Mapping De-Implementation Strategies To Identified Determinants of Low-Value Statin Prescription for Primary CVD Prevention in Primary Care

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Research

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Abstract

Background

Despite clear recommendations supporting healthy lifestyle promotion interventions for the primary prevention of CVD in low-risk patients, a considerable number of these people continue to receive inappropriate statin prescriptions. The present study reports on the structured process based on theory and evidence carried out for the design of de-implementation strategies to reduce the inappropriate prescription of statins and to increase the promotion of healthy lifestyles, in CVD prevention practice of primary care professionals for patients with low cardiovascular risk.

Methods

A phase I formative study following a structured theory-informed process combining the Theoretical Domains Framework (TDF) and the Behavior Change Wheel (BCW) was conducted, comprising: semi-structured interviews (n=5) with primary care professionals to delimitate and define the problem in behavioral terms; focus groups (4 groups with 21 physicians; 1 group with 6 patients) to identify the determinants of potentially inappropriate prescribing [PIP] of statins and healthy lifestyle promotion actions; mapping of behavioral change interventions operationalized as de-implementation strategies for addressing identified determinants; and consensus techniques for the prioritization of strategies based on perceived effectiveness, feasibility and acceptability.

Results

Numerous multilevel determinants of both PIP of statins and healthy lifestyle promotion embracing almost all of the TDF dimensions have been identified. Guided by the BCW established procedure, 13 potential de-implementation strategies have been mapped to identified determinants. Those assessed as potentially more feasible, acceptable and potentially effective by the professionals themselves were: 1) Information/knowledge dissemination strategies: a corporate dissemination campaign on “Abandonment of Low-Value Practices”; a Clinical Pathway for the primary prevention of CVD in low-risk patients, accompanied with audiovisual and paper-based training resources; 2) Strategies for presenting relevant information for decision-making: an audit/feedback system regarding CVD prevention practice performance indicators; and 3) Strategies for helping clinical decisions: reminders, alerts, and a decision support tool incorporated into the REGICOR CVD risk calculator in the electronic clinical record.

Discussion

The methodology established by the TDF/BWC for the design of behavior change interventions has been useful for the development of de-implementation strategies targeting the decision-making process of clinicians to favor the uptake of recommended clinical practice for CVD prevention in low-risk patients.

TRIAL REGISTRATION

Clinicaltrials.gov identifier: NCT04022850. Registered 17 July 2019, <https://www.clinicaltrials.gov/ct2/show/NCT04022850>

Contributions To The Literature

- One of the first studies presenting the use of a theory- and evidence-based methodology, the Behavior Change Wheel, to develop de-implementation strategies for reducing low-value practices
- The systematic process dictated by the BCW helps to identify the specific determinants related to the prioritized target behavior for change, i.e. the decision-making process about intervention options for CVD prevention in low-risk patients
- The BCW also facilitates the design of sets of interventions comprising several potential de-implementation strategies sufficient to impact the mechanisms that need to be changed and to bring about the desired behavioral change

Background

De-implementation or abandonment of ineffective or low-value healthcare has gained great interest in many countries in recent decades, due, among other factors, to the growing empirical evidence of its high prevalence and its impact on patient safety, resource consumption and social inefficiency [1, 2]. As a consequence of this interest, knowledge based on theoretical or empirical evidence about the process of abandonment of practices, in particular the key factors (barriers, facilitating factors, etc.) required for the design and application of effective interventions that promote and accelerate the abandonment of low-value healthcare, is growing rapidly [4, 5].

In light of the advances made both in the implementation of evidence-based interventions and in the de-implementation of practices of little value in the clinical context, several fundamental aspects can be deduced: firstly, factors driving the implementation of both evidence-based and inappropriate interventions in the clinical setting are multi-level, complex, and context specific [2]. Therefore, a wide array of factors related to the intervention or practice to be de-implemented, the agents involved in this practice (e.g. health care professionals, patients) and other inner and outer contextual factors, should be taken into account; secondly, to be able to change a certain clinical practice, it is desirable to adapt the interventions to the specific determinants of the practice faced by both health providers and patients to motivate change, calling on these agents in the process of identifying the determinants of practice, in the design of intervention and implementation strategies and in the preparation of their evaluation [6, 7]. And thirdly, the intervention design should be carried out following a process of formal analysis of the target behavior and its action mechanisms, all guided by models or theories that cover the entire range of possible influences or determinants of the behavior in question [8, 9]. Evidence and theory from behavioral science and behavior change theory can aid in better identifying and understanding the multilevel mechanisms that influence clinical behavior and in the selection of focused, effective techniques to support behavior change of healthcare professionals [10, 11]. Examples of such theories or frameworks for the development or planning of interventions are

the PRECEDE-PROCEED model [12], Implementation Mapping [13], or the Behavior Change Wheel (BCW) [14]. Though there is a wealth of recent literature on the development of intervention or implementation strategies to facilitate the uptake of innovative or evidence-based practices, the application of behavioral science theory for the development of de-implementation interventions is scarce [15–17].

The DE-imFAR (from the Spanish for DE-implementation of low-value pharmacological prescribing) study aims to carry out a structured, evidence based and theory-informed process involving the main stakeholders (health managers, professionals, patients, and researchers) for the design, deployment and evaluation of targeted de-implementation strategies for reducing low-value pharmacological prescribing [18]. Specifically, the low-value practice in question is the pharmacological prescription of statins in primary prevention of cardiovascular disease (CVD) in low-risk patients (<10% CVR according to the REGICOR equation). Based on the evidence and the practice recommendations established by this evidence, it is recommended not to start treatment with statins in this population; further, in primary prevention of CVD, the promotion of healthy lifestyles through diet, physical activity and cessation of smoking should remain the preferred activities [19, 20]. Despite these clear recommendations, the consumption of statins in the Basque Country has grown in recent years caused, in part, by an approach to cardiovascular risk (CVR) focused on the control of lipid levels and the use of medications. Thus, according to the descriptive observational study carried out by our group as part of the DE-imFAR project based on data in electronic health records (EHR) on the inappropriate prescription rate of statins in patients aged 40 to 75 years, without CVD, with high cholesterol but a CVR <5% (REGICOR), a prevalence of potentially inappropriate prescribing [PIP] for statins of around 16% and an incidence of new inappropriate prescriptions of 12.6 per 100,000 people/year has been estimated. Furthermore, 60% or more of the EHRs of these people with PIP do not have a record of being given advice on physical activity or a healthy diet. Likewise, 49% did not receive preventive advice on giving up smoking [data not published].

In this paper we will report on phase I of the De-IMFAR study, which aims to design and develop de-implementation strategies to favor the reduction and/or abandonment of low-value prescribing of statins in primary prevention of CVD, addressing the main determinants (barriers and facilitators) of this clinical practice in the specific context of the Basque Health care system (Osakidetza). To achieve this objective, De-imFAR applies a systematic, comprehensive and evidence-based framework for the design of de-implementation strategies, the Theoretical Domains Framework (TDF) [21, 22] and the BCW [14]. Specifically, this first phase is based on conducting a formative research process to: i) understand the problem of statin PIP in primary prevention of CVD and define it in behavioral terms; ii) identify the main determinants of this clinical practice (e.g. at personal, inter-personal, organizational, social level) that must be addressed to change this behavior, and iii) map potential de-implementation strategies. In a second phase of the study, the feasibility and effectiveness of one or more de-implementation strategies will be evaluated to reduce the PIP of statins and strengthen the recommended clinical practice, of promoting healthy habits, in primary prevention practice on CVD in low-risk patients by health professionals and Primary Care teams.

Methods

Design

A Phase I formative study for the collaborative design and development of a de-implementation strategy to favor the abandonment of low-value pharmacological prescribing of statins in primary prevention of CVD. The DE-imFAR study protocol was reviewed and approved by the Clinical Research Ethics Committee of the Basque Country (Ref: PI2019102, approved on 10 April 2019) and has been registered in the US NLM's clinical trials database (clinicaltrials.gov NCT04022850, 17 July 2019).

A working group composed of experts in the design of implementation strategies, methodologists, pharmacists, qualitative researchers, clinicians and health service managers carried out a structured and theory-informed process – specifically, the BCW [14, 23] – to map implementation strategies seeking to address the key determinants of low-value pharmacological prescribing in CVD primary prevention. In short, the BCW was used to identify, select, adapt and define possible behavioral change interventions operationalized as de-implementation strategies to address the prioritized determinants of PIP of statins in CVD primary prevention. This process involved eight steps grouped into the three following stages:

1st stage - Understand the behavior

step 1) define the problem in behavioral terms; step 2) select the target behaviors; step 3) specify the target behaviors; and step 4) identify what needs to change.

