</i>
"A beginner can be affected compared to a person who has been smoking for 15 years and nothing happened to them as a result of smoking"	<i>(Male non-smoker, <25y, rural)</i>
"Non-smokers will be more affected by it, smokers won't be much affected"	<i>(Female, non-smoker, >25y, semi-urban)</i>
"It could affect those who want to start smoking, but the older smokers won't be affected much"	<i>(Male, smoker, <25y, semi-urban)</i>

***The age group of participants was categorized as > or < 25 years, because we were interested in highlighting the views of young adults who may be at higher risk of experiencing WTS or maybe non-established WT users yet, versus older adults who might more likely have established a smoking or non-smoking behaviour.**

Discussion-Strengths and Limitations

To our knowledge, this is the first qualitative study to assess smokers' and non-smokers' awareness and acceptance of currently used and novel WT PHWs with plain packaging. Our novel warnings simulated how PHWs appear (or could appear) on packs and devices, we explored projected rather than real-life responses. Experimental work could estimate the likely impact of our new label designs, including more targeted PHWs, on waterpipe smokers' risk perceptions, attitudes and likely cessation responses. Future research could also develop a more comprehensive analysis of factors motivating and reinforcing WTS uptake. Given our findings that PHWs have the potential to reduce WTS initiation, it is also important to test whether the PHW themes we developed could be used in wider health promotion campaigns to reduce the appeal and perceived acceptability of WTS. Future research could explore how WT warnings featuring waterpipe-specific messages would affect awareness and perceptions of WTS.

Our small sample means we cannot generalize our findings, though we note a sample of 90 individuals is still substantial, and saturation had been reached in the responses received. Despite these limitations, our study provides novel insights into the factors supporting WTS uptake, suggests themes PHWs could feature, and outlines how PHWs' format could be improved. We recognize this work programme faces challenges, given the limited resources and capacity in low- and middle-income countries; nonetheless, our findings represent an important step in supporting a comprehensive regulatory framework that reduces WTS and the harm this form of tobacco use causes.

Reporting checklist for qualitative study.

Based on the SRQR guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SRQR reporting guidelines, and cite them as:

O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. Standards for reporting qualitative research: a synthesis of recommendations. *Acad Med.* 2014;89(9):1245-1251.

	Reporting Item	Page Number
	#1 Concise description of the nature and topic of the study identifying the study as qualitative or indicating the approach (e.g. ethnography, grounded theory) or data collection methods (e.g. interview, focus group) is recommended	1,3, 8 & 9
	#2 Summary of the key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results and conclusions	3, 4
Problem formulation	#3 Description and significance of the problem / phenomenon studied: review of relevant theory and empirical work; problem statement	3, 5-9
Purpose or research question	#4 Purpose of the study and specific objectives or questions	3, 8
Qualitative approach	#5 Qualitative approach (e.g. ethnography,	8, 9

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	and research paradigm	grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g. postpositivist, constructivist / interpretivist) is also recommended; rationale. The rationale should briefly discuss the justification for choosing that theory, approach, method or technique rather than other options available; the assumptions and limitations implicit in those choices and how those choices influence study conclusions and transferability. As appropriate the rationale for several items might be discussed together.	See 5 and Supplementary file page 8 for more on limitations
23 24 25 26 27 28 29 30 31 32 33 34 35 36 37	Researcher characteristics and reflexivity	#6 Researchers' characteristics that may influence the research, including personal attributes, qualifications / experience, relationship with participants, assumptions and / or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results and / or transferability	11, 12 for reflexivity Researchers are trained or experienced in qualitative methods. Word count limited detailing qualifications and other items listed here.
38 39 40	Context	#7 Setting / site and salient contextual factors; rationale	8, 9, 11
41 42 43 44 45 46 47 48	Sampling strategy	#8 How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g. sampling saturation); rationale	9, 10, 12
49 50 51 52 53 54 55 56 57	Ethical issues pertaining to human subjects	#9 Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	9, 11
58 59 60	Data collection	#10 Types of data collected; details of data	10, 11

1	methods		collection procedures including (as	
2			appropriate) start and stop dates of data	
3			collection and analysis, iterative process,	
4			triangulation of sources / methods, and	
5			modification of procedures in response to	
6			evolving study findings; rationale	
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9				
10	Data collection	#11	Description of instruments (e.g. interview	10, 11
11	instruments and		guides, questionnaires) and devices (e.g.	
12	technologies		audio recorders) used for data collection; if	
13			/ how the instruments(s) changed over the	
14			course of the study	
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18	Units of study	#12	Number and relevant characteristics of	9, 10
19			participants, documents, or events	
20			included in the study; level of participation	
21			(could be reported in results)	
22				
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25	Data processing	#13	Methods for processing data prior to and	11
26			during analysis, including transcription,	
27			data entry, data management and security,	
28			verification of data integrity, data coding,	
29			and anonymisation / deidentification of	
30			excerpts	
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35	Data analysis	#14	Process by which inferences, themes, etc.	11, 12
36			were identified and developed, including	
37			the researchers involved in data analysis;	
38			usually references a specific paradigm or	
39			approach; rationale	
40				
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43	Techniques to	#15	Techniques to enhance trustworthiness	12
44	enhance		and credibility of data analysis (e.g.	
45	trustworthiness		member checking, audit trail, triangulation);	
46			rationale	
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50	Syntheses and	#16	Main findings (e.g. interpretations,	12
51	interpretation		inferences, and themes); might include	
52			development of a theory or model, or	See 9 for theory
53			integration with prior research or theory	
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57	Links to empirical	#17	Evidence (e.g. quotes, field notes, text	13-17
58	data		excerpts, photographs) to substantiate	
59				
60				

analytic findings

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2			
3	Intergration with prior	#18	Short summary of main findings;
4	work, implications,		explanation of how findings and
5	transferability and		conclusions connect to, support, elaborate
6	contribution(s) to the		on, or challenge conclusions of earlier
7	field		scholarship; discussion of scope of
8			application / generalizability; identification
9			of unique contributions(s) to scholarship in
10			a discipline or field
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15	Limitations	#19	Trustworthiness and limitations of findings
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21	Conflicts of interest	#20	Potential sources of influence of perceived
22			influence on study conduct and
23			conclusions; how these were managed
24			
25			
26	Funding	#21	Sources of funding and other support; role
27			of funders in data collection, interpretation
28			and reporting
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18-21

See also 3, 5 and
Supplementary file page 8
for more on limitations

5 and Supplementary file
page 8 for more on
limitations

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Plain Packaging of Waterpipe Tobacco? A Qualitative Analysis Exploring Waterpipe Smokers' and Non-smokers' Responses to Enhanced versus Existing Pictorial Health Warnings in Egypt

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Manuscripts

RESEARCH ARTICLE**Plain Packaging of Waterpipe Tobacco? A Qualitative Analysis Exploring Waterpipe Smokers' and Non-smokers' Responses to Enhanced versus Existing Pictorial Health Warnings in Egypt**

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ABBREVIATIONS

FCTC — Framework Convention on Tobacco Control

PHWs — Pictorial Health Warnings

WHO — World Health Organization

WT — Waterpipe Tobacco

WTS — Waterpipe Tobacco Smoking

WTPs — Waterpipe Tobacco Packs

ABSTRACT

Objectives Despite the global increase in waterpipe tobacco smoking (WTS) including in Egypt, few studies have assessed the effectiveness of waterpipe tobacco (WT) health warnings. Egypt has used pictorial health warnings (PHWs) on waterpipe tobacco packs (WTPs) and has rotated these every two years since 2008. We explored in this qualitative study how participants perceived existing PHWs on WTPs, assessed how they interpreted novel plain packaging of WT featuring enhanced PHWs, and probed perceptions of how existing and novel sets would affect uptake or cessation of WTS.

