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# Development of an intervention for smoking cessation in pregnant women using a theory-based approach

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# **Abstract**

**Background** While the global prevalence of smoking during pregnancy is 1.7%, it rises to 8.1% in Europe, where it is the main modifiable risk factor for morbidity and mortality during pregnancy. However, pregnancy is a key time to implement smoking cessation interventions, as women are more likely to adopt health-promoting behaviours during this period. Despite the availability of resources (e.g. policies, tools) and strategies (e.g. nicotine replacement therapy) to address smoking, their implementation remains neither optimal nor systematic. To address this, a multi-disciplinary multi-professional team developed the 5A-QUIT-N intervention to promote smoking cessation in pregnant women, by mobilising health professionals and optimising existing resources. Rather than creating new resources, the intervention uses existing tools and strategies and better integrates them into the pregnancy monitoring process. This article describes the development and operationalisation of the 5A-QUIT-N intervention.

**Methods** The development of the 5A-QUIT-N intervention involved three stages. First, its components were established according to national recommendations and a final list was validated by a scientific committee. Next, obstacles and levers that could influence their implementation and effectiveness were identified through a scoping review and semi-structured interviews. The resulting data were then used to design the first version of the intervention.

**Results** Findings from the literature and field experiences highlighted the need for better mobilisation and coordination of the existing resources. The 5A-QUIT-N intervention was developed to address these issues by improving resource organisation within each region. At the clinical level, it aims to enhance healthcare professionals' skills in smoking cessation practices using existing resources. At the organisational level, it promotes closer coordination between perinatal and smoking cessation professionals. The involvement of local stakeholders and local resources is an integral part of the intervention, as these vary from one region to another.

**Conclusion** This intervention was made possible thanks to the combination of a literature search, a qualitative study, and commitment from stakeholders from grassroots level upwards.

**Keywords** Tobacco, Pregnancy, Smoking cessation, Innovation, Health promotion, Evidence-based health promotion, Theory-based

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# Introduction

While the global prevalence of smoking during pregnancy is 1.7%, it is 8.1% in Europe [1]. Although awareness of this problem among health professionals has increased in France in recent years [2], prevalence remains twice as high as the European average [1]. Smoking represents the main modifiable risk of morbidity and mortality during pregnancy [3] due to the increased risk of pregnancyrelated events, such as intrauterine growth restrictions, prematurity and sudden infant death syndrome. In addition, the long-term economic consequences of preterm birth and low birth weight are high at both the individual and societal level [4]. The consequences for children also extend to the long term. Children of smokers face higher mortality rates and an increased likelihood of developing health issues such as respiratory diseases [5, 6]. Furthermore, they are at greater risk of smoking later in life [7].

Smoking cessation interventions during pregnancy should be tailored [8], since those targeting the general population are reportedly less effective in pregnant women [9–11]. Only 13% of women who did not spontaneously stop smoking during pregnancy quit when they received treatment. Of these women, 43% resumed smoking 6 months after delivery [12]. Passive smoking, parental and spousal smoking status, psychological factors, motivation and involvement of health care personnel all play a role in smoking and smoking cessation. The majority of these factors are modifiable and provide opportunities for intervention [13–15].

In practice, there are already resources (e.g. information, policies, tools) and effective strategies (e.g. nicotine replacement therapy) for promoting smoking cessation, but their implementation is less than optimal. For example, the availability of help to stop smoking is not systematically discussed during prenatal visits. According to the 2021 French national perinatal survey, more than one in three pregnant smokers reported not having received any advice about quitting smoking despite the numerous contacts they had with their health care providers during their pregnancy [2]. Furthermore, the success of the numerous schemes to help people stop smoking tend to depend on the availability of local logistic and human resources, so they do not necessarily reach specific target populations [16, 17]. Support for pregnant women who try to stop smoking should therefore involve the restructuring and reorganisation of existing resources, as recommended by the French group of experts on the management of smoking during pregnancy [18].

In this context, a multi-disciplinary multi-professional team designed the  $5\,\mathrm{A}\text{-}\mathrm{QUIT}\text{-}\mathrm{N}$  (5 As model for Quitting

tobacco in Nouvelle-Aquitaine region of France<sup>1</sup>) intervention. Implemented during pregnancy, this intervention aims to promote smoking cessation in pregnant women by the more global involvement of health professionals and by making better use of existing resources in the French region Nouvelle-Aquitaine. Since there are already several interventions in France to reduce smoking among pregnant women, it was not deemed necessary to produce new resources but rather to better use existing ones. The 5 A-QUIT-N intervention is part of the broader 5 A-QUIT-N project, which contains three phases, as recommended by the framework of the Medical Research Council for developing and evaluating complex interventions [19]: (i) the development of the intervention; (ii) a real-life pilot study that assesses its viability [20, 21], acceptability amongst professionals, and its health outcomes; (iii) a randomized controlled trial to study its effectiveness. It has three secondary aims: to identify the conditions that determine its effectiveness, to assess its transferability and sustainability, and to evaluate smoking relapse during the postpartum year [22]. This article describes its development from the design of the intervention to its operational translation.