2nd stage - Identify intervention options

step 5) select intervention functions; step 6) select the specific behavior change techniques.

3rd stage - Identify implementation procedures

step 7) select strategies and specific intervention techniques; step 8) select the execution mode of the intervention.

1st stage - Understand the behavior: step 1) define the problem in behavioral terms; step 2) select the target behaviors; step 3) specify the target behaviors; step 4) Identify what needs to change

With the goal of defining the problem in behavioral terms (step 1), we conducted a semi-structured interview with a sample of Family Physicians (FPs) (n=3) and Practice Nurses (n=2) in order to identify the overall behavioral scenario and break down the chain of behaviors and concomitant non-behavioral (e.g., contextual) elements. The interview script was centered on determining how physicians address and manage the clinical encounters related to CVD prevention, and what the main steps taken are. Three members of the working group independently reviewed the recordings of the interviews, and identified and proposed a set of possible target behaviors. Subsequently, based on the information compiled from the interviews and using matrices and exercises

proposed by the BCW [23], the working group proceeded to vote and discuss until agreement in order to select (step 2) and to specify (step 3) the final target behaviors most likely to lead to the desired behavior change, to be the focus of the next steps.

In order to explore the practice determinants of statin PIP in primary prevention of CVD and of the previously identified and selected target behaviors in the context of Osakidetza, a qualitative study comprising two sub-studies was designed and carried out: focus groups with FPs and one focus group with patients. The main goal of this qualitative inquiry process was to identify the main facilitators of the selected target behaviors related to the low-value pharmacological prescribing practice and the barriers to the provision of recommended clinical practice for primary prevention of CVD, i.e. the systematic and active promotion of healthy lifestyles.

For the recruitment of the healthcare professionals, emails were sent to all the Health Centers in the Ezkerraldea-Enkarterri-Cruces (n = 83) and Barakaldo-Sestao (n = 123) areas with a brief explanation of the project and the invitation to participate in it. Of the total number contacted, it was possible to recruit 21 FPs. Four focus groups were developed, two for each HD, with between 4 to 7 attendees in each group. Moreover, patients with statin PIP were identified in the patient lists of the participating professionals (n = 11), and consent for contacting them was requested from the doctor they were registered with. Finally, a discussion group made up of 6 patients who agreed to participate was held.

The groups were led by two researchers with experience in qualitative research methods, as well as knowledge of the clinical field and the study objectives. The focus groups were audio recorded and transcribed verbatim. Informed consent for all participants was obtained prior to any research procedure. The script of the focus groups explored in-depth potential determinants with questions formulated to cover each of the TDF dimensions [22], and it was developed by researchers with experience in behavioral change and implementation research, together with clinicians with expertise in the primary prevention of CVD in primary care settings. Further, in order to facilitate the analysis, a coding scheme regarding the TDF dimensions and their relative constructs was also developed. Two researchers independently reviewed and coded the transcripts and iteratively discussed possible discrepancies until reaching a consensus. As a result, facilitators and barriers for PIP and the provision of advice in promoting healthy habits were identified in the group of professionals. In the case of patients, the following aspects were explored: how the pharmacological treatment was started; if it was a decision made in conjunction with the doctor; how they were informed; what factors could determine this action (preference or health problem, and at patient, professional, health center level), patient comfort with treatment, and so on.

2nd stage - Identify intervention options: 5) select intervention functions; 6) select the specific behavior change techniques.

The goal at this stage was to identify the behavior change techniques for each of the agreed determinants of selected target behaviors in our context. Two researchers from the working group proceeded to map each of the identified barriers and facilitators grouped in the TDF domains with intervention functions, policy categories, and behavior change strategies most likely to produce a change, using the process established by the BCW [23].

3rd stage - Identify implementation procedures: 7) select strategies and intervention techniques; 8) select the mode of execution of the intervention.

Final definition, packaging and selection of previously identified de-implementation strategies were carried out through a participatory consensus process, involving the working group as representatives of the main stakeholders. Further, a clear layout of the techniques to be applied (i.e., the actual content of the interventions, their possible formats and modes of execution) was specified for each of the possible interventions identified through this structured mapping process. In addition, and with the aim of helping to determine the format and mode of delivery of identified de-implementation strategies, examples of interventions and strategies identified in the literature were studied.

Finally, in order to prioritize the de-implementation strategies derived from the mapping conducted, a poll process using the LimeSurvey platform involving FPs who collaborated in the Focal Groups was carried out. Specifically, they assessed the potential effectiveness, acceptability and feasibility of each identified strategy. Those considered potentially effective while highly acceptable and feasible for enacting behavior change were prioritized as the final set of specific strategies, to be contained in at least one broad de-implementation strategy seeking to reduce low-value pharmacological prescribing in the primary prevention of CVD.

Results

1st stage - Understand the behavior.

Steps 1, 2 and 3. Define the problem in behavioral terms, select the target behaviors and specify the target behaviors.

A set of 5 semi-structured interviews with FPs (n=3) and practice nurses (n=2) with recognized expertise and experience in CVD prevention was carried out with the purpose of defining the problem in behavioral terms and generating a list of candidate target behaviors. In short, physicians were asked to describe in detail the steps taken when addressing CVD primary prevention clinical encounters. After reviewing the recordings and performing the exercise established by the BCW, the working group first defined the target behavior as (Table 1):

Table 1
Target behavior description

Who needs to perform the behavior?	Family physicians and nurses
What do they need to do differently to achieve the desired change?	Provide the recommended healthy lifestyle promotion intervention, instead of prescribing statins, for the primary prevention of CVD in low-risk patients
When do they need to do it?	In opportunistic or programmed screening/management of CVD risk factors
Where do they need to do it?	Opportunistic or programmed consultations/visits
How often do they need to do it?	At any encounter feasible
With whom do they need to do it?	Patients with low CVD risk (<10) aged ≥ 40 years old in men and ≥ 45 years old in women
Target behavior	<i>Reduce the prescription of statins in the context of the primary prevention of CVD in low-risk patients (REGICOR <5%) and favor the adoption and implementation of the recommended intervention, the promotion of healthy habits (regular physical activity, healthy diet and cessation of smoking) at any opportunistic or programmed screening or addressing of CVD risk factors in health center visits.</i>

Reduce the prescription of statins in the context of primary prevention of CVD in low-risk patients (REGICOR <5%) and favor the adoption and implementation of the recommended intervention, the promotion of healthy habits (regular physical activity, healthy diet and giving up smoking) at any opportunistic or programmed health center visit for screening or addressing CVD risk factors.

Following this, an effort was made to breakdown the target behavior into the chain of behaviors involved and the concomitant precipitating factors (Appendix Table 1). Three precipitating factors for the practice of primary prevention of CVD were identified: i) alarm systems integrated within the EHR prompting the fulfillment of the PAPPs: Preventive Activities Program; ii) the presence of an elevated cholesterol level within an analytical test; or, iii) the presence of a prescription initiated or suggested by another professional (specialized or private). Regarding the preventive action behaviors by physicians and nurses, 7 main steps were identified, ranging from the initial general approach for CVD primary prevention focused on CVD risk and the cholesterol level to the enactment of the decided treatment or intervention, the options being the prescription of a statin, the delivery of a healthy lifestyle promotion intervention, or both. Then, the working group, using the tools proposed by the BCW within this step, prioritized the following specific behavior, described according to who needs to do what, when, where, how often, how and with whom, as that most likely to bring about change:

The FP considers options and makes the clinical decision on intervention/treatment to be provided, based on the result of the CVD risk estimation, on knowledge and heuristics in relation to the recommended practice, their attitudes, expectations and abilities, and other contextual factors (time, work overload, organizational norms, decisional fatigue, etc.).

Step 4. Identify what needs to change.

