

# Healthcare professionals' perspectives on the use of PCSK9 inhibitors in cardiovascular disease: an in-depth qualitative study

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## Aims

Injectable medicines such as PCSK9 inhibitors are increasingly used to manage risk factors for cardiovascular events with little information around the perceptions of healthcare professionals (HCPs) on the administrative and clinical practicalities. The aim was to identify the facilitators and barriers on the use of injectable therapies with cardiovascular benefits through interviews with HCPs.

## Methods and results

Qualitative interviews were conducted in the UK (London and Leeds) and Italy (Rome and Milan) in 2021. Coding was undertaken using NVivo and thematic analysis performed. A total of 38 HCPs were interviewed, 19 in each country composing of physicians ( $n = 18$ ), pharmacists ( $n = 10$ ), nurses ( $n = 9$ ), and pharmacy technician ( $n = 1$ ). Four themes emerged: (i) clinicians' previous experiences with injectable therapies, (ii) challenges with patients' behaviours and beliefs, (iii) clinicians' knowledge of injectable therapies and therapeutic inertia, and (iv) organizational and governance issues. The behaviour and beliefs from HCPs focused on facilitating behaviour change as well as the poor interdisciplinary working and collaboration. Therapeutic inertia was raised where physicians either lacked awareness of injectable therapies or were unwilling to prescribe them. The importance of facilitating patient education on injection techniques was highlighted, while organizational and governance issues identified the lack of guidance to inform practice. Clear pathways are required to identify those who were eligible for injectable therapies as well as on how injectables should be prescribed.

## Conclusion

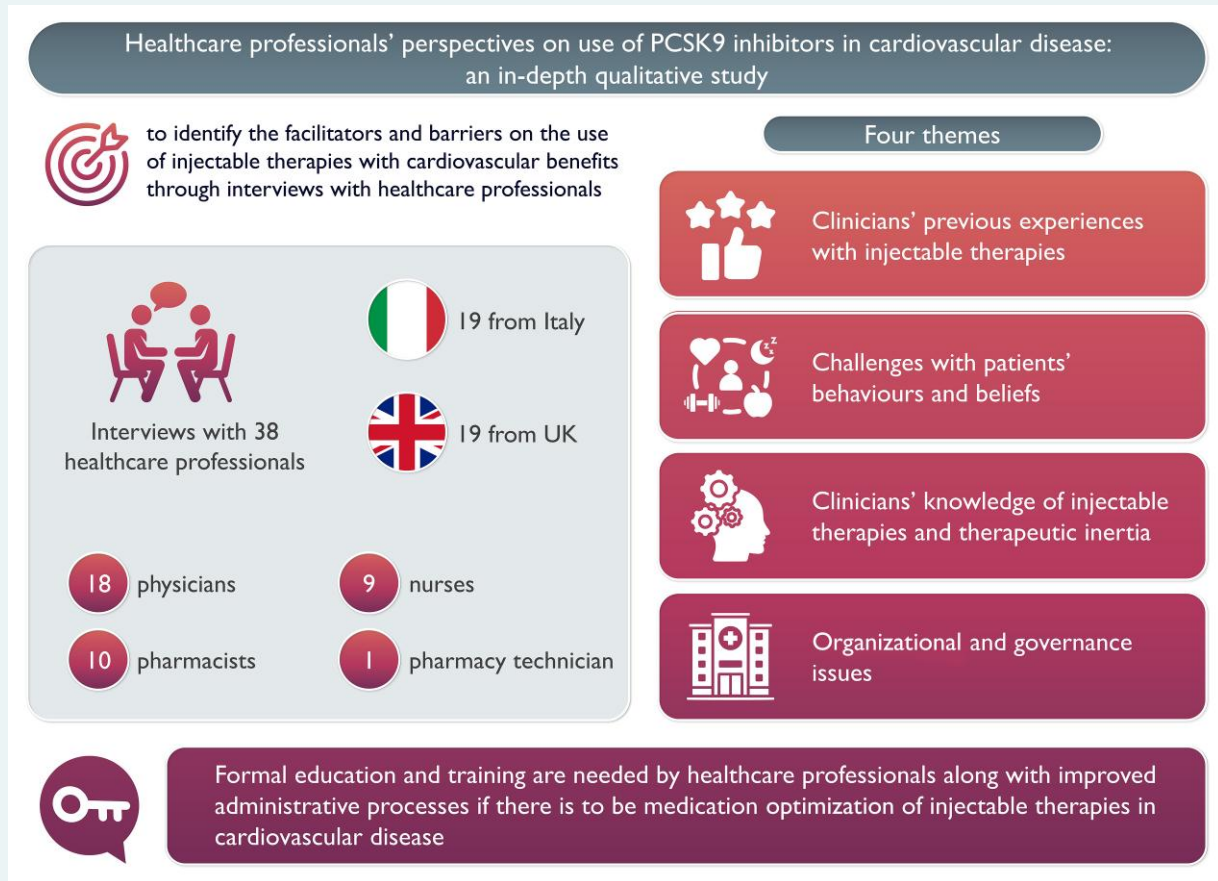
If medicine optimization is to be achieved, there need to be structured processes in place to identify eligible patients and the development of educational material.