Design We conducted ten qualitative focus groups and ten in-depth interviews. We explored participants' views of the four existing PHWs (occupied 50% of the front and back of WTPs, displayed cancers, and featured colourful fruits and flavors) and four novel PHWs (occupied 80% of the front and back of WTPs, displayed different topical content, with plain packaging). Transcripts were analyzed using thematic analysis.

Setting Rural Menoufia, urban and semi-urban Cairo, Egypt.

Participants 90 waterpipe smokers and non-smokers, males and females, aged 18 years or older.

Outcomes Perceived potential effect on WTS uptake or cessation, probing factors related to PHW content and WTP design.

Results Participants in focus groups and in-depth interviews thought existing WT PHWs elicited affective responses, but found them unclear or unrealistic and thought the colourful packaging detracted from the warnings. In contrast, they thought novel and larger WT PHWs presented in plain packaging might prevent WTS initiation or trigger quit attempts. Participants regarded warnings featuring proximal health risks as most likely to be acceptable.

Conclusions Our exploratory study suggests larger WT PHWs featuring proximal risks and

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3 presented on plain WTPs could potentially deter experimentation with WT products among non-
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5 users and promote cessation among existing users.
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9 The abstract of this study has been presented at the World Conference on Tobacco or Health,
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11 2018 in South Africa: <https://doi.org/10.18332/tid/84640>.
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For peer review only

ARTICLE SUMMARY

Strengths and limitations of this study

- This is the first qualitative study to explore plain packaging of waterpipe tobacco products in a country that has existing waterpipe tobacco pictorial health warnings.
- We provide novel insights from both non-smokers and smokers into potential policy-relevant outcomes, particularly uptake and cessation of waterpipe tobacco smoking.
- Use of combined focus groups and in-depth interviews as qualitative methods offered rich understanding of perceptions related to waterpipe tobacco labelling, with respect to which contents pictorial health warnings might feature, and how design of waterpipe tobacco packs might be improved.
- Our sample of 90 individuals means we cannot generalize our findings, however we included a variety of participants, and achieved data saturation.
- While we explored projected rather than actual responses to existing and novel waterpipe tobacco pictorial health warnings with plain packaging, our findings could guide future experimental studies and assist policy-makers to improve waterpipe tobacco regulations.

KEY WORDS

Plain packaging, Health warnings, Waterpipe tobacco, Uptake, Cessation, Qualitative research

INTRODUCTION

The introduction of flavoured tobacco and the lack of regulatory policies have seen waterpipe tobacco smoking (WTS) increase globally.^{1,2} Misperceptions that WTS is a safe alternative to cigarette smoking may also have contributed to rising waterpipe tobacco (WT) use,³ even though WTS causes respiratory illnesses, cardiovascular diseases and adverse perinatal outcomes.⁴ These factors have helped WTS become more socially acceptable globally, especially among youth^{5,6} and women.^{7,8}

WT use has extended beyond the East, where it has been present for decades, and is increasingly popular in the West, where WTS rates have reached 10% among some young adult populations in the United States and the UK.^{9,10} The WHO Eastern Mediterranean Region (EMR) remains home to the highest WTS rates worldwide;^{1,11} in some EMR countries, WTS has surpassed cigarette smoking in females and adolescents.^{12,13} Egypt has witnessed a rising trend in WT use; adolescent girls (3.4%)¹⁴ and university students (12.2%)¹⁵ report higher WTS rates than their older counterparts (0.3% in women¹⁴ and 6.2% in men¹⁶), and rurally-located Egyptian males smoke WT more (7.5%) than men living in urban regions (4.9%).¹⁶ This global surge in WTS makes examining the perceived effectiveness of existing WT control policies important to inform a much needed WT regulatory framework.¹⁷⁻¹⁹

Applying health warnings to tobacco products can cost-effectively increase public awareness of smoking's risks, increase the likelihood of quitting among smokers, and deter smoking initiation among non-smokers.²⁰ These outcomes are mediated by several measures of effectiveness that have been organized, based on behavioural theories, within conceptual frameworks of health

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3 warning impact.²¹⁻²⁴ In line with this evidence, guidelines for implementing Article 11 of the
4 WHO's Framework Convention on Tobacco Control (WHO FCTC) call for on-pack pictorial
5 health warnings (PHWs), and recommend plain packaging and increasing warning size.²⁵ Egypt,
6 a signatory country to the WHO FCTC, has applied generic PHWs to waterpipe tobacco packs
7 (WTPs).²⁶ Since 2008, a set of four PHWs has appeared on the bottom half of the front and back
8 of WTPs; these warnings carry the quitline number and rotate every two years.²⁷ However,
9 WTPs still depict colourful fruits and flavours in brand imagery.²⁷

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12 Several observational²⁸ and experimental studies,²¹ suggest plain packaging with larger PHWs²⁹
13 could more effectively reduce tobacco smoking through increasing warning salience, making the
14 packaging and smoking less appealing, and reducing misperceptions about product harm,^{30,31}
15 especially in non-smokers or non-established smokers.³² Yet, while this evidence is encouraging,
16 these studies have focussed largely on cigarettes and we know little about how PHWs could
17 reduce non-cigarette tobacco use, particularly WTS.³³