Numerous determinants, facilitators of the inappropriate statin prescription and barriers towards healthy lifestyle promotion emerged from the focus groups with healthcare professionals and patients. Determinants were identified from the quotes extracted from the focus group guided by a pre-specified coding. Table 2 presents some examples of quotes classified by the domains of the TDF. Apart from one TDF dimension, Optimism, all the rest of the dimensions were covered in the FPs' discourses (See Table 2 for extracted quotes):

Table 2
Quotes extracted from FPs discussion groups by TDF determinant dimensions

TDF Dimension	Extracted quotes
Knowledge	<p><i>"When you called me, what struck me was that I don't see so many people who should not take statins and are taking them." (K_Q1)</i></p> <p><i>"Then also, the issue of the reliability of the guidelines is an issue... the sensitivity and specificity you have when making a decision... the issue of cholesterol is quite controversial." (K_Q2)</i></p> <p><i>"Cholesterol levels have been very variable, and we didn't know if it was necessary to treat this in primary or secondary prevention, but then it became clear that it was in secondary, not in primary, that diabetics are in secondary, and if they're not... there we've also had a bit of trouble and so that could also be the cause of this prescription" (K_Q3)</i></p> <p><i>"I think that we have to be clear about that at least, that there's no evidence for giving statins, unless there's a family history, yes." (K_Q4)</i></p> <p><i>"We are seeing that there are other added risk factors, there are diseases that we are seeing that have a greater risk of having that disease, rheumatism for example, but some other things aren't. In the analysis that you have made of Osakidetza, this might be there or not, but you probably haven't been able to see if they have a family history of sudden death, you cannot see if in addition to this they have other diseases that have to do with greater risk, which are being seen today. We don't see many of these." (K_Q5)</i></p>
Skills	<p><i>"...For us it is also easier to prescribe a pill... It's simple, I ask you to take a test in two months, and ask 'Is everything okay? Does anything hurt? See you next year' and, that's it, it was a test and two appointments." (Sk_Q1)</i></p> <p><i>"We have a training deficit in terms of the prescription of physical exercise and the prescription of nutrition in general and if you have some training it is because you have asked for it, because you have read about it, because you have shown interest. I believe that the way we are working, it is very complicated in the appointment with the patient, with the time we have and all the things we have to do..." (Sk_Q2)</i></p>
Beliefs about capabilities	<p><i>"It is much harder to change the habits of someone who comes to have their cholesterol tested if they are about 40 or 45, with settled habits that are difficult to change... that's harder than, 'Give me a pill and I am going to do it quickly', and I have peace of mind." (Cap_Q1)</i></p> <p><i>"Walking progressively without getting tired, that works for everyone. I am not ready to prescribe physical activity. I think we can, but it is not effective." (Cap_Q2)</i></p> <p><i>"This age group is people who are working and do not come to consult you except when they are sick for some reason, so they often pass under the radar. You ask them for a test, and their cholesterol is skyrocketing, but you don't get them to come to a consultation to see where they are failing, to be able to treat changes in habits... it is difficult to make them come to the health center, and it is also difficult to get them to make the changes... I think that there is a lot we don't see." (Cap_Q3)</i></p>
Beliefs about consequences	<p><i>"And the decision is always going to be, just in case, I'm going to give it to them. And then you also defend yourself just in case." (Con_Q1)</i></p> <p><i>"Also, in the real world, statins are a spectacular, very effective drug. I have 270 cholesterol, I go on a diet or exercise and I get down to 240 and that's that. However, if I take the pill, after 3 months I am at 200" (Con_Q2)</i></p> <p><i>"On the one hand we have the problem on both sides, we who find it more work and have a reward in the medium to long term in terms of results, and on the other hand what the user wants is immediacy now. They've come to ask us to solve it now." (Con_Q3)</i></p> <p><i>"Patients also hear that statins are bad, that they can cause diabetes and brain hemorrhages... some stop taking them because they have heard that it can cause some problems, or there have been people who for muscular reasons have had to stop taking them and take others... there was one statin that came out and they had to withdraw it from the market... all of these are little things... but, well..." (Con_Q4)</i></p>
Motivation, goals, intent	<p><i>"My experience is that maybe you have been saying to the patient for 2 or 3 years, 'You have to take exercise, go for a walk'... and they always look for an excuse, 'I can't because of my work...', so in the end you say, 'Well, leave it then' and you give up." (M_Q1)</i></p> <p><i>"In the end it depends on the conviction that you have, if you are more convinced, you will dedicate more time. Personal conviction and what you want." (M_Q2)</i></p>
Memory, attention, decision making	<p><i>"We doctors are inert by definition. Clinical and therapeutic inertia is part of our makeup. We are very inert, whether to prescribe or to stop prescribing." (MAD_Q1)</i></p> <p><i>"Often, when you are not sure, the most normal thing that we doctors learn is to see something and prescribe, as that it is the fastest thing we have.... so we don't have to explain... it's easier to give medicine than to explain." (MAD_Q2)</i></p> <p><i>"You are seeing patient 141, you are already tired, and someone has made an appointment for you to give them statins, they tell you that if something happens to them you will be responsible... And on top of it all, at that time of day you have low blood sugar... I ask you how you would manage that situation." (MAD_Q3)</i></p> <p><i>"...the matter of the asterisk, and what happens when we see one... just today someone came to me with cardiovascular risk of 3 or 4, and had an LDL that was almost 190. This was a young woman of 40, with low cardiovascular risk, and she asked me if she had to take something for it." (MAD_Q4)</i></p> <p><i>"And one thing, they should take away the asterisks, as we spend a lot of time explaining asterisks when we shouldn't have to." (MAD_Q5)</i></p>

TDF Dimension	Extracted quotes
Environmental context, Resources, constraints	<p><i>"Sometimes, most of the time, we don't have enough time, and the time factor is important for everyone I think, to tell them, to try to convince them." (E_Q1)</i></p> <p><i>"...I think that the pressure of attending patients may have too much influence on the matter of prescription." (E_Q2)</i></p> <p><i>"The Regicor does not mean you stop being a doctor, you have to continue being a doctor, just like we use the stethoscope as a tool. And the problem of the risk scale is good for the population, it is very good for population risks, but not for individuals, they weren't designed for that." (E_Q3)</i></p> <p><i>"Well, that allows me to put if the patient is in primary or secondary prevention, if they have anxiety or not, are stressed or not... that allows me to modulate those risk modifiers, and gives me peace of mind in both senses. This patient doesn't need statins, I'm sure, and that one does need statins, certainly." (E_Q4)</i></p> <p><i>"My nurse does it very well. I am very lucky, she is a highly trained woman who does it very well. So I delegate some things to her. But unfortunately, nowadays she is not always there, and not all nurses are trained..." (E_Q5)</i></p> <p><i>"... But it has to be at another level, multidisciplinary, health policies, health policies, lifestyle, which do not necessarily have to be based at the health center. It should also be involved but should not be the greatest weight and we should invest more in health policies especially in these types of people, the population base with least risk but who in the end are the ones that we can really prevent getting ill." (E_Q6)</i></p> <p><i>"This age group includes people who are working and do not come to consult you except when they are sick for some reason, so they often pass under the radar. You ask them for a test, and their cholesterol is skyrocketing, but you don't attract them to a consultation to see where they are failing, to be able to treat changes in habits. That is the problem that I think we have in this age group. With older people who come to the health center more often, it's much easier. But with people who are at work... it is difficult to make them come to the health center, and it is also difficult to get them to make the changes... I think that there is a lot we don't see." (E_Q7)</i></p> <p><i>"It is very difficult to get hold of them and to continue to call them in to make them get tests, like cholesterol, as they don't think much about prevention, because nothing hurts, and on top of that you restrict them a little, and in their life it is difficult for them to make those changes of habits so they don't come." (E_Q8)</i></p>
Social and Professional Role and Identity	<p><i>"I've had the experience of stopping a patient's statins, and the endocrinologist asked them what the family practitioner thought they were doing, taking them off statins... and then in the end the endocrinologist or the cardiologist put them back on them." (RoL_Q1)</i></p> <p><i>"You see that a patient who has been to the ... endocrinologist or ... a patient who is seen in oncology, then comes to us in a state because they tell them that the doctor has to lower their cholesterol. These colleagues have a completely different view from ours, that this is a disease, and it can be important, except for very high numbers, which is a separate issue. The cardiologist who sees patients every day with heart attacks and things like that is much more likely to prescribe statins than we are, who see that much less." (RoL_Q2)</i></p> <p><i>"This work is a bit beyond our usual work, but it should be a bit, it should direct us to giving a good prescription for physical education, where we can do this, or where there can be a good health provider who works in this way." (Role_Q3)</i></p>
Social Influences	<p><i>"Cholesterol doesn't hurt, but it is so well-known that people are terribly afraid of it. On the other hand, they are not afraid of weighing 100 kilos, or smoking, or not exercising, but cholesterol is something objective..." (SL_Q1)</i></p> <p><i>"Maybe the message of the media has a lot of influence, maybe we should try to change it, so that people become more aware of what cardiovascular risk means, as they're not aware. I think that's where we spend most time, explaining it to them." (SL_Q2)</i></p> <p><i>"I believe that, on this issue, unlike other health issues, people come with a very preconceived idea, because there is pressure. In fact, when people do some tests, the first thing they ask you when they come for the results, is how high their cholesterol is." (SL_Q3)</i></p> <p><i>"But I am referring to the advertising in which exercise, healthy food is being promoted more... that is what needs to be promoted. In the past, people didn't know much about exercise, but now they are a little more aware. Another thing is to get them to do it on a regular basis. That is what is difficult for the patients." (SL_Q4)</i></p> <p><i>"For the patient, when you explain these dietary hygiene measures, it's like you aren't telling them anything... 'What did the doctor tell you? Nothing, the usual...' So it has little weight and little value for them, it's like not telling them anything. However, if you give them a pill and send them to have tests, that's different." (SL_Q5)</i></p> <p><i>"Sorry, I have to go now. I signed up for a congress to prescribe exercise, and they didn't accept me. I was amazed. The reply from the person in the department where I applied was: 'That is not a primary medicine matter.' I was amazed. To cap it all, I was the first at that time." (SL_Q6)</i></p> <p><i>"We travel thanks to the pharmaceutical companies and we go to congresses thanks to the pharmaceutical companies and inadvertently there is always some contact in some way because they have given us training, which our company didn't do..." (SL_Q7)</i></p> <p><i>"I suppose these are the questions that (patients) often keep asking themselves, due to ignorance of the professionals, due to pressure from pharmaceutical companies, the media ... and they think that if you don't take it you will have a heart attack, sure." (SL_Q8)</i></p> <p><i>"... there is a lot of obesity, people eat very badly... you tell them, eat fish. Maybe fish is the most expensive thing there is, maybe that person cannot afford it ... there are many factors at play." (SL_Q9)</i></p> <p><i>I believe that the socioeconomic and cultural level of the patients is very important because it's the people who have a lower cultural and socioeconomic level who are the ones we should invest in more, though it is harder for us, we know that we have to try harder. (SL_Q10)</i></p>