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## Graphical Abstract



## Keywords

Cardiovascular disease • Dyslipidaemia • Healthcare professionals • Injectable therapies

## Novelty

- This study provides in-depth analysis from interviews of allied health professionals on novel injectable therapies in two distinct locations.
- Cardiovascular disease (CVD) injectable therapies have different challenges compared to other injectables such as insulin.
- The study adds further knowledge to perceptions on the use of injectable therapies for CVD.
- We identified specific barriers to the administration and prescription of injectable therapies.

## Introduction

Despite mortality from cardiovascular disease (CVD) decreasing, a significant number of people continue to have risk factors including dyslipidaemia [that is, increased levels of serum total cholesterol, high triglycerides, and/or increased low-density lipoprotein cholesterol (LDL-C)], which is associated with a greater risk of a cardiovascular event.<sup>1</sup> As such, injectable therapies to lower cholesterol (PCSK9 monoclonal antibody medication for example) have been shown to be effective for primary prevention and secondary prevention of CVD.<sup>2</sup> Optimization in lipid therapy has been shown with evolocumab and alirocumab as well as inclisarin with reductions in total cholesterol and LDL-C.<sup>3</sup> These medications require regular injections for a person's lifetime, and these can be administered by a healthcare professional (HCP), the patient, or a caregiver. A recent

study reported that injectable therapies were acceptable to patients while also highlighting several barriers in terms of their use including needle phobia and lack of accessible patient educational material as well as a lack of a standardized clinical support monitoring system.<sup>4</sup> A survey of HCPs across Europe on injectable therapies for CVD revealed organizational and administrative problems as well as a lack of educational material that could be used in clinical practice.<sup>5</sup> The results confirmed the findings from an integrative review on injectable therapies that reported a lack of studies on these novel injectable therapies.<sup>6</sup> The European Society of Cardiology recommends the use of these medications in those at high risk of CVD with nurses and allied HCPs playing a key role in the assessment, treatment, and management of patients who require these injectable therapies. Other injectables have been developed including glucagon-like peptide 1 (GLP1) agonists, and these are in use for those with obesity and diabetes;

the recent 2023 European Society of Cardiology guidelines recommend GLP-1 agonists for those who have or at risk of CVD.<sup>7</sup> The STEP-HFpEF trial that used once weekly GLP-1 agonist, semaglutide, for patients with heart failure and obesity demonstrated improvements in heart failure symptoms and greater weight loss compared to placebo in those with heart failure with preserved ejection fraction.<sup>8</sup> However, widespread implementation and use cannot be achieved without clinicians being confident and competent in managing, educating, and monitoring patients who are prescribed PCSK9 inhibitors as well as GLP-1 agonists and other injectable therapies. The aims of the study were to identify the education and training needs of HCPs on the PCSK9 inhibitor injectable therapies in Italy and the UK and identify the facilitators and barriers relating to their use in clinical practice.

## Methods

The study is reported in accordance with the Consolidated Criteria for Reporting Qualitative Research (COREQ).<sup>9</sup>

### Ethics

The study respected the principles of the Helsinki Declaration. Ethics approval was obtained from each centre in Italy (Institutional Review Board Lazio 2 in Rome ref: 22.21 and the Institutional Review Board of San Raffaele in Milan ref: 365.2020). The UK site deemed the project as a service evaluation, and ethics approval was not required.