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20 To our knowledge, only a few studies have examined the impact of WT PHWs: two online
21 surveys from Canada³⁴ and the United States,³⁵ three qualitative studies from the UK,³⁶ Egypt³⁷
22 and the EMR,³⁸ and one recent Egyptian survey.³⁹ The two online surveys tested hypothetical
23 warnings shown on computer screens rather than on WTPs and examined the effectiveness of
24 text-only versus PHWs.^{34,35} Both studies found that PHWs had a modest impact on established
25 waterpipe smokers.^{34,35} The UK qualitative study found that when warnings increased in size and
26 packs became less branded, participants felt WTPs were less attractive and warnings were more
27 impactful.³⁶ EMR study participants reported that PHWs improved respondents' knowledge
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3 about WTS health hazards.³⁸ These studies are important but were confined to waterpipe
4 smokers;^{34-36,38} while it is important to examine how WT PHWs might pertain to both smokers
5 and non-smokers. The Egyptian qualitative study examined smokers' and non-smokers'
6 responses to placement of PHWs on the waterpipe device. Participants reported this approach
7 could potentially increase salience of WT PHWs, deter initiation of WTS and prompt non-
8 established waterpipe smokers to quit.³⁷ The Egyptian survey reported that only half of 1048
9 waterpipe smoker and non-smoker participants thought that existing PHWs on WTPs were
10 visible; they expressed varying views on the effectiveness of WT PHWs across several measures
11 (such as salience, credibility, perceived harm, affective reactions).³⁹ However, this survey did not
12 examine whether participants perceived existing WT PHWs effective in deterring uptake or
13 quitting of WTS.
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31 Given rising WTS rates in Egypt,¹⁴⁻¹⁶ in 2015 the Tobacco Control Unit in the Egyptian Ministry
32 of Health proposed amending PHW regulations and introducing plain packaging. Specifically, it
33 recommended increasing PHW size to 80% of the pack surface, and removing colours and
34 flavour imagery from tobacco packs. To provide preliminary insights into the potential effects of
35 this approach, we used qualitative methods, which are particularly suited to exploring
36 understudied areas.^{40,41} To inform WT labelling policy, we explored how participants perceived
37 existing PHWs on WTPs, assessed how they interpreted a hypothetical scenario where WT was
38 presented in plain packaging and featured enhanced PHWs, and probed perceptions of how
39 existing and novel PHWs would affect uptake or cessation of WTS.
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54 **METHODS**

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Design

The study comprised ten focus group discussions and ten in-depth interviews that took place in urban and semi-urban regions in Cairo, and a rural area in Menoufia governorate. We utilized both focus groups and in-depth interviews as complementary approaches; focus groups explored participants' interactions and whether and how consensus views evolved while in-depth interviews allowed detailed probing and deeper understanding of participants' views.^{40,41} Some sessions were conducted in WTS usage settings, such as cafes, where we observed social and cultural dynamics of WTS and assessed WT PHW's visibility to others.

Our conceptual framework drew on the theory of planned behavior,⁴² as outlined in IARC Handbooks of Cancer Prevention, Tobacco Control, Methods for Evaluating Tobacco Control Policies 2008.²⁴ We explored policy-relevant outcomes with respect to the perceived potential effect on WTS uptake and cessation, and probed factors related to PHW content and WTP design, including salience, affective reactions, perceived harm and credibility. This study was approved by the Ethical Review Board of the Faculty of Medicine, Ain Shams University (FMASU R 10/2015). We used SRQR guidelines for reporting qualitative research.⁴³

Sample

Our sample comprised men and women, 18 years of age or older, who lived in rural, urban, and semi-urban locations. We included self-identified waterpipe smokers (exclusive WT or dual users of WT and cigarettes) and non-smokers (non-users of any tobacco product), as we were interested in how warnings could influence WTS initiation as well as cessation. Participants were recruited using snowball sampling,⁴⁴ which enabled us to access female waterpipe smokers more

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3 easily and thus address calls for more research into this hard-to-reach group. We explained the
4 study purpose to people who made contact, invited them to participate in a one-on-one interview
5 or focus group, and then set a meeting date and time. Participants did not discernibly differ by
6 type of interview chosen.
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14 In total, 90 individuals participated, including 80 in homogenous focus groups (with respect to
15 age, gender, smoking status) with 6–8 individuals per group, and 10 in in-depth interviews (see
16 **Supplementary Table 1**). As WT use in Egypt is generally higher among males,¹⁶ more males
17 participated in our sessions. **Supplementary Table 2** contains details of participants'
18 demographic characteristics.
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28 **Tools**

29 *Interview Guide*

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31 We developed the interview guide in Egyptian colloquial Arabic and incorporated qualitative
32 measures used to assess tobacco labelling policies.²⁴ We pilot tested the interview guide for
33 clarity and comprehensiveness, tested the appropriateness of our prompts and questions after the
34 pilot sessions, and made modifications following discussions with the research team. We used
35 the same guide with focus groups and in-depth interviews and probed participants' experiences
36 of WTS, their knowledge of WT PHWs, their views on the existing and novel PHWs on WTPs,
37 and their perceptions of placing PHWs on waterpipe devices (see **Supplementary for interview**
38 **guide**). In this article, we focus on discussing PHWs on WTPs.
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53 *Pictorial Health Warnings on Waterpipe Tobacco Packs*

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3 The existing PHWs depicted cancers of lung, throat, mouth, and face, covered 50% of the lower
4 surface of the front and back of the WTP against a colourful background depicting fruit and
5 flavour imagery. The warnings included pictures, generic text and the quitline number (**Figure**
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14 We adapted novel PHWs from a health warning database⁴⁵ and followed WHO FCTC
15 recommendations for plain packaging²⁵ and WHO's publication on Evidence, Design and
16 Implementation of Plain Packaging⁴⁶ building on the proposal of the Tobacco Control Unit of
17 the Egyptian Ministry of Health; the PHW thus covered 80% of the upper surface of the front
18 and back of the WTP against a dark uniform plain background not depicting any fruit or flavour
19 imagery, with the remaining 20% depicting only the brand name in standardised font. The novel
20 PHWs included pictures, text and the quitline number. Dark plain packs are perceived as more
21 harmful⁴⁶ and culturally as more negative (when compared with the bright background colors of
22 the existing WTPs) and we therefore used a drab dark brown colour (similar to that used in
23 Australian packaging) on novel WTPs. Feedback from pilot testing indicated that the dark
24 background color contrasted well with the white color of the textual message and the yellow
25 background of the quitline number, making both more clear and salient. We applied newly
26 designed PHWs to used WTPs to promote authenticity. We pilot tested health warnings
27 messages with corresponding images for clarity and comprehension: ("Smoking kills,"
28 "Smoking causes lung cancer", "Smoking causes clotting of blood vessels", "Smoking causes
29 blindness", "Smoking during pregnancy harms fetus", and "Don't let your children inhale your
30 smoke"). The warnings used were selected following discussions amongst the research team and
31 feedback from pilot sessions, and reflected the best available evidence on WTS health
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3 outcomes.⁴⁷ WTS share common harms with those caused by cigarette smoking.⁴ We sought
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5 topical content showing less severe harms than those depicted in existing PHWs. The four novel
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7 warnings selected included the effect of smoking during pregnancy on the fetus, effects of
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9 peripheral vascular diseases affecting the feet and eye, and effects on teeth and gums (**Figure 1**
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11 **B**). Although it was important to adapt the textual message to be waterpipe-specific, we did not
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13 test this in the study reported here; this was assessed separately in another study of our research
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15 project.
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21 **Data Collection**