TDF Dimension	Extracted quotes
Emotion	<p><i>"Then too, the issue of the reliability of the guidelines is an issue... the sensitivity and specificity you have when making a decision... the issue of cholesterol is quite controversial." (Em_Q1)</i></p> <p><i>"Perhaps I should also add, to all these causes which are variable, that at the beginning it was necessary to treat cholesterol no matter what. So perhaps we also have that inertia internalized, followed by all the other factors. The cholesterol figures have been very variable, we did not know if it was necessary to treat it in primary or secondary prevention, and then it was clarified and it was in secondary, not in primary, diabetics are secondary, if they are not ... there we have also had a bit of a mess so that could also be the cause of this prescription. (Em_Q2)</i></p> <p><i>"I think it also affects you a bit, that little voice in the head that we all have, that maybe you still find a cholesterol level of 300 with low cardiovascular risk and you say, uff, they have 300, the risk is 2 and a half ... and even though you yourself have explained to the patient and others, that also influences things, I mean, what if ... and then there's what Javi said about the penetration on the subject of cholesterol in all areas, which makes you always think about it, and say, what if I don't treat them?" (Em_Q3)</i></p> <p><i>It is much harder to change the habits of someone who comes to check their cholesterol when they are 40 or 45, when they are set in their ways, which are difficult to change ... it is harder than 'Give me a pill so that I will do it quickly and have peace of mind'. (Em_Q4)</i></p> <p><i>The ease, it is very easy to prescribe and it is also easily observable with the figures, that's it, ... You feel good and the patient too (Em_Q5)</i></p> <p><i>"If you can get a patient to lose those kilos and on top of that stop smoking, there is no tool to measure it, but that's a great satisfaction. (Em_Q6)</i></p>
Behavioural Regulation	<p><i>I always comment on a lack of quality in the health center... and I still see that we do not stop and think, that there is no culture of quality evaluation, of demanding minimum standards and it seems to me that it's the most serious thing wrong with the public services. (BR_Q1)</i></p> <p><i>I think [data] is useful and we are all open to using it. When you are under this healthcare pressure, you are not aware of the way you are working day to day, if you see 30 patients a day, you do not remember if you have prescribed 2 statins or ... I do not see it as intrusive, I see it as data, it helps me, it is a reflection. (BR_Q2)</i></p> <p><i>... Motivation is what drives everything, being aware of it. And for practical purposes I would ask the company for a tool.... I often want to see how my patients are doing, how many diabetics, under what conditions, but I can't. Before, we asked for this information and they gave it to us, but after a while you had to ask again ... We shouldn't have to ask for it, we should be able to access it... to monitor yourself and do self-evaluation and then that's what would really change, if the company asks me, 'Hey what are you doing?'... (BR_Q3)</i></p> <p><i>What was really useful for me in the center is to make small resolutions to make small changes that you are willing to make and that you feel capable of making, and once you have done them it is much better to keep them and then make a few more and if you have not been able to do them, you have to work on why not, if it was too excessive, if you think you can do a little less, if you can change it and solve it. (BR_Q4)</i></p>
Reinforcement	<p><i>But Thomas, if you don't comply, what happens? And if you comply, what happens? Nothing, neither positive nor negative incentives, so... (Re_Q1)</i></p> <p><i>If you do it really well, and I do it really badly, they pay us the same, so... it doesn't matter. (Re_2)</i></p>

Knowledge

Participants felt that lack of awareness of the problem, doubts, clinical guidelines being out of date, and lack of consensus on or variability of recommendations, are central facilitators for an inappropriate prescription (see quotes K_Q1-Q3; Table 2). They believe that clearer evidence and getting a broader vision considering further risk factors would help to prescribe properly (K_Q4,Q5).

Skills

Differential required skills of alternative behaviors, statin prescription versus healthy lifestyles promotion, due to their perceived or experienced ease/difficulty seem to be, on the one hand, a facilitator of an inappropriate prescription and on the other, a barrier to the recommended practice to be provided, especially regarding the prescription of physical activity (Sk_Q1,Q2).

Beliefs about capabilities

The main determinant related to capabilities is the low perceived confidence in prescribing healthy lifestyles, a clinical practice considered difficult in itself as compared to prescribing a statin (Cap_Q1, Q2). This problem is augmented by the difficulties faced by professionals to tackle healthy lifestyle promotion actions as a means of preventing CVD in low-risk patients, who are not usually frequent attenders (Cap_Q3).

Beliefs about consequences

The fear of negative consequences of not treating seemed to be a powerful driver of inappropriate prescribing (Con_Q1). This "defensive medicine" was also enhanced by the perceived effectiveness of statins in decreasing cholesterol levels (Con_Q2). Obtaining such a positive clinical result in the short term contrasted with the long term (and somewhat unperceived) benefits of healthy lifestyle promotion actions (Con_Q3). The adverse effects associated with statins seemed to be a potential barrier to statin prescription (Con_Q4).

Motivation, goals, intent

The mentioned scarcity of positive expected results from healthy lifestyle promotion actions has derived in the low motivation of professionals (M_Q1). Actual intention in the form of action plans or goals, both for not prescribing statins and also for providing healthy lifestyle promotion interventions, is seen as a necessary condition for endorsing guideline-concordant CVD primary prevention efforts (M_Q2).

Memory, attention, decision-making

A repeated theme in physicians' discourse is the influence of clinical inertia in decision-making favored by contextual factors such as lack of time and heavy workload (MAD_Q1,Q2). Pharmacological prescription is perceived to require less cognitive effort in a saturated clinical practice that leads to decisional fatigue. A defensive medicine mindset is always present when deciding upon treatments (MAD_Q3). Physicians also requested the removal of asterisks in patients' reports of analytics (i.e., an asterisk is placed alongside cholesterol measured level when value is equal or greater than 200 mg/dl) as this visual stimulus induces patients' concerns regarding cholesterol levels (MAD_Q4,Q5). Such markers incite cholesterol-control-focused clinical actions.

Environmental context, resources, constraints

As previously commented, lack of time and the heavy workload experienced in Primary Care are the main obstacles for prevention efforts (E_Q1,Q2). Physicians also perceived that tools within the EHR are useful but limited for both estimating cardiovascular risk, for reminding and fomenting guideline-concordant CVD primary prevention practice, and for restricting inappropriate statin prescribing (E_Q3, Q4). Teaming up with an involved Practice Nurse for sharing prevention efforts facilitated adequate healthy lifestyle promotion actions in primary prevention of CVD (E_Q5). Lack of external resources inside and outside the clinical setting (i.e., allied health professionals, community resources, etc.) limits the reach of prevention efforts, especially in low-risk young adults, as a non-frequent-user population (E_Q6-Q8).

Social and Professional Role and Identity

Lack of coherence in prescription criteria among the different healthcare professionals (i.e., cardiologists, neurologists and interns in addition to FPs) that attend the same patients dilutes responsible clinical practice (RoL_Q1, Q2). Uncertainties regarding limits in responsibility with respect to healthy lifestyle prescribing and fear of questioning each other's clinical decisions help to maintain inappropriate treatments (RoL_Q3).