### Design and recruitment

A qualitative constructionist methodology was employed to capture the experiences of HCPs in practice that would lead to informing and improving clinical practice.<sup>10,11</sup> The study was conducted between late 2020 to August 2021 using a convenience sample of clinicians working in the UK (Leeds and London) and Italy (Milan and Rome). These sites were chosen as both were identified as using PCSK9 inhibitors and represent locations in the north and south of Europe, and these countries were used as both were using PCSK9 inhibitors as treatment for cardiovascular conditions. Healthcare professionals involved in care of CVD patients (i.e. registered nurses, pharmacists, and/or any HCP directly involved in injectable therapies and included several departments—cardiology, lipidology, and diabetes/endocrine) were eligible, and those not working with CVD patients were excluded. All those who fitted the inclusion criteria were sent an email about the study and asked if they wished to participate in the study and asked to contact the researchers if they wished to participate.

### Materials and procedure

Once consent was completed, experienced qualitative researchers undertook the interviews using MS Teams or Zoom (A.D. and M.K.; this was because there were restrictions on face-to-face meetings with COVID 19 restrictions).

Healthcare professionals were asked the following questions in a semi-structured interview.

- (i) What are the facilitators and barriers to prescribing injectable therapies?
- (ii) What would help you make prescribing decisions on prescribing injectable medicines?
- (iii) What are your educational needs in relation to administering and managing injectable therapies?

Participants were also asked their opinions on the products, their practical use, side effects, pharmaceutical form, and storage. One change was required between sites—the term 'implementation' was used instead of 'prescription' (in Italy, nurses and pharmacist cannot prescribe these medications). The UK allows physicians and pharmacists to prescribe injectable therapies, but there are different constraints in Italy. These questions were based on previous literature and questions that were developed for patients.

Interviews were conducted in the native local language (i.e. Italian and English) and lasted between 30 and 60 min. All interviews were recorded using the built-in function within Zoom and Teams with the permission of the participants. In order to preserve the meaning of idiomatic expressions, the interviews from Italy were not translated but directly coded into English, and a table of the most significant quotations was then constructed in dual language by fluent and certified English-speaking researchers.<sup>12</sup> Using a schematic content analysis approach, an interim analysis was done, which highlighted emerging themes and determined data saturation using NVivo 11. Standard process of inductive thematic content analysis was undertaken with 19 initial codes identified and, through refinement, reduced to 13 final codes by E.E.B. and G.A.L.<sup>13</sup> The MIRACLE Framework was used to guide the abstraction and ensure an in-depth description of the themes.<sup>14</sup> The same process of analysis was applied to identify the facilitators and barriers to using injectable therapies. All quotes from participants were anonymized.

## Results

### Participant demographics

A total of 38 HCPs were interviewed, 19 in each country and composed of physicians ( $n = 18$ ), pharmacists ( $n = 11$ ), and nurses ( $n = 9$ ). The participants worked in cardiology, lipidology, and endocrinology.

### Themes

Four main themes were identified: (i) clinicians' previous experiences with injectable therapies, (ii) challenges with patients' behaviours and beliefs, (iii) clinicians' knowledge of injectable therapies and therapeutic inertia, and (iv) organizational and governance issues. Within each of these broad themes, facilitators, barriers, and solutions were identified and categorized across the data ([Graphical Abstract](#)).

#### Theme 1: clinicians' previous experiences with injectable therapies

A clinician's previous clinical experience in using injectable therapies was seen as strongly influencing their ability to interact with patients who were eligible for PCSK9 inhibitors. Their previous experience of educating patients on moving from oral medication to injectables and ensuring they had a good injection technique was identified as important by participants.