#### **Methods**

# Theoretical and conceptual framework

While the 5A-QUIT-N intervention involves perinatal and addiction professionals and the manner in which they are organised, it is pregnant women who are its ultimate beneficiaries. This type of health care intervention is complex to set up. Since its purpose, legal framework, governance, financing and functioning may vary according to the context in which it is to be implemented [17], it is important to define all its components at all levels of the health system. The 5A-QUIT-N intervention had to cover a wide spectrum, from asking pregnant women if they smoke to organising professional follow-up for smoking cessation. This trajectory may be influenced by several barriers or facilitators, such as the amount of training received by health care professionals and the local political and administrative context.

To meet this challenge, we used two existing theoretical frameworks to develop the 5 A-QUIT-N intervention. The first is the organisational framework developed by the European Observatory on Health Systems and Policies which distinguishes three levels of intervention: the health system, the organisation level and the clinical level [23]. It provides a structured approach to identifying barriers and facilitators at each level, such as legislation and regulation at the health system level, training

 $<sup>^{\</sup>rm 1}$  In French," 5 A-QUIT-N"and"Aquitaine"are pronounced in the same way.

and organisational processes at the organisational level, and clinical practices and tools at the clinical level. By addressing these interconnected levels, it ensures that the intervention considers all the factors influencing its effectiveness, thereby enhancing its viability and sustainability.

The second framework is the 5As model, which is a counselling method considered effective with a high level of evidence for smoking cessation in the general population [24, 25]. The acronym '5 As' describes the five chronological steps that health professionals are encouraged to follow when supporting a patient attempting to quit smoking: ask, advise, assess, assist and arrange. The model offers the basis of long-term support for smoking cessation, which then needs to be adapted to the population and to the existing local resources. In our intervention, the 5As model serves as a framework for structuring the components of the intervention within the perinatal care pathway.

# Stages of development

The 5A-QUIT-N intervention was developed in three stages (Fig. 1). First, a thorough review of the national recommendations led to the identification of the different components and strategies that the intervention should include. These components were then discussed and validated by a multidisciplinary scientific committee. Next, the obstacles and levers that could influence their implementation and effectiveness were collected through

a scoping review of the literature and semi-structured interviews with local stakeholders. The findings allowed the first version of the intervention to be drafted.

Identification and validation of intervention components

### a) Recommendations

To identify the strategies and components of the intervention, a literature review of the national guidelines/recommendations on the topic was conducted. Two investigators carried out the selection and analysis process. The data from these recommendations were then extracted, analysed and classified using the five stages of the 5 As model.

# b) Expert consultation

Twenty-five experts were asked to form the scientific committee of the 5A-QUIT-N project. Its first task was to discuss, modify and validate the components identified in the preceding stage. The experts included general practitioners, pharmacists, obstetrician-gynaecologists, midwives, psychiatrists, smoking cessation and addiction specialists, specialists in occupational health, perinatal care, economics and management, public health and prevention, statisticians and

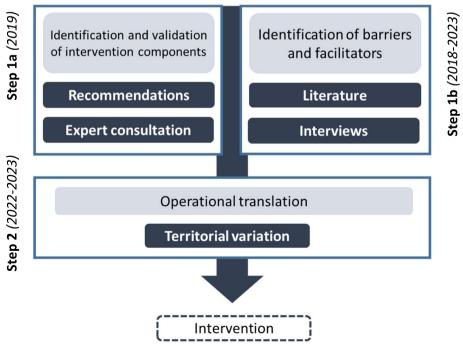


Fig. 1 Flow chart of methodology

methodologists. The Delphi method was used as a basis for communication. The first round was carried out by email in September 2019 in order to discuss the components of the intervention. An electronic form detailing the components of the intervention was sent to each member of the scientific council. On each item, the experts voted "agree", "disagree" or "discuss". Any item that did not receive a unanimous "agree" or "disagree" vote was discussed in a second round of face-to-face discussions until a consensus was reached.

Following this consultation process, the list of intervention components was updated (appendix 1). It was this final version that was used to design the intervention.

- Identification of barriers and facilitators to implementation
  - a) Scoping review of the literature

The scoping review sought to identify barriers and facilitators for implementing the "5As" smoking cessation model. For this purpose, the terms smoking cessation, "pregnan\*" and ("5A" or "5As") were used in the PubMed and Scopus databases. Two reviewers independently performed the selection and analysis process. The data from the different studies were extracted using a grid specifically developed for this study and then analysed thematically and classified according to the three categories of the European Observatory on Health Systems and Policies framework described above [23]. The scoping review is the subject of a separate article [26].

# Semi-structured interviews

The objective of the semi-structured interviews was to identify and understand the usual practice of health-care professionals concerning smoking cessation and the influence of the local context on them.