Social Influences

Patients' lack of awareness together with a perception of low susceptibility and vulnerability regarding cardiovascular risk hamper physicians' primary prevention efforts (SL_Q1, Q2). In contrast, due to the importance given by the media and probably fueled by the pharmaceutical industry, cholesterol is "the bad guy" everybody is worried about and needs to be addressed (SL_Q3). Another ambivalence occurs with healthy lifestyles. On the one hand, the population seems to be more conscious about the overall benefits of healthy behavior. But on the other hand, patients seem to have become so used to the message about the need to change to healthy habits that some prefer to take a "magic" drug in the belief that there is no need to change habits (SL_Q4, Q5). In fact, neither the internal context in the health system which does not prioritize healthy lifestyle promotion practice, nor the external context at societal level influenced by media messages and the economic interests of the pharmaceutical industry targeting cholesterol reduction exclusively, are conducive to good CVD primary prevention practice (SL_Q6-Q8). Professionals also perceive that in certain sectors of the population, such as those with lower socio-economic status, the promotion of healthy habits, although being recommended practice, is very difficult to implement (SL_Q9, Q10).

Emotion

Mixed emotions are reported by physicians who mainly favor inappropriate prescribing. Professionals must make decisions in an emotional climate marked by uncertainty due to the variability of recommendations and limitations of the Clinical Practice Guidelines and fear of consequences of not treating (Em_Q1-Q3). The feeling of pleasing the patient coupled with peace of mind after prescribing statins and obtaining "positive" cholesterol results are factors that seem to weigh substantially on decision making (Em_Q4, Q5). In contrast, positive emotions associated with successful healthy lifestyle changes seen in patients are the only emotional asset that favors continuing the work of promoting healthy lifestyles (Em_Q6).

Behavioral Regulation

Professionals complain of a poor quality assessment culture in the healthcare system and of lack of standards and indicators established by the organization to anchor and guide clinical performance (BR_Q1). Data are needed to be able to reflect on performance and to be able to set goals, monitor progress and provide useful feedback, and the lack of access to such data prevents reflection and the establishment of objectives, both of which are seen as necessary to correct the problem of inadequacy in drug prescription (BR_Q2-Q4).

Reinforcement

In addition to the above-mentioned in relation to objectives and performance indicators, the results of the evaluations of indicators carried out by the organization do not translate into incentives/disincentives for professionals, which generates demotivation among those professionals willing to do things well (Re_Q1,Q2).

Moreover, we carried out one focus group with six patients. We must highlight that the majority of the participants indicated a lack of explanation in the treatment prescribed and their desire to be more involved in the treatment decision. Moreover, they believe that family history has a lot of weight in the decision and they are concerned about it. They report that only some professionals recommended healthy habits with or without prescription of statins. When we asked about their preferences for doing physical activity or taking a cholesterol drug in a context of low CVR, different positions arose: some prefer

physical activity and others prefer to combine exercise and pharmacological treatment. Overall, they are satisfied with taking statins although they prefer not to think about the adverse effects.

2nd Stage. Identify Intervention Options

Steps 5 and 6. Select intervention functions and specific behavior change techniques

The identified determinants in the form of “what needs to change” categorized in the COM-B and TDF dimensions were linked to the intervention functions guided by the BCW instructions and suggestions. Then, all potential policy categories were also identified. Lastly, potential BCTs were determined. Table 3 summarizes the mapping process conducted, linking practice determinants for PIP of statins (mainly facilitators) and for providing healthy lifestyle promotion interventions (mainly barriers), to intervention functions and policy categories, ending with potential BCTs for attaining the desired target behavior. For example, the lack of awareness among patients regarding the problem of inappropriate pharmacological prescription (Facilitator of the low-value practice) can be addressed through persuasion (Intervention function) and communication actions (Policy category) enacted by techniques focused on providing information about health consequences (BCT) of this low-value practice.

Table 3. Mapping matrix of potential intervention functions, policy categories and behavior change interventions to identified determinants of inappropriate statin prescription and healthy lifestyle promotion categorized by COM-B/TDF dimensions identified from the qualitative study.

Target behavior: Reduce the prescription of statins in the context of the primary prevention of CVD in low-risk patients and favor the promotion of healthy habits (regular physical activity, healthy diet and giving up smoking) at any opportunistic or programmed office visit for screening or addressing CVD risk factor and/or prevention.

COM-B	TDF	What needs to change (Statin prescription/ <i>Healthy lifestyles promotion</i>)	Int Pe En
Psychological capability	Knowledge	Be aware of the problem of inappropriate statin prescription	Ed Tr Pe En
		Be knowledgeable of the CVD prevention clinical guidelines, especially regarding adequate or recommended care depending on actual CVD risk	
		Have updated and unified clinical practice criteria based on independent scientific evidence	Re pr Gl ch se
		<i>Be aware of the beneficial impact of healthy habits for the prevention of CVD (professionals and patients)</i>	Se Cc
		<i>Be knowledgeable of the evidence-based healthy lifestyle promotion intervention in primary care (physical activity and healthy diet)</i>	
	Cognitive and Interpersonal skills	Increase skills to estimate and to address/communicate on CVD risk with a focus that goes beyond the numbers and risk factors Increase skills for appropriate statin prescription <i>Have skills in prescribing physical activity and other healthy habits (healthy diet, giving up smoking)</i>	Ed Tr Pe En En Se (C Gl ch pr Cc Re
		<i>Have a standardized protocol that facilitates clinical actions to promote habits</i>	
	Memory, attention, and decision processes	Remember to provide the recommended clinical practice in CVD primary prevention Remove visual cues that induce an inappropriate approach to high cholesterol in low-risk patients	Tr En En

	Behavioral regulation	Reflect on the performance/practice of inappropriate prescription of statins in primary prevention of CVD	Ed
			Tr
		Have clear and specific objectives, at a personal and organizational level, in reduction of inappropriate statin prescription in primary prevention of CVD	Mc
			En
Physical opportunity	Environmental context and resources	Have access to data on inappropriate statin prescribing in primary prevention of CVD.	Se
		<i>Have access to data on practice in promoting healthy habits</i>	
		Have a simple tool that favors correct estimation of CVR, according to evidence, that considers additional characteristics of the people (e.g. antecedents, other risk factors)	En
			En
		Have support systems in the electronic records that remind about and promote practice in primary prevention of CVD according to the CPGs (avoiding statins and recommending promotion of habits)	Re
			Tr
		Restrict or impede the inappropriate prescription of statins because of simplicity and speed of clinical prescribing conduct	Gl
			Se
			su
		<i>Having tools for a feasible (fast) and effective intervention in healthy habits</i>	Et
		<i>Having access to resources within/outside the health care setting to favor the provision of recommended primary prevention of CVD practice (i.e., healthy lifestyle resources in the community)</i>	
		<i>Nursing participation in the primary prevention of CVD: provision of the recommended intervention (habits) to avoid inappropriate prescription</i>	
Social opportunity	Social influences	Patients should be aware of the problem of inappropriate statin prescribing: Risks vs. Benefits	Pe
			Ed
		Patients must have knowledge of the criteria and practice guidelines: cholesterol, CVD, CVR (patients)	En
			Re
		The general population must be aware of the problem of excessive medication	En
		The organization must continuously become aware of the problem of inappropriate prescription of statins in healthcare practice (Adaptation; Priority health policies)	Cc
			Re
		The organization must have up-to-date clinical criteria, established in the guidelines based on independent scientific evidence	En
			pl
			Gl
		The organization must have a focus beyond the figures and risk factors, both in CPGs and in risk-screening tools and/or interventions	Le

Reflective motivation	Professional/social role and identity	Believe that adequate CVD prevention is considered important at their peer and organizational level	Ed
			Pe
		Be clear about the criteria for action and responsibilities at the inter-institutional and inter-sectorial level (external: e.g., business medicine) in CVD prevention, based on indication (primary, secondary prevention, etc.)	Mc
			En
		Understand that the role of the doctor goes beyond prescribing drugs	Co
		Re	
		pr	
	The Family Medicine and Community Health professional establishment should feel like a protagonist (leadership, responsibility) with regard to the practice of primary prevention of CVD	GL	
		ch	
		se	
		Se	
	Beliefs about capabilities	Perceive that one is able and has the necessary skills to provide the healthy lifestyle promotion	Ed
			Tr
Perceive that statin prescribing is not such a simple (low skill) or safe practice		Pe	
		Mc	
Perceive that one is competent and confident enough to carry out the CV risk screening process		En	
		Perceive that one is competent and confident enough to respond to the sporadic arrival of patients in the target population for CVD primary prevention (they come infrequently), through the promotion of good habits	GL
			Se
			an
		Perceive that statin treatment is not so easy for the patient (dosage)	tra

Have a sense of self-confidence in prescription of physical activity and other healthy habits

Not have a perception of difficulty in modifying habits (compared to taking a pill)