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23 Data were collected from October 2015 to February 2016 at the Faculty of Medicine, Ain Shams
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25 University in Cairo (five focus groups and five in-depth interviews), and at participants' homes
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27 or in cafés for those in rural and semi-urban areas (five focus groups and five in-depth
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29 interviews). All participants received an information letter explaining the study and were asked
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31 to provide verbal consent prior to each discussion or interview commencing. Participants were
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33 advised their data and identity would be confidential, and told they could withdraw from the
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35 study at any time.
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40 Each focus group or interview was moderated by two of the co-authors (AM, WS, ME, and WM)
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42 and audio-recorded; each session was about one hour long. The facilitator and note taker
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44 regularly switched roles to promote reflection, and the wider team critically reflected on the
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46 interviews during team meetings. The facilitators followed standard procedures when discussing
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48 the interview guide topics and introduced the PHW stimuli when the relevant topic was opened
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50 for discussion. No further sessions were scheduled once data saturation had been reached, i.e. no
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52 new themes were being generated during the discussions.⁴⁸
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Analysis

Two authors independently transcribed verbatim the recorded sessions in their original language then translated these into English before comparing the two transcripts to ensure inclusivity and accuracy (WH, HM); a third author (AM) back translated the transcripts independently for validity purposes; any discrepancies were resolved through discussion. Considering the identical aims and topics explored, data from focus groups and interviews were analyzed together. We analysed the data using a thematic approach.^{49,50} We coded transcripts as the study progressed using a three-phase process that began by organizing ideas in relation to the research questions, then involved independent reviews of transcripts to identify preliminary themes and create an initial coding list.⁵¹ We finally independently refined this list (AM, AA), added new codes where appropriate, and developed broader themes, that one author (HM) then reviewed across all cases. We resolved minor inconsistencies during discussion sessions and after extensive reviews of transcripts before we finalized the themes and subthemes (see **Supplementary Table 3**). In this article, we focus on policy-relevant outcomes relevant to PHWs on WTPs as described above in methods “design”.

Patient and Public Involvement

Patient and public were not involved in the development of the research question and outcome measures, the design, recruitment and conduct of the study. The results of this study will be disseminated to study participants via newsletters and social media outlets.

RESULTS

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3 The 90 participants in focus groups and interviews comprised more males (72.2%) than females
4 (27.8%) and participants' mean age was 33.4 ±11.6 (see **Supplementary Table 2**). We
5 identified the overall themes: warning label content and pack design features, and discuss these
6 in relation to WTS uptake and cessation comparing throughout existing and novel sets. During
7 analysis of the transcripts, we did not detect differences between the focus group and individual
8 interview data. Therefore, we report below results from both focus groups and individual
9 interviews. We cite exemplar quotations below and provide a more detailed set of quotations in
10 **Supplementary Table 4**, where we also indicate the gender, age group, smoking status, location
11 of participants, and source of quotations.
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26 Most participants were aware of warning labels on WTPs and reported seeing these when
27 purchasing or preparing their tobacco. However, those using waterpipes in cafes or were less
28 likely to see WTPs as WT was prepared out of their sight "*I was downtown and we saw smokers*
29 *in cafes but shisha is always served ready...I never saw the packs*" (Female non-
30 smoker, >25y, semi-urban, FGD).
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39 **Warning label content – perceived likely effect of existing and novel PHWs**

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41 Participants who were aware of existing WTP warnings recalled these as disturbing; however,
42 several felt these warnings had limited impact. Many recalled the lung cancer PHW and the text
43 “smoking is hazardous to health and causes death” as the most believable warning, yet also the
44 least impactful, because of wearout: "*...the other warnings like the lung cancer one...people got*
45 *used to them after a while*" (Male smoker, >25y, rural, IDI). Participants found the existing
46 warnings, which all featured cancer-related harms, frightening and disgusting, and non-smokers,
47 particularly, avoided looking at them. Nonetheless, several questioned the harms existing PHWs
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3 featured and saw these as exaggerated: *"I don't want to look at it from near or far...they want to*
4 *send us a message that it is harmful but in an awful and overstating way"* (Female smoker, <25y,
5 *urban,FGD*).
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12 Some also found existing warnings difficult to understand: *"It looks like a bad thing but it is not*
13 *clear what it is"* (Female non-smoker, >25y, semi-urban, FGD). These participants saw existing
14 PHWs as unconvincing and exaggerated as they had not seen such conditions in real life and
15 sometimes knew people who had smoked for many years with apparent impunity: *"I have seen*
16 *the warning on the packs but I have never seen anything such as that in real life...I know a*
17 *person who has been smoking since the eighties and nothing happened to him"* (Male
18 *smoker, >25y, rural, FGD*).
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31 Participants often denied risks associated with occasional smoking; one exempted himself from
32 harm on the grounds that he did not smoke heavily and had seen no direct evidence of the harms
33 presented in PHWs: *"I don't think I can be affected by smoking, because I don't smoke heavily;*
34 *only once a day, besides...we have never seen the conditions in the warnings in real life"* (Male
35 *smoker, >25y, rural, IDI*). Several thought harms would not occur until they were older, and
36 believed that, if and when they experienced these, they could quit.
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47 By contrast, most participants favoured the new PHWs, which they first viewed during the
48 interview sessions. They found these clearer, more understandable and realistic than existing
49 PHWs, and more likely to capture their attention. Participants also commented that the new
50 PHWs were easily understood even without text and thus likely to be effective among people
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3 with varying literacy: *"This one is more realistic for its purpose and understandable; even*
4 *without any text...it is a more convincing warning"* (Female non-smoker,>25y,semi-
5 *urban,FGD*).
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11 Specifically, participants found the new warnings featuring more immediate, proximal risks had
12 the strongest perceived impact, particularly those showing harmful effects on teeth. Female
13 participants also felt strongly affected by the PHW illustrating harm to unborn babies, which
14 forced them to confront the harm they imposed on others: *"The baby warning is effective*
15 *because it is not about me anymore...This is something way more important than me...I fear for*
16 *my kid more than I fear for myself"* (Female non-smoker,>25y,semi-urban,FGD). However,
17 some continued to see images showing potential harms they may experience as overstated and
18 unlikely to happen in the near future: *"This didn't happen before to anyone (foot*
19 *warning)...we're still young...we won't get this"* (Female smoker,<25y,urban,FGD).
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34 Although participants saw the new PHWs as more effective, they suggested improvements to the
35 warning content. In line with earlier comments about perceived exaggeration, they sought greater
36 credibility: *"It is very important that you convince me...put something there that I'll believe"*
37 (Male smoker,>25y,semi-urban,IDI). Some suggested presenting testimonials: *"Show smokers*
38 *live people who were damaged because of shisha smoking and others who quit and improved"*
39 (Male non-smoker,>25y,rural,FGD) and others recommended illustrating the effects WTS has
40 on women by featuring relevant cancers and congenital diseases: *"Direct warnings addressing*
41 *women like cancer of the breast or the uterus or congenital anomalies to the fetus"* (Female non-
42 *smoker,>25y,semi-urban,FGD*). Some also thought PHWs targeting women could encourage
43 them to persuade their partners to quit.
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6 Several participants thought PHWs should target youth before they start smoking and suggested
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8 warnings showing how WTS smokers' social relationships (e.g., sexual dysfunction warnings)
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10 would have high impact: *"We want a real effect that already happened...like for example the*
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12 *side effects on sexual functioning...that will definitely affect smokers"* (Male non-
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14 *smoker,>25y,rural,FGD).*