Three panels of professionals were selected for their involvement at local level and their expertise in smoking addiction and perinatal care. The first panel comprised institutional representatives (funders and professionals working in the specialised professional networks and in addictology associations), the second included physicians (addictologist<sup>2</sup> and obstetrician-gynaecologist), and the third was composed of midwives practising in hospitals,

in private practices and in Maternal and Child Protection (PMI) services. Three investigators undertook this step, each being responsible for collecting data and analysing a particular panel. A cross-analysis was carried out by one of the investigators. When contacted by e-mail or telephone, all the professionals agreed to participate in the survey. The interviews took place in person at the respondent's workplace in a quiet space or by telephone. The interviews were conducted using an interview guide specifically designed for this study. The interviews addressed the professional's usual practices, the local context, and the potential obstacles and levers to the implementation of a smoking cessation intervention for pregnant women in their area. The interviews lasted anywhere between 17 and 120 min. They were recorded using a voice recorder, then transcribed and analysed using the Microsoft® suite. The transcripts were analysed thematically, vertically and horizontally, in order to identify the main results. The analysis grid evolved along with the results until data saturation was achieved. Finally, the results of the cross-analysis of these interviews were classified according to the three levels of intervention of the European Observatory on Health Systems and Policies framework: health system level, organisational level and clinical level [23].

#### 3. Operational translation

To finalise the intervention, an inventory of the existing resources (tools, associations, networks of professionals, care pathways) in Nouvelle-Aquitaine region of France was carried out and partnerships were established with the relevant stakeholders. Then, the components of the intervention were defined on the basis of these resources in order to build an intervention that is both integrated into the perinatal care pathway and specific to the local context. Finally, consultations were carried out with regional experts in order to take the experience and knowledge of local stakeholders into account. The intervention was therefore based entirely on existing local resources.

# **Results**

- 1. Identifying the components of the intervention
  - a) Recommendations

A total of seven reports from different national institutions were included: recommendations specific to smoking cessation management and the 5 As model [24, 27], recommendations from

<sup>&</sup>lt;sup>2</sup> The addictologist is a physician who has completed specific training and who has specialised in physiological and psychological addictions.

# **Table 1** Components of 5A-QUIT-N intervention

#### Components of intervention

#### Ask

Professionals ask about patient's smoking status (consumption prior to pregnancy, changes in consumption since pregnancy and current consumption)

#### Advise

Professionals in contact with pregnant women systematically advise their patients to stop smoking

Professionals are careful not to make moral judgements about the pregnant woman's tobacco consumption to avoid making her feel guilty

Professionals point out that quitting smoking may require medical care from a professional

Professionals do not bring up the unborn child: it is up to the pregnant woman to talk about it if she wishes

#### Assess

Professionals assess severity of addiction (e.g. when evaluating patient for an NRT prescription or deciding whether to refer to a specialist)

Professionals assess vulnerability factors of pregnant woman (psychiatric, addictive (due to co-consumption), clinical and social factors)

Professionals assess pregnant woman's motivation to quit smoking

Professionals ask pregnant woman if she is considering quitting smoking

Professionals assess whether they are able to support pregnant woman

# Assist

Professionals accompany pregnant woman in her choice of weaning strategy

Professionals use motivational interviewing or equivalent methods

Professionals integrate the entourage due to importance of social support in success of smoking cessation

Professionals help pregnant woman to identify sources of support within her environment

Professionals systematically provide information on aids available, their effectiveness, their advantages and disadvantages and how to use each aid, through a simple mediation tool

#### Arrange

Professionals organise regular follow-up visits for support during attempt to quit

expert groups on the management of smoking during pregnancy [18, 28, 29], and recommendations on the organisation of care pathways and the role of prevention in primary care [16, 17].

- b) Consultation of the Scientific Committee
  This data collection resulted in an initial list of
  73 components which was then submitted to the
  expert committee for validation. Fifty-six components were deleted, 8 were modified, 6 were
  validated without modification and 3 were added.
  This resulted in a second version containing the
  remaining 17 components (see Appendix 1).
- c) Components of the intervention
   Table 1 shows the final list of components.
- 2. Identification of barriers and levers for implementation
  - a) Scoping review of the literature

Of the 38 articles initially identified, 13 were included. In total, 48 barriers and levers were identified that could influence the implementation and effectiveness of the 5 As model. These barriers and levers were classified into nine categories: clinical practice, organisation of prac-

tices, resources, support for professionals, representation of the 5 As model, professional role and identity, professionals' representations of pregnant women, influence of pregnant women and political environment. These nine categories were then sub-divided into health system level, organisational level and clinical level [26].

## b) Semi-structured interviews

A total of 13 semi-structured interviews were conducted with a multidisciplinary panel of professionals (see Table 2). This allowed the exploration of various issues concerning the barriers and facilitators to the implementation of the 5As model.