Beliefs about consequences	Perceive that not prescribing statins in primary prevention of CVD is not “not treating”	Ed
		Pe
	Perceive that statins are not more effective than the promotion of habits to avoid CV events in primary prevention of CVD	Mc
		Inc
	Perceive that the statin, in primary prevention of CVD, may have adverse effects and is not entirely safe	Cc
		Gl
	<i>Have an expectation of the benefits of healthy lifestyle promotion actions (short, medium and long term)</i>	di
		Se
		(ca
Intentions	Should have a strong intention not to prescribe statins inappropriately in primary prevention of CVD	Ed
		Pe
	<i>Should have a strong intention to provide interventions to promote healthy habits for the primary prevention of CVD</i>	Inc
		Mc
		Cc
		(ei
		Re
		pr
		Gl
		ch
		pr

	Goals	Have organizational objectives related to the reduction of inappropriate prescription of statins (drugs) in primary prevention of CVD	Ed Pe Inc Mc En
		Should consider the practice of primary prevention of CVD a priority in accordance with the recommendations.	
		Should be committed to carrying out a practice of primary prevention of CVD according to the recommendations	Re pr
		<i>Have the motivation (priority and commitment) to promote habits in primary prevention of CVD</i>	Gl ch pr Se
Automatic motivation	Reinforcement	Receive positive or negative reinforcement related to adequate ECV prevention performance	Tr Inc Co En
		Should avoid prescribing out of habit, routine or inertia (to treat cholesterol)	
			Se Re pr
	Emotion	Not feel threatened (fear) for not prescribing a drug	Ed Pe Inc Co
		Feel confident about not prescribing a statin for primary prevention of CVD	
		Experience positive feelings/emotions associated with not doing defensive medicine	Gl Co mi Re
		Experience negative emotions when making an inappropriate prescription	
		Feel safe and confident with the action guidelines	

3rd stage. Identify implementation procedures

Steps 7 and 8. Select strategies, intervention techniques and modes of execution

The final selection of previously identified de-implementation strategies was performed through a participatory consensus process involving the working group, all healthcare professionals involved in the discussion groups conducted and representatives at managerial level of the two HDs from the Basque Healthcare System.

Informed by previous studies in the field and several team members' experience in the design of implementation strategies, the working group decided upon potential intervention formats and modes for their execution and drew up a list of 13 potential de-implementation strategies. Lastly, these potential strategies were sent back to all the health care professionals involved in the discussion groups and two health managers for their evaluation regarding three dimensions: acceptability, feasibility and potential effectiveness. Thirteen complete evaluations (13/23) were received that permitted the prioritization of the de-implementation strategies (See Table 4).

Table 4. Prioritization of the 13 de-implementation strategies derived from the mapping process

	<p><i>Potential effectiveness</i></p> <p><i>To what extent do you think this intervention can achieve the desired results in the target population?</i></p> <p><i>1: unlikely, 2: unlikely but deserves consideration, 3: likely, 4: very likely</i></p>	<p><i>Acceptability</i></p> <p><i>To what extent is it acceptable for key agents (PHC professionals, patients, managers, etc.) to use this intervention?</i></p> <p><i>1: unacceptable, 2: not very acceptable but deserves consideration, 3: acceptable, 4: highly acceptable</i></p>	<p><i>Feasibility</i></p> <p><i>To what extent do you consider that this intervention can be implemented in the routine clinical context?</i></p> <p><i>1: unfeasible, 2: unfeasible but deserves consideration, 3: feasible, 4: highly feasible</i></p>
New or optimized CVR calculation tool, adding other important risk factors (e.g., family history) to the estimation and/or to help in decision-making	Very likely	Highly acceptable	Highly feasible
Alert and reminder systems (notifications, pop-ups, messages, etc.) in the Medical Record and/or in the prescription system to promote the practice according to the evidence in primary prevention of CVD	Very likely	Highly acceptable	Feasible
Alert and message reminder systems using printed material (e.g., posters, manuals, information sheets, etc.) or interactive means (emails, information capsules, newsletters, etc.) to encourage practice according to the evidence in primary prevention of CVD	Very likely	Acceptable	Feasible
Planning and organization of shared action at health center level, between medicine and nursing, for the provision of clinical intervention in promoting healthy habits	Very likely	Acceptable	Feasible
Formation of a committee of experts to update or develop a corporate guidance document on primary prevention of CVD that includes: a) evidence-based clinical practice recommendations; b) unified criteria for action and responsibilities at the inter-institutional and inter-sectorial level; c) establishment of practice/performance objectives in primary prevention of CVD	Likely	Highly acceptable	Feasible
Elimination of the "asterisk" in analytical reports and/or adaptation of the criteria for identification and marking of "case" (e.g., asterisk on cholesterol number >240 mg/dl)	Likely	Acceptable	Highly feasible
Training workshops on primary prevention of CVD and promotion of healthy habits, including training support resources (e.g., clinical intervention manual for promoting healthy habits)	Likely	Acceptable	Feasible
IT tools that facilitate the execution of an intervention to promote habits based on evidence	Likely	Acceptable	Feasible
Corporate campaign "Giving up pharmacological prescriptions of little value" promoted by Osakidetza and the Department of Health	Likely	Acceptable	Feasible
Tools to aid clinical decision-making in the electronic prescription system, which restrict or hinder the inappropriate prescription of statins	Likely	Acceptable	Feasible
Active involvement of the patient in a shared decision-making process in CVD preventive action	Likely	Acceptable	Feasible
Inclusion of practice indicators in primary prevention of CVD in the management and evaluation tools for care performance: a) CV risk registration rate, b) rate of inappropriate prescription of statins in primary prevention in low-risk patients; c) rate of performance of actions to promote habits	Likely	Acceptable	Feasible
Audit/feedback system: Periodic sending of practice or performance indicator reports in inappropriate prescription of statins and actions to promote habits	Likely	Acceptable	Feasible
Edition and publication of educational and informative materials on primary prevention of CVD for patients	Unlikely	Acceptable	Feasible

Discussion

This study aimed to report on the application of a systematic, comprehensive, theory-and evidence-informed framework to design potentially effective and feasible de-implementation strategies to favor the abandonment of low-value pharmacological prescribing in CVD primary prevention of persons with low CVD risk [18]. Specifically, guided by the TDF and the BCW frameworks [14, 21–23], we have conducted a series of actions for identifying determinants of low-value practices and behavioral objectives as areas for improvement, which have helped us to design, operationalize and prioritize various de-implementation strategies. These actions or tasks were as follows: semi-structured interviews with a sample of Family Physicians in order to identify the overall behavioral scenario and break down the chain of behaviors and concomitant factors and to define the problem in behavioral terms; a qualitative study through discussion groups to identify the main determinants of the low-value pharmacological prescription in CVD primary prevention (e.g. personal, inter-personal, organizational, social level), and those relevant for promoting the implementation of the recommended practice (healthy lifestyle promotion interventions);

mapping and operationalization of the de-implementation and/or implementation strategies; prioritization of strategies based on professionals' perceived acceptability, feasibility and potential effectiveness.

Avoiding or substituting proven potentially harmful, ineffective or inefficient medical practices is important for improving the quality of healthcare while ensuring sustainability of healthcare systems, which is why in recent years the interest in and the evidence base related to successful de-implementation strategies to favor the abandonment of low-value practices has grown quickly. Statins are among the most widely prescribed medications globally and are increasingly used to prevent cardiovascular disease (CVD) in people without CVD ('primary prevention'). However, statins have no or little value for the primary prevention of CVD in low-risk patients [19, 20]. On the other hand, healthy lifestyle promotion interventions in clinical settings have been shown to be effective and are the preferred recommended practice, especially in low-risk patients.

From the growing scientific evidence in implementation research it is known that factors determining the implementation of both evidence-based and inappropriate interventions in the clinical setting are multi-level, complex, and context specific [2]. Consequently, the design of interventions should be carried out following a process of formal analysis of the objective behavior and its theoretically predicted mechanisms of action, all guided by models or theories that cover the entire range of possible influences or determinants of the behavior in question [8–11]. Through the performed qualitative study with both main involved healthcare professionals (family physicians and nurses) and affected users (low-CVR-risk patients with PIP of statins), we have identified multilevel determinants of the target low-value practice within the context of two HD in our Basque public healthcare service. Almost all of the dimensions of the TDF have been called into play, as at least one practice determinant (barrier or facilitator) has been included in these dimensions. Some of the most consistently reported determinants among interviewed professional groups were the lack of time and external resources, preferences and characteristics of patients, limitation of available clinical tools and CPGs, social pressures, fears about negative consequences of not treating high cholesterol levels with drugs, and lack of skills and training of professionals in healthy habit promotion. Patients' main determinants were the lack of explanation of the situation during the medical appointment, the desire to be more involved in the treatment decision, belief and concern about family history in the decision, and the lack of healthcare professional's recommendation about healthy habits with or without prescription of statins.