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19 In addition, participants also suggested printing text warnings including details of the hazardous
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21 ingredients of smoke, with more information on health risks and cessation options inserted on the
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23 inside or outside of the WTP, together with external PHWs would promote cessation behaviour,
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25 and enhance the impact of novel warnings.
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30 31 **Design Features of WTPs – perceived likely effect of existing and novel PHWs**

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33 As well as responding to the different warning content, participants also noted that the different
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35 design elements used in the novel PHWs had improved the impact these had. Several commented
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37 on how bright colours and fruit imagery deflected attention away from PHWs and promoted
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39 experimentation: *"The peach drawing is appetizing... [and] drawing attention away from the*
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41 *warning...better put the warning on the top! The pack should be dark...this colour is very*
42
43 *bright... just like bonbon packs"* (Female non-smoker,>25y,semi-urban,FGD). They found it
44
45 difficult to associate fruit flavours with harm and thought the images invited trial: *"The pictures*
46
47 *and the smell of fruits make a passerby want to try them all"*(Female non-smoker,>25y,semi-
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49 *urban,IDI).*
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3 By contrast, participants thought the plain background, contrasting colours, absence of fruit and
4 flavour images, and larger warning images shown on the proposed new PHWs increased impact,
5 reduced distraction, and encouraged participants to look more closely at the pack. One noted:
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10 “Here the picture is bigger and the text has a clear message...together with this dark colour...it
11 makes me focus only on the warning...all this makes it more effective” (Male
12 smoker,<25y,urban,FGD). Together, the altered content and enhanced design attributes
13 increased participants’ perceptions of the impact the novel PHWs would have.
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21 Overall, most waterpipe smoker and non-smoker participants thought PHWs would deter non-
22 smokers from trying WTS but were less optimistic about the effects on smokers. One noted: “If
23 we (non-smokers) lusted to smoke it and saw pictures like these...we won’t smoke, but those who
24 do actually smoke already would be indifferent” (Male non-smoker,>25y,urban,FGD). Smokers
25 themselves also felt PHWs had less effect because they had become accustomed to seeing the
26 images: “I used to think about the hazards a lot when the pictures first appeared...then I got
27 used to them...I don’t pay them attention anymore” (Male smoker,<25y,semi-urban,IDI). Others
28 reported using stickers to obscure PHWs or avoiding packs with PHWs they found particularly
29 confronting: “I avoid buying the picture of the tongue in particular (referring to the mouth cancer
30 warning)” (Male smoker,<25y,semi-urban,FGD)
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47 As with the current PHWs, most waterpipe smoker and non-smoker participants thought the
48 proposed PHWs would have a stronger effect on non-smokers than on long-term smokers,
49 though some indicated they would avoid some warnings and may reduce their WTS: “If I go to
50 buy moassel (waterpipe tobacco) and found this pack, I’ll go to another shop to buy another
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3 *one...if I don't find a picture that makes me comfortable...I won't smoke that day...but if they're*
4 *all like this...I guess I'll try to quit...or... at least decrease my habit" (Male*
5 *smoker,>25y,rural,IDI). In general, participants thought that the new PHW set had greater*
6 *potential to deter WTS, especially among new smokers: "If I'll smoke and saw it... for sure I*
7 *won't smoke at the moment...it's disgusting" (Male non-smoker,<25y,rural,FGD).*
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17 **DISCUSSION**

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19 Our qualitative study found that participants privileged the short-term benefits they received over
20 the longer-term risks they faced. They saw existing PHWs as less likely to influence long-term
21 smokers,⁵² especially if they had not experienced any health effects. This finding is consistent
22 with other studies that found age is negatively associated with perceived risks of smoking and
23 with attention to either graphic or text warnings on tobacco packages.⁵³
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33 However, the existing and novel PHWs tested appeared more likely to influence non-smokers
34 and less-experienced smokers by creating awareness of the health risks WTS presents. These
35 findings are in line with previous research³² and address calls for research into the effects of
36 tobacco packaging on smoking uptake.⁵⁴ We also provide preliminary evidence that presenting
37 WT in plain packaging could deter non-smokers from experimenting WTS. The existing and the
38 novel PHWs differed in three main ways: the topical imagery content, the size of the warning,
39 and the pack design. We explain below how policymakers should consider these three elements
40 when adopting or amending regulations for PHWs on WTPs.
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53 Although existing PHWs induced strong negative emotional reactions, several participants
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3 viewed these warnings as exaggerated and felt the health risk depicted was unlikely to occur.
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5 While PHWs that arouse fear may increase risk perceptions, they did not necessarily promote
6
7 greater message acceptance,⁵⁵⁻⁵⁷ Our findings also show a complex relationship between the
8
9 emotional response elicited and the salience and perceived impact of a message. The PHW
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11 depicting oral harm was minimally disturbing, yet participants saw it as the strongest and the
12
13 most salient warning; by contrast, participants regarded the confronting vascular harm PHW as
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15 less effective because the condition was less salient and seen as more distal. Our findings thus
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17 support earlier studies analysing the relationship between risk perception, believability, and
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19 temporal distance.⁵⁸
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26 Young adults and women found gender- and age-specific messages more persuasive,⁵⁹
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28 suggesting strategies targeting these demographic groups are crucially important⁶⁰ For example,
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30 messages about negative health effects from passive smoking, sexual dysfunction and intimacy,
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32 miscarriages, and harmful effects on infants and children were considered more persuasive
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34 among younger adults and women than other messages.
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40 Another plausible approach suggested by participants was to develop a visible and sensible
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42 message in both text and graphic formats that target waterpipe smokers with detailed cessation
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44 information inserted on the WTP. Combined text and graphic warnings elicit adverse reactions to
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46 smoking among non-smokers and smokers,⁶¹ especially on the sustainability of quit behaviour.⁶²
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48 In line with these suggestions, the design of novel warnings helped make the cessation quit line
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50 more prominent by the contrasting dark plain background.
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3 We also found specific design elements that could inform future PHW development. Some
4 participants thought plain packs increased the salience and effectiveness of the warnings, and
5 reduced the appeal of the packaging and misperceptions of harm. These findings are consistent
6 with the literature on plain packaging.^{46,54} Evidence that flavoured cigarettes reduce harm
7 perceptions appears relevant to WT^{63,64} as participants noted that images of fruits or appealing
8 flavours attracted them to WTS and deflected their attention from warning information.
9 Furthermore, image clarity and size enhanced acceptance and risk perception among participants,
10 a finding also reported by Jawad and colleagues.³⁶
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22 **Strengths and Limitations**