Some barriers and levers were identified only through interviews but were not found in the literature. These included (i) promotion of existing communication tools (e.g. in waiting rooms), (ii) considering the accessibility of the health system for pregnant women (geographical and economical), (iii) adapting the intervention to the existing territorial resources, (iv) considering the complexity of specific local issues such as the succession of plans over time, the need for global coher-

**Table 2** Characteristics of respondents

	Profession	Place of work	Further training in smoking cessation/addictology	Gender
E1	Representative of a health institution	Regional Health Agency	Not relevant	Male
E2	General Practitioner Associate Professor of General Medicine	Private practice Regional association in the field of addictions	Addictology	Male
E3	Midwife	Medical and general coordinator of a regional network in the field of perinatal care	Not reported	Female
E4	Obstetrician gynaecologist	University Hospital	Not reported	Male
E5	General Practitioner	Committee for the Study and Information on Drugs and Addictions	Not reported	Female
E6	Midwife	Level 2 hospital	None	Female
E7	Midwife	Rural private practice	None	Female
E8	Midwife	Urban private practice	None	Male
E9	Midwife	Rural and semi-rural mother and child welfare	Training with the regional association and health insurance	Female
E10	Midwife	Urban private practice	Conferences on the theme	Female
E11	Midwife	Rural and semi-rural mother and child welfare	Training with the regional association	Female
E12	Midwife	Level 3 hospital	None	Female
E13	Midwife	Level 3 hospital	University diploma in perinatal psychiatry and environmental health	Female

ence and concrete measures, and (v) appointing referents in health care institutions.

# c) Overall results

The scoping review and the interviews generated 54 barriers and levers to the 5A-QUIT-N intervention. Of these, 25 were common to both sources of data, 23 were specific to the review and 6 were specific to the interviews. Table 3 presents these results.

# 3. Operational translation

The different organisational strata and the care system have been brought together in a territorial network that combines perinatal professionals (obstetricians-gynaecologists, midwives, general practitioners) and addictology professionals (smoking cessation and addiction specialists) via a system for referring pregnant women according to their vulnerability. This system is incorporated into the usual care pathway for pregnant women, taking existing local policies and strategies and established organisations into account. This organisation is represented in Fig. 2. An intervention booklet has been produced in order to describe in detail and manage the implementation of the intervention in each area. The booklet illustrates each component of the intervention, explains the obstacles and levers, and the timeline of its deployment. At the clinical level, a booklet detailing all of the pre-existing tools, has been produced. Its aim is to raise the awareness of professionals working with pregnant women who smoke tobacco. It also informs them about the tools available for increasing their skills in supporting their patients' efforts to stop smoking.

As a demonstrator, the intervention is planned to be implemented in a pilot area in France as follows.

The coordination team, composed of members from the research team and a coordinating unit specializing in addiction resources, begins by mapping existing resources. These include training programs, tools, and human resources such as healthcare professionals already involved in smoking cessation and those providing pregnancy care. The team contacts the resource coordinators to present the intervention, discuss their resources, needs, and capacity to engage in the project, and determine the extent of their involvement. This initial step allows the intervention to be tailored to the local context and helps create a supportive environment for its acceptance by the targeted professionals.

Next, the coordination team meets individually with each healthcare professional involved in pregnancy care at their workplace. During these visits, the coordination team presents the resources available for addressing smoking, including tools, training programs, and referral pathways for pregnant women who smoke and require specialized care. The team offers practical help and demonstrates how to incorporate smoking cessation into pregnancy care consultations using the 5 As model. When, during the "assess" step, the professionals consider that a woman requires a referral, the coordination team explains how to refer her to addiction care services,

**Table 3** Barriers and levers to implementation of 5 A-QUIT-N intervention

Theoretical framework	Categories	Sub-categories	Barriers and levers	Review	Interview
Clinical level	Clinical practices	Posture	Has a trusting relation- ship and positive attitude towards pregnant woman	Х	X
			Takes pregnant woman into account as a whole	X	X
			Takes pro-active approach dur- ing every contact with pregnant woman	X	
		Multi-professional	Builds multi-professional part- nership	X	X
			Establishes communication between stakeholders (professionals, partners)	X	X
			Knows network of local stake- holders	X	X
			Makes available list of stakeholders who can provide care		X
		Clinical support tools	Uses motivational interviewing	Х	Χ
			Produces informational materials for pregnant women	X	X
			Promotes existing communication tools (e.g. in waiting rooms)		X
Clinical level	Representations of 5 As model	Takes doubts of professionals about the effectiveness of the 5 As model into account		X	X
		Provides information on effectiveness of referring		Х	
Clinical level	Professional role and identity	Perceived role	Clarifies importance of tobacco management during pregnancy follow-up	X	
			Encourages professionals to embrace their role	X	X
		Motivation	Builds on interest and motiva- tion of professionals for 5 As model and its implementation	X	X
			Builds on willingness of profes- sionals to change smoking behaviour	X	
			Pays particular attention to the fact that gynaecologists do not feel concerned by pre- vention	X	
			Involves midwives and nurses	Х	
		Self-efficacy	Improves self-efficacy of professionals	X	X
			Improves legitimacy of pro- fessionals regardless of their personal smoking status	X	
Clinical level	Representations of pregnant	Takes the representation of smoking as a choice into account		X	
	women by HPs	Takes negative perception of pregnant woman into account		X	X
		Takes fear of losing relations	ship with pregnant woman into account	X	X
		Takes accessibility of health system for pregnant women (geo- graphical and economical) into account			X