The identified determinants are in line with other determinants identified or reported in previous studies regarding determinants of low-value practice and of low-value pharmacological prescription. Regarding determinants, uncertainty due to the variability and/or conflict of the guidelines with respect to the recommended practice, the pressures and demands on the part of the patients, the need for rapid and decisive action in response to the reasons for consultation and the desire to please the patients have been identified as interconnected motives that justify maintaining low-value practices in general [24]. With regard to inappropriate prescription of drugs in general, a systematic review published by Anderson *et al* [25], in which the barriers and facilitators for inappropriate prescription are explored, highlights four aspects that facilitate or hinder professionals' decisions when faced with a possible pharmacological prescription: first, awareness of the problem, i.e., knowing to what extent the clinical practice of each professional conforms to what is recommended in clinical practice guidelines, as well as knowing the consequences of treating a patient pharmacologically or not. Second, self-efficacy, which encompasses the professional's ability to manage the clinical situation based on their knowledge or their ability to offer a non-pharmacological alternative, among others. The third aspect to highlight is inertia, which is a barrier to change in clinical practice; and finally, feasibility, where all the external factors that affect the clinical decision would be included: patient characteristics and preferences, social/cultural factors, prescriptions made by another professional, group pressure and so on. Regarding studies carried out exclusively on the inappropriate prescription of statins, they emphasize the influence of the perception that professionals have of the cardiovascular risk of each patient and their opinion about the effectiveness and safety of statins [26], beliefs or attitudes toward behavior and perceived control [27]; the additional risk factors that the patient may present and the patient's preferences about receiving drug treatment or not [28].

One peculiar aspect in this point is that, due to the clinical scenario addressed (the reduction of low-value prescribing of statins in CVD primary prevention where the promotion of healthy lifestyles is the alternative, recommended practice), this project has attempted to simultaneously identify determinants of both clinical practices. Although it may seem obvious, in such clinical scenarios, stress must be placed on identifying the factors that facilitate or maintain the low-value practice, and on the other hand, the barriers that impede the recommended practice [29].

With the main goal of designing and developing specific strategies that address the specific determinants of CVD prevention practice in Osakidetza, the main study action at the current stage has been to carry out a mapping process of simultaneous de-implementation and implementation strategies in order to reduce low-value practices (inappropriate statin prescribing) and promote the implementation of recommended practice (healthy lifestyle interventions), based on the determinants of routine practice reported by practitioners in the focus groups, following the procedure established by the BCW. The 13 de-implementation strategies that have emerged from these performed structured and theory-informed processes are all "old known" strategies and interventions. Specifically, in the context of the reduction in the prescription of low-value statins, a certain effectiveness of dissemination strategies, informative web pages, and the implementation of electronic clinical practice guidelines has been observed, compared with routine practice [30–34]. However, dissemination strategies such as educational or training actions for professionals (webinars and workshops) were not effective by themselves, only when used as multi-component strategies, combining workshops and informative web pages [30, 31]. Finally, an intervention based on sending a scenario with a clinical case and audit/feedback to professionals [35] and techniques to aid decision-making, aided by communication of risk to the patient and audit/feedback, achieved good results in calculating cardiovascular risk and in adjusting the prescription [36–38]. Though not innovative interventions or strategies, those identified are those that address the specific determinants identified by the protagonists. Furthermore, the agents involved have prioritized the resulting potential de-implementation strategies after assessing their perceived acceptability, feasibility and potential effectiveness.

Finally, both actions, determinant identification and mapping of strategies, aim to target the specific clinical behavior most likely to enable the desired change prioritized by the research group and professionals involved early in BCW steps 1 to 3: physicians' decision-making regarding the therapeutic option. Following a taxonomy of choice architecture techniques [39], all except two of the 13 identified strategies may be categorized as influencing decision-making through three different modes: decision information, decision structure, and decision assistance. The other two consist in patient-mediated intervention and an

interprofessional collaboration intervention in which FPs and their corresponding Practice Nurses agree, plan and organize how to collaboratively proceed in and provide CVD prevention intervention actions.

Conclusion

The study aims to contribute to the body of currently scarce literature available on practical de-implementation initiatives by providing detailed illustrations/explanations of our stepped, systematic approach to the design and development of targeted behavior change actions based on prominent available frameworks and theories, mostly from implementation science. Key research questions in implementation science also involve determining what implementation strategies should be provided, to whom, and when, to achieve optimal success in implementing evidence-based clinical practice. As the same paradigm must apply for de-implementation of low-value practices, we propose now to investigate the comparative effectiveness of some/different types or intensities of the prioritized strategies in phase II of the DE-imFAR project. The evaluative phase of our study will have the aim of increasing evidence on whether the specific strategies that address determinants of recommended practice in CVD prevention, some similar to those evaluated in the few studies conducted to date, are also effective in our context. If the strategies explored are successful, health planners and managers will have the evidence needed to support the introduction of such structured strategies, informed by the application of methods and procedures of the emerging science of implementation and de-implementation.

Declarations

Ethics approval and consent to participate

The research protocol has been approved by the Basque Country Clinical Research Ethics Committee (Ref: PI2019102, approved on 10/04/2019). The Primary Care Research Unit of Bizkaia is explicitly authorized by the Healthcare Management of the Basque Health System to extract and use data from its electronic health records for research purposes.

Consent to publication

Not applicable

Availability of data and materials

Since data supporting the present study will mostly concern routine data retrieved from the electronic health records of the Basque Health Service-Osakidetza, it will be only shared on justified request to the study guarantors.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

AS, JIP and GG conceived the idea and are the study guarantors. They are primarily responsible for the study design and planning, as well as the funding obtained, and will be responsible for project coordination and supervision, analysis and interpretation of results and manuscript preparation. SP, PML, AGA, GL, JIA, IL, RSR and CH collaborated in the study design, and funding obtained, and will be responsible for study coordination, interpretation of results and manuscript preparation. AS, JIP and AG will be responsible for the analysis of results and critically reviewing the manuscript. All contributors approved this version submitted for publication. All authors have read and approved the final manuscript.

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References

1. Brownlee S, Chalkidou K, Doust J, et al. Evidence for overuse of medical services around the world. *Lancet* 2017;390:156–68.
2. Norton WE, Chambers DA. Unpacking the complexities of de-implementing inappropriate health interventions. *Implement Sci.* 2020;15(1):2