23 To our knowledge, this is the first qualitative study to assess smokers' and non-smokers'
24 awareness and acceptance of currently used and novel WT PHWs with plain packaging. Our
25 novel warnings simulated how PHWs appear (or could appear) on packs and devices, we
26 explored projected rather than real-life responses. Experimental work could estimate the likely
27 impact of our new label designs, including more targeted PHWs, on waterpipe smokers' risk
28 perceptions, attitudes and likely cessation responses. Future research could also develop a more
29 comprehensive analysis of factors motivating and reinforcing WTS uptake. Given our findings
30 that PHWs have the potential to reduce WTS initiation, it is also important to test whether the
31 PHW themes we developed could be used in wider health promotion campaigns to reduce the
32 appeal and perceived acceptability of WTS. Future research could explore how WT warnings
33 featuring waterpipe-specific messages would affect awareness and perceptions of WTS.
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51 Our small sample means we cannot generalize our findings, though we note a sample of 90
52 individuals is still substantial, and saturation had been reached in the responses received. Despite
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3 these limitations, our study provides novel insights into the factors supporting WTS uptake,
4 suggests themes PHWs could feature, and outlines how PHWs' format could be improved. We
5 recognize this work programme faces challenges, given the limited resources and capacity in
6 low- and middle-income countries; nonetheless, our findings represent an important step in
7 supporting a comprehensive regulatory framework that reduces WTS and the harm this form of
8 tobacco use causes.
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19 *Conclusions*

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21 This exploratory study suggests that PHWs on WTPs have the potential to reduce uptake and cue
22 quit attempts but might be more effective if PHWs used more impactful designs. Specifically, we
23 provide preliminary evidence that enhanced PHWs using contrasting background colours and
24 plain packaging, offering no association to fruits or flavours, targeting age and gender, and
25 displaying proximal health risks, might enhance both warning impact and risk perception. These
26 alternative designs could be further developed and tested in other studies. The findings offer
27 policymakers designing and implementing health warnings on WT products clearer evidence on
28 which to base their decisions.
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19
20 and wrote the first draft of this article. AM, ME, WS, WMH carried out the study. SL provided
21
22 approval for using PHWs. WMH and HM transcribed the data. AA, HM, AM and JH analyzed
23
24 the data. AM, HM, AA and JH further developed the paper. All authors critically revised
25
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51 of Medicine, Ain Shams University (FMASU R 10/2015).
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55 **CHECKLIST FOR REPORTING GUIDELINES** We used SRQR guidelines for reporting
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8 **DATA SHARING STATEMENT** No additional data are available.
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3 **Figure 1. Pictorial Health Warnings used in this study**
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For peer review only



1 2 3 4

A. Current PHW set used in the qualitative study

(1)Face cancer, (2) Lung cancer, (3) Mouth cancer, and (4) Throat cancer



1 2 3 4

B. Alternative PHW set used in the qualitative study

(1)Fetal harm, (2) Blindness, (3) Blood vessel clotting, (4) Tooth and gum decay

Figure 1. PHWs used in the study

Figure 1. Pictorial Health Warnings used in this study

297x300mm (300 x 300 DPI)

Supplementary

Table 1. Total number of interviews and focus group discussions conducted by demographic profile of participants

	FGDs (10, total participants=80)				IDIs (10)			
	Males (7)		Females (3)		Males (7)		Females (3)	
Age	S	NS	S	NS	S	NS	S	NS
	(5)	(2)	(2)	(1)	(6)	(1)	(2)	(1)
18-24	2	1	1		3	1	1	
25+	3	1	1	1	3		1	1

FGDs=Focus group discussions, IDIs=In-depth interviews, S=Waterpipe smoker, NS=Non-smoker

Table 2. Sociodemographic characteristics and waterpipe smoking status of participants

	N=90	%
Gender		
Male	65	72.2
Female	25	27.8
Age (range 18-73)		
Mean age ± standard deviation	33.4 ± 11.6	
Age group, years		
18-24	21	23.3
25+	69	76.7
Education level		
Primary or lower	16	17.7
Secondary	32	35.6
Tertiary	42	46.7
Occupation		
Employed professional	42	46.7
Employed non-professional	34	37.8
In further study or seeking employment	14	15.5
Residence		
Rural	20	22.2
Semi-urban	51	56.7
Urban	19	21.2
Smoking status		
Waterpipe smoker	62	68.9
Non-smoker	28	31.1
Ever noticed PHWs on WTPs		
Yes	53	58.9
Where		
At cafés	17	32.1
At home	11	20.8
Buying tobacco	25	47.2

Interview guide *

Interview guide questions	Parts relevant to this article
<p>Introductory questions</p> <p><i>In general, what do you think of waterpipe smoking?</i></p> <p>Personal experiences of waterpipe smoking</p> <p><i>Tell me about your waterpipe smoking, habits, duration, etc...Tell us more on how did you start smoking?</i></p> <p><i>Could you describe the setting in which you smoked waterpipe last time?</i></p>	
<p>Awareness of pictorial health warnings</p> <p><i>Have you ever noticed the pictorial health warnings on waterpipe tobacco packs?</i></p> <p><i>Where did you see them? Can you tell us more about the setting?</i></p> <p><i>How do they look like?</i></p>	√
<p>Positive and negative characteristics of the current/alternative set of PHW</p> <p><i>Have you ever come across the warning on this pack before? What is your first impression about it?</i></p> <p><i>What do you think/feel when you see it?</i></p> <p><i>In your opinion, what is good and is bad about it? Why do you think so?</i></p> <p><i>Do you think it is/would be effective? Why and how do you think so?</i></p>	√
<p>Reactions to placing PHW on the waterpipe device</p> <p><i>What is your first impression about putting the warning in this spot?</i></p> <p><i>What do you think/feel when you see there?</i></p> <p><i>In your opinion, what is good and is bad about this spot? Why do you think so?</i></p> <p><i>Do you think people will notice the PHW on this spot?</i></p> <p><i>Would it be effective? Why and how do you think so?</i></p>	

***This guide contains core questions. Probing questions were used when necessary (examples include questions on salience, affective reactions, perceived harm, credibility)**

Table 3. Themes and subthemes identified from focus groups and in-depth interviews*

Themes	Subthemes	Themes covered in this article
General perceptions of waterpipe smoking	Factors contributing to WTS Factors affecting WTS initiation and continuation WTS setting Patterns of WTS consumption Social and cultural context of WTS WTS compared to cigarette smoking Tobacco product characteristics Perceived health consequences Reasons for quitting	
Views on pictorial health warning labels on waterpipe tobacco packs	General knowledge /awareness of PHWs on WTPs Sources of awareness Most salient/recalled labels, reasons Cessation helpline Perception of PHWs on WTPs motivating and discouraging factors related to viewing PHW labels	Partly
Perceptions of existing waterpipe tobacco warnings	General impressions, attitude (appeal, affective reactions, avoidance, wear out) Positive and negative characteristics of design and content Participants views of the most effective one in general Possible effects on quitting and/or initiating WTS	√
Insights into novel waterpipe tobacco warnings	General impressions, attitude (appeal, affective reactions, avoidance) Positive and negative characteristics of design and content Participants views of the most effective one in general Possible effects on quitting and/or initiating WTS	√
Avenues for development	Participant suggestions of improved label characteristics regarding content, design, location Participant suggestions for other placement locations	Partly
Best location for inserting labels on the waterpipe device and accessories	Views behind choosing each location Concerns about each location Possible effects on quitting and/or initiating WTS	
Participant suggestions for reducing tobacco use in general and WTS in particular	Further strategies for improved regulations Enforcing existing laws Posting warnings in public and other places Associate warnings with mass-media anti-tobacco campaigns, increase taxation and other suggestions	