**Table 3** (continued)

Theoretical framework	Categories	Sub-categories	Barriers and levers	Review	Interview
Clinical level	Influence of beneficiaries	Takes lack of knowledge about health effects of tobacco on women and children into account		Х	х
		Takes lack of motivation of p	pregnant women into account	X	х
		Takes underestimation of difficulty of smoking cessation into account		X	
		Takes dissatisfaction of pregnant women with professionals into account		X	
Organisational level	Organisation of practices	Healthcare pathway	Uses time in waiting room for smoking prevention	X	X
			Uses time during examination for smoking prevention	X	
			Integrates smoking cessation into pre-existing consultations	X	X
			Offers consultations dedicated to tobacco management	X	
		Deployment	Develops a 5 As model deployment protocol	X	
			Involves managers in commu- nication in relation to the 5 As model	X	X
			Involves expert opinions in communication of the 5 As model	X	
			Sets up monitoring of implementation of the 5 As model	X	
			Adapts intervention according to existing local resources		X
Organisational level	Resources	Financial resources	Takes cost of implementation into account	X	X
		Time resources	Takes time available into account	X	X
			Prioritizes issues to be addressed during perinatal consultations	X	
			Takes patient's comorbidities into account	X	
Organisational level	Support for professionals	Training	Follows training on the 5 As model	X	X
			Acquires skills (e.g. having a positive attitude towards woman's smoking history, communicating on risks for the foetus, implementing each step of the 5 As model)	X	
			Acquires knowledge (e.g. on NRTs, on addictions and on specific risks of tobacco on the foetus)	X	
		Resources for professionals	Develops clinical guidelines	X	х
			Develops and disseminates expert recommendations	X	X
			Sets up automatic computer reminders	X	
			Trains professionals in the 5 As model to support perinatal professionals	X	
			Provides feedback on the practices of professionals	X	

Table 3 (continued)

Theoretical framework	Categories	Sub-categories	Barriers and levers	Review	Interview
Health system level	Political environment	Involves patient organisat	ions (advocacy)	Х	
		Has commitment from m	anagement	X	X
		Makes smoking cessation teams, authorities, expert	a priority (support from management groups, etc.)	X	X
		Takes local complexities (: ence and concrete measu	succession of plans, need for global coher- ures) into account		X
		Sets up referents in health	n care institutions		X

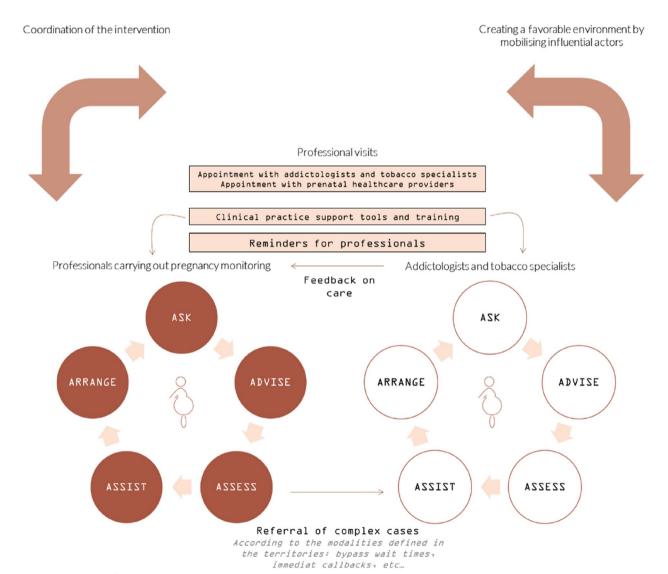


Fig. 2 Organisation of the 5 A-QUIT-N intervention

highlighting the fast-track referral pathways established within the  $5\,A\text{-}QUIT\text{-}N$  intervention for pregnant smokers.

As part of the care provided by the addiction services, the latter are expected to keep the healthcare professionals involved in pregnancy care informed about the progress of their patients' treatment. By fostering collaboration between healthcare professionals and connecting different disciplines, the intervention promotes the development of a systematic, team-based, multidisciplinary approach to care.

A few months after these visits, the coordination team follows up the professionals by phone. The purpose of the call is to promote the adoption of new preventive clinical practices and help address any challenges the professionals may encounter.

# Discussion

#### Main results

The first main finding is the need to coordinate and mobilise the resources already available in a region. The 5 A-QUIT-N intervention thus proposes a new, more efficient usage of existing resources instead of attempting to re-invent the wheel. At the clinical level, it aims to increase the skills of professionals by drawing on existing tools and training modules. At the organisational level, it proposes better coordination between the perinatal professionals and smoking cessation specialists, as well as the sharing of their respective resources and skills. Furthermore, the local context constitutes an integral and essential aspect of the intervention.

# An intervention based on theory and experience

The intervention is theory-based. A theory-based public health intervention is one whose foundations are based on one or a set of theories that have been shown to be relevant in a given field. Such interventions are co-constructed with the key stakeholders and require a multidisciplinary approach [19]. To design the 5A-QUIT-N intervention, the starting point was to define the theoretical frameworks underpinning it. The frameworks used were the 5As model and the conceptual framework representing the three levels of action within the health system (health system level, organisational level and clinical level). It was thus possible to analyse the existing resources and the potential obstacles and levers to the implementation of the intervention.