3. Colla CH, Mainor AJ, Hargreaves C, et al. Interventions aimed at reducing use of low-value health services: a systematic review. *Med Care Res Rev.* 2017;74:507–50.
4. Brownlee S, Chalkidou K, Doust J, Elshaug AG, Glasziou P, Heath I, et al. Evidence for overuse of medical services around the world. *Lancet* 2017;390(10090):156–68.
5. Grimshaw JM, Patey AM, Kirkham KR, Hall A, Dowling SK, Rodondi N, et al. De-implementing wisely: developing the evidence base to reduce low-value care. *BMJ Quality & Safety* 2020;29(5):409–417..
6. Parchman ML, Henrikson NB, Blasi PR, Buist DS, Penfold R, Austin B, Ganos EH. Taking action on overuse: Creating the culture for change. *Healthc (Amst).* 2017;5(4):199–203.
7. Willis CD, Saul J, Bevan H, Scheirer MA, Best A, Greenhalgh T, Mannion R, Cornelissen E, Howland D, Jenkins E, Bitz J. Sustaining organizational culture change in health systems. *J Health Organ Manag.* 2016;30(1):2–30.
8. Michie S, Johnston M, Abraham C, et al. Making psychological theory useful for implementing evidence based practice: a consensus approach. *Qual Saf Health Care* 2005;14:26–33.
9. Eccles M, Grimshaw J, Walker A, Johnston M, Pitts N. Changing the behavior of healthcare professionals: the use of theory in promoting the uptake of research findings. *J Clin Epidemiol.* 2005;58(2):107–112.
10. Atkins L, Francis J, Islam R, O'Connor D, Patey A, Ivers N, Foy R, Duncan EM, Colquhoun H, Grimshaw JM, Lawton R, Michie S. A guide to using the Theoretical Domains Framework of behaviour change to investigate implementation problems. *Implement Sci.* 2017;12(1):77.
11. Michie S, Richardson M, Johnston M, Abraham C, Francis J, Hardeman W, et al. The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: building an international consensus for the reporting of behavior change interventions. *Ann Behav Med.* 2013;46(1):81–95.
12. Glanz, K. and Rimer, B. *Theory at a Glance: A Guide for Health Promotion Practice*, 2nd Edition. U.S. Department of Health and Human Services. National Institutes of Health. Bethesda: National Cancer Institute, 2005.
13. Fernandez ME, Ten Hoor GA, van Lieshout S, Rodriguez SA, Beidas RS, Parcel G, Ruiters RAC, Markham CM, Kok G. Implementation Mapping: Using Intervention Mapping to Develop Implementation Strategies. *Front Public Health.* 2019;7:158.
14. Michie S, van Stralen MM, West R. The behaviour change wheel: a new method for characterising and designing behaviour change interventions. *Implement Sci.* 2011;6:42.
15. Skolarus TA, Hawley ST, Wittmann DA, Forman J, Metreger T, Sparks JB, Zhu K, Caram MEV, Hollenbeck BK, Makarov DV, Leppert JT, Shelton JB, Shahinian V, Srinivasaraghavan S, Sales AE. De-implementation of low value castration for men with prostate cancer: protocol for a theory-based, mixed methods approach to minimizing low value androgen deprivation therapy (DeADT). *Implement Sci.* 2018;13(1):144.
16. Thompson LM, Diaz-Artiga A, Weinstein JR, Handley MA. Designing a behavioral intervention using the COM-B model and the theoretical domains framework to promote gas stove use in rural Guatemala: a formative research study. *BMC Public Health.* 2018;18(1):253.
17. Voorn VM, Marang-van de Mheen PJ, So-Osman C, Vlieland TP, Koopman-van Gemert AW, Nelissen RG, van Bodegom-Vos L; LISBOA Study Group, Brand A, Engberts DP, van der Hout WB, Kaptein AA, van Mourik JB. Designing a strategy to implement cost-effective blood transfusion management in elective hip and knee arthroplasties: a study protocol. *Implement Sci.* 2012;7:58.
18. Sanchez A, Pijoan JI, Pablo S, Mediavilla M, de Rozas RS, Lekue I, Gonzalez-Larragan S, Lantaron G, Argote J, García-Álvarez A, Latorre PM, Helfrich CD, Grandes G. Addressing low-value pharmacological prescribing in primary prevention of CVD through a structured evidence-based and theory-informed process for the design and testing of de-implementation strategies: the DE-imFAR study. *Implement Sci.* 2020;15(1):8.
19. San Vicente Blanco R., Pérez Irazusta I., Ibarra Amarica J., Berraondo Zabalegui I., Uribe Oyarbide.F., Urraca Garcia de Madinabeitia J., Samper Otxotorena.R., Aizpurua Imaz I., Almagro Mugica F., Andrés Novales J., Ugarte Libano R. Guía de Práctica Clínica sobre el manejo de los lípidos como factor de riesgo cardiovascular. Osakidetza. Vitoria-Gasteiz. https://portal.guiasalud.es/wp-content/uploads/2018/12/GPC_567_Lipidos_Osteba_compl.pdf
20. Byrne P, Cullinan J, Smith A, et al. Statins for the primary prevention of cardiovascular disease: an overview of systematic reviews. *BMJ Open* 2019;9:e023085.
21. French SD, Green SE, O'Connor DA, McKenzie JE, Francis JJ, Michie S, Buchbinder R, Schattner P, Spike N, Grimshaw JM. Developing theory-informed behaviour change interventions to implement evidence into practice: a systematic approach using the Theoretical Domains Framework. *Implement Sci.* 2012 Apr 24;7:38.
22. Cane J, O'Connor D, Michie S. Validation of the theoretical domains framework for use in behaviour change and implementation research. *Implement Sci.* 2012;7(1):37.
23. Michie S, Atkins L, West R. (2014) *The Behaviour Change Wheel: A Guide to Designing Interventions*. London: Silverback Publishing.
24. Ingvarsson S, Augustsson H, Hasson H, Nilsen P, von Thiele Schwarz U, von Knorring M. Why do they do it? A grounded theory study of the use of low-value care among primary health care physicians. *Implement Sci.* 2020;15(1):93.
25. Anderson K, Stowasser D, Freeman C, Scott I. Prescriber barriers and enablers to minimizing potentially inappropriate medications in adults: a systematic review and thematic synthesis. *BMJ Open* 2014;4:e006544.
26. Bonner C, Jansen J, McKinn S, Irwig L, Doust J, Glasziou P, McCaffery K. How do general practitioners and patients make decisions about cardiovascular disease risk? *Health Psychol.* 2015;34(3):253–61.
27. Rashidian A, Russell I. Intentions and statins prescribing: can the theory of planned behaviour explain physician behaviour in following guideline recommendations? *J Eval Clin Pract.* 2011;17(4):749–57.

28. Clough JD, Martin SS, Navar AM, Lin L, Hardy NC, Rogers U, Curtis LH. Association of Primary Care Providers' Beliefs of Statins for Primary Prevention and Statin Prescription. *J Am Heart Assoc.* 2019;8(3):e010241.
29. Karina W Davidson, Siqin Ye, George A Mensah. Commentary: De-implementation Science: A Virtuous Cycle of Ceasing and Desisting Low-Value Care Before Implementing New High Value Care. *Ethn Dis.* 2017;27(4):463–468
30. Etxeberria A, Alcorta I, Pérez I, Emparanza JI, Ruiz de Velasco E, Iglesias MT, Rotaecche R. Results from the CLUES study: a cluster randomized trial for the evaluation of cardiovascular guideline implementation in primary care in Spain. *BMC Health Serv Res.* 2018;18(1):93.
31. Keller H, Hirsch O, Kaufmann-Kolle P, Krones T, Becker A, Sönnichsen AC, Baum E, Donner-Banzhoff N. Evaluating an implementation strategy in cardiovascular prevention to improve prescribing of statins in Germany: an intention to treat analysis. *BMC Public Health.* 2013;13:623.
32. Keller H, Krones T, Becker A, Hirsch O, Sönnichsen AC, Popert U, Kaufmann-Kolle P, Rochon J, Wegscheider K, Baum E, Donner-Banzhoff N. Arriba: effects of an educational intervention on prescribing behaviour in prevention of CVD in general practice. *Eur J Prev Cardiol.* 2012;19(3):322–9.
33. Comin E, Catalán-Ramos A, M Verdu J, Iglesias-Rodal M, del Val García JL, Grau M, Amado E, Pons A, Consola A, Ciurana R, Franzi A, Mata M, Cos X, Frigola E, Davins J. Impact of the implementation of electronic guidelines for cardiovascular prevention in primary care: study protocol. *Inform Prim Care.* 2012;20(2):129–39.
34. Comin E, Catalan-Ramos A, Iglesias-Rodal M, Grau M, Del Val JL, Consola A, Amado E, Pons A, Mata-Cases M, Franzi A, Ciurana R, Frigola E, Cos X, Davins J, Verdu-Rotellar JM. Impact of implementing electronic clinical practice guidelines for the diagnosis, control and treatment of cardiovascular risk factors: A pre-post controlled study. *Aten Primaria.* 2017;49(7):389–398.
35. Dormuth CR, Carney G, Taylor S, Bassett K, Maclure M. A randomized trial assessing the impact of a personal printed feedback portrait on statin prescribing in primary care. *J Contin Educ Health Prof.* 2012;32(3):153–62.
36. Peiris D, Usherwood T, Panaretto K, Harris M, Hunt J, Patel B, Zwar N, Redfern J, Macmahon S, Colagiuri S, Hayman N, Patel A. The Treatment of cardiovascular Risk in Primary care using Electronic Decision supOrt (TORPEDO) study-intervention development and protocol for a cluster randomised, controlled trial of an electronic decision support and quality improvement intervention in Australian primary healthcare. *BMJ Open.* 2012;2(6).
37. Peiris D, Usherwood T, Panaretto K, Harris M, Hunt J, Redfern J, Zwar N, Colagiuri S, Hayman N, Lo S, Patel B, Lyford M, MacMahon S, Neal B, Sullivan D, Cass A, Jackson R, Patel A. Effect of a computer-guided, quality improvement program for cardiovascular disease risk management in primary health care: the treatment of cardiovascular risk using electronic decision support cluster-randomized trial. *Circ Cardiovasc Qual Outcomes.* 2015;8(1):87–95.
38. Patel B, Peiris D, Usherwood T, Li Q, Harris M, Panaretto K, Zwar N, Patel A. Impact of Sustained Use of a Multifaceted Computerized Quality Improvement Intervention for Cardiovascular Disease Management in Australian Primary Health Care. *J Am Heart Assoc.* 2017;6(10).
39. Münscher R, Vetter M, Scheuerle T. A Review and Taxonomy of Choice Architecture Techniques. *Journal of Behavioral Decision Making* 2015;29(5):511–524.

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