*** Themes presented in this article were synthesized in respect to warning content and pack design and their perceived likely effect on uptake or cessation of waterpipe smoking, comparing existing versus novel warnings.**

Table 4. Selected participants' quotes representing views of the current and alternative pictorial health warning labels on waterpipe packs. Quotes are presented by gender, age group*, smoking status, and region of participants

<i>Warning label content – perceived likely effect of existing and novel PHWs</i>	
"The picture of a bent cigarette (i.e. representing sexual dysfunction) caught people's attention considerably...but the other warning...people got used to them after a while"	<i>(Male smoker, >25y, rural, FGD)</i>
"The most commonly known warning is that of the lungs"	<i>(Male smoker, >25y, semi-urban, FGD)</i>
"The picture is disgusting and frightening..."	<i>(Male non-smoker, <25y, rural, IDI)</i>
"Pictures are scary and unpleasant"	<i>(Male smoker, >25y, semi-urban, FGD)</i>
"The pictures make me sick..."	<i>(Male smoker, >25y, urban, IDI)</i>
"The warning shouldn't be that it causes cancer and that's it...that is just routine talk"	<i>(Male non-smoker, >25y, urban, FGD)</i>
"I just don't believe it...nobody reaches this stage"	<i>(Female smoker, <25y, urban, IDI)</i>
"I don't believe the warnings...I know smoking is harmful but not to that extent. This is unrealistic"	<i>(Male smoker, <25y, rural, FGD)</i>
"We want to see the normal lung beside the diseased one...but this one straight is not clear"	<i>(Male non-smoker, >25y, urban, FGD)</i>
"The pictures are not realistic, we never see such things in real life"	<i>(Male non-smoker, >25y, semi-urban, FGD)</i>
"The pictures are extremely exaggerated"	<i>(Male smoker, <25y, urban, IDI)</i>
"Is this a burnt piece of pizza? (face cancer warning)...this one won't be clear to illiterates...I didn't get it before reading the text beneath"	<i>(Male non-smoker, >25y, urban, FGD)</i>
"The picture is frightening and is very disgusting"	<i>(Male smoker, >25y, urban, IDI)</i>
"It can make me want to look closely to see what the illness shown is"	<i>(Female non-smoker, >25y, semi-urban, FGD)</i>
"For me, the most effective one is picture of teeth affection...it's very scary and upsetting. I see that content of the warning is much more important than size"	<i>(Male smoker, >25y, semi-urban, FGD)</i>
"With this shape (deformed teeth and gums) I may disturb my son when I come close to kiss him...now that will hurt me"	<i>(Male smoker, >25y, semi-urban, IDI)</i>
"The baby's picture may affect women more than me"	<i>(Male smoker, >25y, semi-urban, IDI)</i>
"If a pregnant woman saw this picture...she would fear for her unborn child to have anomalies"	<i>(Female smoker, >25y, semi-urban, FGD)</i>
"Explain the components of tobacco as glycerin and the hazards of each of them...tell them: try to smoke each component by itself and see what happens to you"	<i>(Male non-smoker, >25y, semi-urban, FGD)</i>
"Simplify the matter of quitting to people...especially those who have been smoking for a long time..."	<i>(Male nonsmoker, >25 y, rural, FGD)</i>
"If you talk to a smoker about their health...they wouldn't pay attention but there are other aspects as hazards to their children"	<i>(Male non-smoker, >25y, semi-urban, FGD)</i>
"The most effective thing that makes a smoker quit is that they themselves get ill or they see someone get ill"	<i>(Male smoker, >25y, semi-urban, IDI)</i>
"I saw on the internet a pack of cigarettes with a picture of a mother and	<i>(Female smoker, <25 y, urban, IDI)</i>

her child, and on opening it the mother is separated from him. This a new effective idea."	
"A pregnant woman or a mother may ask their smoker husband to stop"	(Female non-smoker, >25y, semi-urban, FGD)
"The only thing that can force me to stop smoking, even if I'm a heavy smoker is the baby affection"	(Female smoker, <25 y, urban, IDI)
"Warnings should target young people under 17 before they attempt smoking"	(Male non-smoker, >25y, semi-urban, FGD)
"Warnings concerning sexual dysfunction can affect young smokers"	(Male non-smoker, >25y, semi-urban, FGD)
"Focus on the damage that the family suffers...there are problems that can occur with the wife because of smoking...so smoking may endanger the family bonds"	(Male smoker, >25y, semi-urban, IDI)
"Pictures should be more realistic, and not only focus on severe side effects like cancers... like if warnings demonstrate just a fingernail affected due to smoking not all the hand, people will be more tempted to believe it"	(Male smoker, <25 year, rural, IDI)
Design Features of WTPs – perceived likely effect of existing and novel PHWs	
"The apples got my attention"	(Female smoker, >25y, semi-urban, IDI)
"After seeing this...(pointing to the fruit depicted on the pack)...it will be hard for me to link the idea with the damage in this picture"	(Male non-smoker, <25y, rural, FGD)
"Pictures of fruits are attractive and appetizing"	(Male smoker, >25y, semi-urban, FGD)
"If there is no flavored tobacco, I will quit"	(Male smoker, <25y, urban, IDI)
"I can't see any flavors on it...I want to hold it closely to know what did they put there instead...if shisha is served as it is...without any flavors?!...I'll quit"	(Male smoker, <25y, urban, FGD)
"If flavors were banned may be some will quit but warnings have no effect"	(Male smoker, <25y, urban, FGD)
"The pictures of fruits must be removed as they are appetizing"	(Male non-smoker, <25y, rural, IDI)
"The dark background makes the writings clearer"	(Male non-smoker, >25y, semi-urban, FGD)
"The alternative pack is clearer regarding the color, the picture and the way of writing"	(Male non-smoker, < 25y, rural, IDI)
"The black color makes the pack a lot chic"	(Male smoker, <25y, urban, FGD)
"The color of the package is dark and it conveys a sense of pessimism"	(Male smoker, >25y, rural, IDI)
"The bigger the picture, the better"	(Male smoker, <25y, semi-urban, FGD)
"The warning should be put on top because the pictures of fruits are drawing attention away from the warning"	(Female non-smoker, >25y, semi-urban, FGD)
"Oh! I didn't realize there was a quit line on the pack before...this dark background made some kind of contrast... the text now is way clearer for me to read"	(Female smoker, <25y, urban, IDI)
"I used to think about the hazards a lot when the pictures first appeared...then I got used to them...I don't pay them attention anymore"	(Male smoker, <25y, semi-urban, IDI)