The intervention also called upon the experience and expertise of professionals through interviews with stakeholders and the participation of a multi-professional scientific committee. In this way, it was possible to tap into the practices of health professionals and their experiences and therefore to adapt the intervention to the needs of the professionals and to their different settings. By identifying the factors that could influence the implementation of the intervention as early as its design stage, it was also possible to anticipate any changes that might be required as well as to refine the components of the intervention and provide a margin of flexibility and

adaptation. This allowed the intervention to be modulated according to the resources and needs identified area by area. *In fine*, the intervention has two major components: a clinical component aimed at increasing the skills and involvement of perinatal professionals in promoting smoking cessation; and a second component focusing on the organisation and rollout of the intervention on the basis of the resources available in each area.

## An organisational challenge

The innovative architecture of the 5A-QUIT-N intervention represents both an opportunity and a major challenge for the implementation and effectiveness of smoking cessation in pregnant women. The components of the intervention interact with each other and with the context and should produce the desired effects [30, 31]. It has been designed to be sufficiently flexible to facilitate its adaptation to other contexts [32]. It should be transferable [33] and could be scaled up in time and space.

# Strengths and limitations

The 5 A-QUIT-N intervention has some limitations. First, it targets tobacco smoking during pregnancy but does not address novel nicotine products like e-cigarettes. While vaping is stable in France (4.3% daily users in 2020) [34], no randomized trials have assessed its safety during pregnancy. International recommendations differ: the U.S. discourages use [35], while the U.K. suggests it may be safer than smoking [36, 37]. In France, guidelines advise against e-cigarette use during pregnancy based on the precautionary principle [38]. In this context, the tools and resources identified as part of the 5A-QUIT-N intervention and distributed to healthcare professionals include information on these topics, in accordance with the current national recommendations. Second, although it was designed using field data, it remains a theoretical intervention, and its implementation and effects have not yet been tested in real-life settings. Third, although it was co-designed with local stakeholders who are the primary targets of the intervention, the women who will benefit from it did not participate in its co-construction. Furthermore, addiction is a chronic condition and therefore, support for smoking cessation is a lifelong issue. While the intervention focuses on the pregnancy period due to time constraints and short deadlines, support during the pre-conception and postpartum phases is equally critical. Postpartum relapse is particularly concerning, with an estimated 80% of women who quit smoking during pregnancy relapsing within the first year postpartum [39].

These limitations will be addressed in future phases of the project. A pilot study, followed by a randomized controlled trial [19, 22], will test the intervention in real-life conditions and allow for necessary adaptations. After each phase of testing, qualitative interviews will be conducted with stakeholders and women to refine the intervention and better align it with their needs. Finally, the effect of the intervention on postpartum relapse will also be investigated as part of the randomized controlled trial.

Of note, the 5 A-QUIT-N intervention was designed specifically for the Nouvelle-Aquitaine region in conjunction with local stakeholders. A transferability study is therefore required to ensure that the expected results can be obtained in other territories, as their resources and policies may differ.

# Conclusion

The approach described in this article has allowed the design of an intervention that is not only theory-based but also capitalises on the experience of local professionals and their knowledge of the environment in which the intervention is to be implemented. A thorough understanding of the local environment is essential if an intervention is to prove viable in a given region. It makes it possible to know whether the effects of the 5 A-QUIT-N intervention are really attributable to its components or if they are due to other contextual parameters that remain to be identified. Once this has been established, the intervention will become transferrable and scalable.

# **Supplementary Information**

The online version contains supplementary material available at https://doi.org/10.1186/s12884-025-07573-5.

Supplementary Material 1.

# Acknowledgements

The authors would like to thank all the people who took part in the interviews for this research, as well as the members of the scientific committee.

# Authors' contributions

Conceptualization: EC, AB, NS, CK, RR, PC, LS, FA and 5A-QUIT-N group. Data collection: EC, AB, NS, MV, PM. Data analysis: EC, AB, NS, MV, PM. Writing of original draft: EC. Writing, reviewing and editing: All authors. English editing: MF. Supervision: FA. Project administration: RR. Funding acquisition: EC, AB, NS, CK, RR and FA.

# **Funding**

This work was funded by three French public grants: (1) the Nouvelle-Aquitaine Regional Health Agency (Agence Régionale de Santé de Nouvelle-Aquitaine) ('ARS FIR 2019' and 'ARS Fonds Addiction'); (2) the French General Direction of Healthcare Supply (Direction Générale de l'Offre de Soins) ('PREPS 2019') and (3) the French National Cancer Institute and the French Institute for Public Health Research (Institut National du Cancer et Institut de recherche en santé publique) ('INCa-IReSP TABAC 2019').

# Data availability

The dataset used and/or analysed during the current study are available from the corresponding author on reasonable request.

#### **Declarations**

#### Ethics approval and consent to participate

This study received a favourable recommendation from the Research Ethics Committee of the University Hospital of Bordeaux. The recommendation has the following reference: CER-BDX 2024–15. For the interviews, oral consent was obtained from all participants, depending on the nature of the data (opinions on existing or potential interventions). The Research Ethics Committee of the University Hospital of Bordeaux approved this procedure.