*I think often it tends to be a mental barrier doesn't it that it feels somewhat like a failure that you are progressing to injectable therapies, and I don't know whether that's something that we as healthcare professionals actually play into in some way ... I don't know whether we're like, OK well this [statins] hasn't worked and therefore you are going to go onto this injectable therapy. It kind of feels like you've failed at something, so it feels like a bit of a negative thing to start off with. (Physician, UK)*

*Some problems, for the adherence of patients, especially some who were not so keen on the method of administration... some were a bit dazed, as if it were something a bit too invasive at first. (Cardiologist, Italy)*

Clinicians' perspective on the prevalence of adverse effects and side effects noted the importance of monitoring and ensuring there were no issues.

*So when we follow them up, we would always ask to see if they are suffering from any adverse effects so we would get that sort of feedback from them. Also, I ask to see how they are getting on with the self-administration and then they can sometimes then offer extra feedback on how they are getting on if I've not covered everything with them in the questioning. (Pharmacist, UK)*

## Theme 2: challenges with patients' behaviours and beliefs

This theme related to challenges identified by clinicians in facilitation of patient behaviour in relation to injection techniques, especially with patients' needle phobia:

*...I think when I speak to patients about injectable medicines there's often that fear of needles.... I think needle phobia associated pain is definitely the biggest one when I speak to patients. (Pharmacist, UK)*

The challenges of facilitating patient education were also noted with some patients reluctant to consider injectable therapies and refused to consider these therapies.

*The patient who declined the therapy, according to him...he could make mistakes and we tried several times to explain that it was quite simple, sure for us it is simple but for him it was not so, but he was afraid, afraid to do something wrong and therefore if he was at home and he did something wrong and he was afraid of the consequences. (Nurse, Italy)*

However, participants were also able to identify the benefits of PCSK9 inhibitors, which support their use in hypercholesterolaemia and can be shared with the patients in terms of the rapid improvement in blood test results.

*A very rapid fall in LDL can be seen from the very first course of treatment. (Pharmacist, Italy)*

## Theme 3: clinicians' knowledge of injectable therapies and therapeutic inertia

A theme around HCPs' therapeutic inertia (therapeutic inertia is defined as the attitude of the physician who, even if aware of the fact that the patient does not reach the treatment's target, does not adopt the needed measures to solve the problem, and it can also refer to missed application of new therapies), with lack of knowledge and awareness about these injectable therapies, was identified. Participants stated that senior clinicians often lacked awareness of these therapies in terms of availability and potential benefits.

*...beyond an inevitable therapeutic inertia that means that any new therapy has to be metabolised before it can become common practice. (Cardiologist, Italy)*

The lack of awareness and the therapeutic inertia highlights the issue of identifying patients who are eligible for these medications or not being able to prescribe them.

*I think also people lack knowledge about [the injectables team]...I don't think in terms of my practice or people that I work with there is a disinterest or barrier to using injectable therapies it's just understanding how it works and how to get people on them. (Physician, UK)*

There was clearly a lack of knowledge about injectable therapies, namely PCSK9 inhibitors, from participants' interactions with their professional colleagues. Further education for clinicians was suggested as a way to improve the level of preparation and education for patients.

*The patient who renounced to the therapy maybe because he was not convinced from the beginning and we tried to make him understand how important could be to enter in this therapeutic plan for his characteristics, at the beginning he accepted, but in the moment of the explanation of how the drug had to be prepared and then how it had to be administered he did not feel able... (Nurse, Italy)*

The need for further education for clinicians was seen as important as a lack of preparedness in dealing with patients' questions could negatively affect patients' decisions to consider injectable therapies.

*I can see how as a clinician who doesn't come across them it could be quite confusing when you see them because it's a monoclonal antibody and usually that sparks alarm bells. But it just requires a bit more education to make sure people don't panic when they see them. (Physician, UK)*

## Theme 4: organizational and governance issues

The final theme identified was around organizational and governance issues and ensuring there was a clear pathway from identification for clinical need to prescription of an injectable product.

*There was a disparity between the indications of the guidelines in terms of the target to which access was given and the indications of the AIFA [Italian authority for prescribing], and therefore of the therapeutic plan. (Cardiologist, Italy)*

The lack of clear evidence-based guidelines was raised by participants.

*I don't think the current guidelines out there are accessible enough for health care professionals to guide us in when we need to be, you know, prescribing someone injectable therapies. So, I don't think there's that much awareness around the protocols so if you don't know about something you can't really feel confident about prescribing it, especially if it's something like an injectable therapy. (Physician, UK)*

Barriers to management in both primary and secondary care settings were noted in both locations.