"I have seen the warnings too often that they no longer frighten me"	<i>(Male smoker, <25y, rural, FGD)</i>
"The pictures are horrible but people got used to them, if a nonsmoker wished to try and saw the warnings they may change their mind but for those who are already smokers, the warnings make no difference"	<i>" (Male non-smoker, >25y, semi-urban, FGD)</i>
"Warnings influence the non-smokers much more than smokers, as non-smokers usually find the picture more disgusting"	<i>(Female, non-smoker, >25y, semi-urban, FGD)</i>
"I avoid buying the picture of the tongue in particular (referring to the mouth cancer warning)"	<i>(Male smoker, <25y, semi-urban, FGD)</i>
"People can go around all day looking for a certain picture (the lungs)"	<i>(Male smoker, >25y, rural, IDI)</i>
"Vendors used to sell the pack with free stickers to cover the warnings"	<i>(Male smoker, >25y, semi-urban, FGD)</i>
"No one would buy a pack with such warning (means warning picturing effect of smoking on children)"	<i>(Female smoker, >25y, semi-urban, IDI)</i>
"If the warning on the pack looks bad, we tend to throw the external package away and put tobacco in another package or may be order a certain warning"	<i>(Male smoker, >25y, rural, FGD)</i>
"The alternative pack may make some smokers reduce smoking"	<i>(Male non-smoker, <25y, rural, FGD)</i>
"A beginner can be affected compared to a person who has been smoking for 15 years and nothing happened to them as a result of smoking"	<i>(Male non-smoker, <25y, rural, FGD)</i>
"Non-smokers will be more affected by it, smokers won't be much affected"	<i>(Female non-smoker, >25y, semi-urban, IDI)</i>
"It could affect those who want to start smoking, but the older smokers won't be affected much"	<i>(Male smoker, <25y, semi-urban, FGD)</i>

***The age group of participants was categorized as > or < 25 years, because we were interested in highlighting the views of young adults who may be at higher risk of experiencing WTS or maybe non-established WT users yet, versus older adults who might more likely have established a smoking or non-smoking behaviour.**

Reporting checklist for qualitative study.

Based on the SRQR guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SRQR reporting guidelines, and cite them as:

O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. Standards for reporting qualitative research: a synthesis of recommendations. *Acad Med.* 2014;89(9):1245-1251.

	Reporting Item	Page Number
	#1 Concise description of the nature and topic of the study identifying the study as qualitative or indicating the approach (e.g. ethnography, grounded theory) or data collection methods (e.g. interview, focus group) is recommended	1,3, 8 & 9
	#2 Summary of the key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results and conclusions	3, 4
Problem formulation	#3 Description and significance of the problem / phenomenon studied: review of relevant theory and empirical work; problem statement	3, 5-9
Purpose or research question	#4 Purpose of the study and specific objectives or questions	3, 8
Qualitative approach	#5 Qualitative approach (e.g. ethnography,	8, 9

<p>1 and research 2 paradigm 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22</p>	<p>grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g. postpositivist, constructivist / interpretivist) is also recommended; rationale. The rationale should briefly discuss the justification for choosing that theory, approach, method or technique rather than other options available; the assumptions and limitations implicit in those choices and how those choices influence study conclusions and transferability. As appropriate the rationale for several items might be discussed together.</p>	<p>See 5 and Supplementary file page 8 for more on limitations</p>
<p>23 Researcher 24 characteristics and 25 reflexivity 26 27 28 29 30 31 32 33 34 35 36 37</p>	<p>#6 Researchers' characteristics that may influence the research, including personal attributes, qualifications / experience, relationship with participants, assumptions and / or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results and / or transferability</p>	<p>11, 12 for reflexivity Researchers are trained or experienced in qualitative methods. Word count limited detailing qualifications and other items listed here.</p>
<p>38 Context 39 40</p>	<p>#7 Setting / site and salient contextual factors; rationale</p>	<p>8, 9, 11</p>
<p>41 Sampling strategy 42 43 44 45 46 47 48 49</p>	<p>#8 How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g. sampling saturation); rationale</p>	<p>9, 10, 12</p>
<p>50 Ethical issues 51 pertaining to human 52 subjects 53 54 55 56 57</p>	<p>#9 Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues</p>	<p>9, 11</p>
<p>58 Data collection 59 60</p>	<p>#10 Types of data collected; details of data</p>	<p>10, 11</p>

1	methods		collection procedures including (as	
2			appropriate) start and stop dates of data	
3			collection and analysis, iterative process,	
4			triangulation of sources / methods, and	
5			modification of procedures in response to	
6			evolving study findings; rationale	
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10	Data collection	#11	Description of instruments (e.g. interview	10, 11
11	instruments and		guides, questionnaires) and devices (e.g.	
12	technologies		audio recorders) used for data collection; if	
13			/ how the instruments(s) changed over the	
14			course of the study	
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18	Units of study	#12	Number and relevant characteristics of	9, 10
19			participants, documents, or events	
20			included in the study; level of participation	
21			(could be reported in results)	
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25	Data processing	#13	Methods for processing data prior to and	11
26			during analysis, including transcription,	
27			data entry, data management and security,	
28			verification of data integrity, data coding,	
29			and anonymisation / deidentification of	
30			excerpts	
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35	Data analysis	#14	Process by which inferences, themes, etc.	11, 12
36			were identified and developed, including	
37			the researchers involved in data analysis;	
38			usually references a specific paradigm or	
39			approach; rationale	
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43	Techniques to	#15	Techniques to enhance trustworthiness	12
44	enhance		and credibility of data analysis (e.g.	
45	trustworthiness		member checking, audit trail, triangulation);	
46			rationale	
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50	Syntheses and	#16	Main findings (e.g. interpretations,	12
51	interpretation		inferences, and themes); might include	
52			development of a theory or model, or	See 9 for theory
53			integration with prior research or theory	
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57	Links to empirical	#17	Evidence (e.g. quotes, field notes, text	13-17
58	data		excerpts, photographs) to substantiate	
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1		analytic findings	
2			
3	Intergration with prior	#18 Short summary of main findings;	18-21
4	work, implications,	explanation of how findings and	
5	transferability and	conclusions connect to, support, elaborate	See also 3, 5 and
6	contribution(s) to the	on, or challenge conclusions of earlier	Supplementary file page 8
7	field	scholarship; discussion of scope of	for more on limitations
8		application / generalizability; identification	
9		of unique contributions(s) to scholarship in	
10		a discipline or field	
11			
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15	Limitations	#19 Trustworthiness and limitations of findings	5 and Supplementary file
16			page 8 for more on
17			limitations
18			
19			
20	Conflicts of interest	#20 Potential sources of influence of perceived	22
21		influence on study conduct and	
22		conclusions; how these were managed	
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26	Funding	#21 Sources of funding and other support; role	22
27		of funders in data collection, interpretation	
28		and reporting	
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 33 <https://www.goodreports.org/>, a tool made by the [EQUATOR Network](#) in collaboration with
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