#### Consent for publication

Not applicable.

#### Competing interests

The authors declare no competing interests.

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Received: 27 November 2023 Accepted: 7 April 2025 Published online: 25 April 2025

#### References

- Lange S, Probst C, Rehm J, Popova S. National, regional, and global prevalence of smoking during pregnancy in the general population: a systematic review and meta-analysis. Lancet Glob Health. 2018;6(7):e769-76.
- Santé publique France, INSERM. Enquête nationale périnatale. 2022. Disponible sur: https://enp.inserm.fr/wp-content/uploads/2022/10/rappo rt-2022-v5.pdf. Cité 31 Oct 2022.
- Haute Autorité de santé. Conférence de consensus. Grossesse et tabac. Lille; 2004. Disponible sur: https://www.has-sante.fr/upload/docs/application/pdf/Grossesse\_tabac\_long.pdf. Cité 23 Juill 2019.
- Petrou S, Sach T, Davidson L. The long-term costs of preterm birth and low birth weight: results of a systematic review. Child Care Health Dev mars. 2001;27(2):97–115.
- DiFranza JR, Aligne CA, Weitzman M. Prenatal and postnatal environmental tobacco smoke exposure and children's health. Pediatrics avr. 2004;113(4 Suppl):1007–15.
- Jedrychowski W, Flak E. Maternal smoking during pregnancy and postnatal exposure to environmental tobacco smoke as predisposition factors to acute respiratory infections. Environ Health Perspect mars. 1997:105(3):302–6.
- Leonardi-Bee J, Jere ML, Britton J. Exposure to parental and sibling smoking and the risk of smoking uptake in childhood and adolescence: a systematic review and meta-analysis. Thorax. 2011;66(10):847–55.
- Cnattingius S. The epidemiology of smoking during pregnancy: Smoking prevalence, maternal characteristics, and pregnancy outcomes. Nicotine Tob Res. 2004;6(Suppl\_2):S125-40.
- Chamberlain C, O'Mara-Eves A, Porter J, Coleman T, Perlen SM, Thomas J, et al. Psychosocial interventions for supporting women to stop smoking in pregnancy. Cochrane Database Syst Rev. 2017;2017(2). Disponible sur: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6472671/. Cité 1 Juin 2020
- Lumley J, Chamberlain C, Dowswell T, Oliver S, Oakley L, Watson L. Interventions for promoting smoking cessation during pregnancy. Cochrane Database Syst Rev. 2009;(3). Disponible sur: https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD001055.pub3/abstract. Cité 1 Juin 2020.
- Stead LF, Koilpillai P, Fanshawe TR, Lancaster T. Combined pharmacotherapy and behavioural interventions for smoking cessation. Cochrane Database Syst Rev. 2016;(3). Disponible sur: https://www.cochranelibrary. com/cdsr/doi/10.1002/14651858.CD008286.pub3/abstract. Cité 1 juin 2020.

- Jones M, Lewis S, Parrott S, Wormall S, Coleman T. Re-starting smoking in the postpartum period after receiving a smoking cessation intervention: a systematic review. Addiction. 2016;111(6):981–90.
- Schoenaker DAJM, Ploubidis GB, Goodman A, Mishra GD. Factors across the life course predict women's change in smoking behaviour during pregnancy and in midlife: results from the National Child Development Study. J Epidemiol Community Health. 2017;71(12):1137–44.
- Baylis V. Factors That Influence Smoking During Pregnancy: An Integrative Literature Review. Grace Peterson Nurs Res Colloq. 2017; Disponible sur: https://via.library.depaul.edu/nursing-colloquium/2017/Fall\_2017/28.
- Riaz M, Lewis S, Naughton F, Ussher M. Predictors of smoking cessation during pregnancy: a systematic review and meta-analysis. Addiction. 2018;113(4):610–22.
- Haut conseil de la santé publique. La place des offreurs de soins dans la prévention. Paris: Haut Conseil de la Santé Publique; 2018. Disponible sur: https://www.hcsp.fr/explore.cgi/avisrapportsdomaine?clefr=689. Cité 26 Juill 2019.
- Haut conseil pour l'avenir de l'assurance maladie. La prévention dans le système de soins. Paris; 2018 p. 24. Disponible sur: https://www.strat egie.gouv.fr/sites/strategie.gouv.fr/files/atoms/files/avis\_prevention\_hcaam\_-\_25\_octobre\_2018.pdf. Cité 1 août 2019.
- Grangé G, Berlin I, Bretelle F, Bertholdt C, Berveiller P, Blanc J, et al. Rapport d'experts et recommandations CNGOF-SFT sur la prise en charge du tabagisme en cours de grossesse—texte court. Gynécologie Obstétrique Fertil Sénologie. 2020;48(7):539–45.
- Skivington K, Matthews L, Simpson SA, Craig P, Baird J, Blazeby JM, et al. A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. BMJ. 2021;374: n2061.
- 20. Chen HT. The bottom-up approach to integrative validity: A new perspective for program evaluation. Eval Program Plann août. 2010;33(3):205–14.
- Decroix C, Kervran C, Cambon L, Alla F. Fitting Health Promotion Research with Real-Life Conditions: Viability Evaluation. In: Potvin L, Jourdan D, éditeurs. Global Handbook of Health Promotion Research, Vol 1: Mapping Health Promotion Research. Cham: Springer International Publishing; 2022. p. 625-40. Disponible sur: https://doi.org/10.1007/978-3-030-97212-7. 41. Cité 9 sept 2022.
- Kervran C, Francis-Oliviero F, Kret M, Burtin A, Ratel R, Clet E, et al. Effectiveness evaluation of an organisational intervention, targeting pregnancy and addiction care professionals, among women who have just given birth in maternity wards and smoked tobacco during pregnancy (5A-QUIT-N): study protocol for a stepped-wedge cluster randomised trial. BMJ Open. 2024;14(11):e087541.
- 23. Legido-Quigley H, McKee M, Nolte E, Glinos IA, European Observatory on Health Systems and Policies. Assuring the quality of health care in the European Union.
- Haute Autorité de santé. Arrêt de la consommation de tabac: du dépistage individuel au maintien de l'abstinence en premier recours.
   2014 p. 60. Disponible sur: https://www.has-sante.fr/upload/docs/application/pdf/2014-01/recommandations\_-\_arret\_de\_la\_consommation\_de\_tabac.pdf.
- Bell R, Glinianaia SV, van der Waal Z, Close A, Moloney E, Jones S, et al. Evaluation of a complex healthcare intervention to increase smoking cessation in pregnant women: interrupted time series analysis with economic evaluation. Tob Control janv. 2018;27(1):90–8.
- Burtin A, Clet E, Stevens N, Kervran C, Frevol M, Ratel R, et al. Factors associated with the implementation of the 5As model of smoking cessation support during pregnancy: A scoping review. Tob Induc Dis. 2023;21:110.
- 27. HAS. Présentation de la méthode des 5A: Annexe à la recommandation de bonne pratique « Arrêt de la consommation de tabac : du dépistage individuel au maintien de l'abstinence ». Haute Autorité de Santé; 2014.
- Koch A, Blanc J, Berlin I. Quelle politique de prise en charge du tabagisme pendant la grossesse? – Rapport d'experts et recommandations CNGOF-SFT sur la prise en charge du tabagisme en cours de grossesse. Gynécologie Obstétrique Fertil Sénologie. 2020;48(7):587–9.
- Peyronnet V, Koch A, Rault E, Perdriolle-Galet E, Bertholdt C. Prise en charge non pharmacologique du sevrage tabagique pendant la grossesse – Rapport d'experts et recommandations CNGOF-SFT sur la prise en charge du tabagisme en cours de grossesse. Gynécologie Obstétrique Fertil Sénologie. 2020;48(7):590–603.
- Hawe P, Potvin L. What Is Population Health Intervention Research? Can J Public Health. 2009;100(1):18-14.

- 31. Cambon L, Alla F. Understanding the complexity of population health interventions: assessing intervention system theory (ISyT). Health Res Policy Syst. 2021;19(1):95.
- Stevens N, Cambon L, Bataillon R, Robin S, Alla F. Décrire l'innovation organisationnelle en santé publique pour favoriser sa dissémination; guide DINOSP (Description des innovations organisationnelles en santé publique). Rev DÉpidémiologie Santé Publique. 2022; Disponible sur: https://www.sciencedirect.com/science/article/pii/S039876202 2007076. Cité 9 sept 2022.
- Wang S, Moss JR, Hiller JE. Applicability and transferability of interventions in evidence-based public health. Health Promot Int mars. 2006;21(1):76–83.
- Pasquereau A, Andler R, Guignard R, Soullier N, Gautier A, Richard JB, et al. Consommation de tabac parmi les adultes en 2020 : résultats du baromètre de santé Santé publique France. 2021.
- US Preventive Services Task Force, Krist AH, Davidson KW, Mangione CM, Barry MJ, Cabana M, et al. Interventions for Tobacco Smoking Cessation in Adults, Including Pregnant Persons: US Preventive Services Task Force Recommendation Statement. JAMA. 2021;325(3):265-79.
- Campbell K, Coleman-Haynes T, Bowker K, Cooper SE, Connelly S, Coleman T. Factors influencing the uptake and use of nicotine replacement therapy and e-cigarettes in pregnant women who smoke: a qualitative evidence synthesis. Cochrane Database Syst Rev. 2020;5(5):CD013629.
- 37. National Health Service. Stop smoking in pregnancy. Disponible sur: https://www.nhs.uk/pregnancy/keeping-well/stop-smoking/.
- Collège National des Gynécologues et Obstétriciens Français, Société Francophone de Tabacologie. CNGOF-SFT Expert Report and Guidelines for Smoking Management during Pregnancy.
- Jones M, Lewis S, Parrott S, Wormall S, Coleman T. Re-starting smoking in the postpartum period after receiving a smoking cessation intervention: a systematic review. Addiction. 2016;111. Disponible sur: http://www.readcube.com/articles/10.1111/add.13309. Cité 6 févr 2018.

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