Poor interdisciplinary working, collaboration, and communication were also identified as a challenge in both countries where not all those working in a hospital are familiar with these therapies:

*I think we all need to be singing off the same hymn sheets/algorithm and I don't think we are currently. You write letters to GPs, and they may check people's traditional cholesterol profile without LDLs or non-HDLs and apply primary prevention algorithms so making sure everyone across the patch....I will write to GPs sometimes and say can you put this chap on 80mgs of Atorvastatin and see what his lipids are like in another 3-months, and they'll come back a year later with 20mgs of Atorvastatin and no blood test done. (Physician, UK)*

In terms of governance, in Italy, there was a lack of integrated care and communication between the hospital setting and primary care and the need for several blood tests that must be organized by the hospital.

*Three cholesterol samples in recent months also required hospital reorganisation. (Cardiologist, Italy)*

*This is because the family doctor is hardly involved. The family nurse is unfortunately a figure that is not yet identified. Thus, the patient does not have many points of reference. (Cardiologist, Italy)*

## Facilitators and barriers

As well as identifying the themes above, participants were specifically asked if there were any facilitators and barriers to prescribing PCSK9 inhibitors and they were able to identify several of each. There were several existing facilitators identified including patients' previous experience of injectables such as insulin, and the clinical goals reached are a good stimulus for the use of PCSK9 inhibitors. One cardiologist in Italy commented that people with diabetes who had been using insulin did not experience the same level of hesitation when considering PCSK9 inhibitor injectables:

*The diabetic patient is used to a different approach. (Cardiologist, Italy)*

Interestingly, word of mouth was a powerful existing facilitator (see [Supplementary material online, Table S1](#)).

## Discussion

This is the first in-depth qualitative paper examining HCPs' perceptions on the use of PCSK9 inhibitors in Europe. All HCPs who were invited to participate did so, and we included a wide variety of professionals. Healthcare professionals from several specialties participated, and they were directly involved in PCSK9 prescribing that included cardiology, lipidology, and endocrinology. The results have added context from a qualitative perspective confirming the findings from a previous European-wide survey of 192 respondents that was undertaken as an earlier component of this project.<sup>5</sup>

Clinicians' knowledge of injectable therapies was a key theme identified with respondents raising some of the issues they have to manage in their clinical practice including teaching patients about self-administration and good injecting technique. Previous studies have focused on clinical outcomes and prescription practices with a paucity of information on clinicians' previous experience with injectable therapies for CVD.<sup>15,16</sup> This theme relates to the theme on clinicians' knowledge of injectables and the need for education when novel therapies are introduced. Formal education and training for all HCPs was one of the main themes identified; this highlights the importance of having clinicians who are competent and confident in providing advice and education to patients and their caregivers. Critically, this included those who were familiar with these therapies (training on injectable techniques and how to respond to patients' beliefs around injectable therapies), as well as managing lack of awareness of these medications as identified by therapeutic inertia. Despite the publication of a clinical practice guideline that includes excellent infographics, participants clearly require local educational opportunities in their workplace.<sup>17</sup> The authors also recognized some of their recommendations were weak, which also highlighted that the majority of published guidelines (from European Society of Cardiology and American Heart Association for example) did not systematically assess the cardiovascular benefits of adding PCSK9 inhibitors and/or ezetimibe for all risk groups across primary and secondary prevention. As well as considering what medication is clinically appropriate, clinicians need to discuss options with patients and their families and cannot under-estimate the importance of shared decision-making.<sup>18</sup> Previous studies have shown that once these therapies are initiated, there was a high adherence rate within the first 6 months and significant reductions in major adverse cardiac events in patients with CVD.<sup>16,19,20</sup> In terms of what needs to be done, the development and use of educational materials for both HCPs and patients/caregivers are key as well as the development of clearer guidance and pathways to improve delivery and optimization of these medications.

Regarding the theme of HCPs' perceived challenges with patient behaviour and beliefs, this theme confirms findings from in-depth interviews with patients.<sup>4</sup> Needle phobia is not unique to CVD injectable therapies and is a well-known barrier to injectable therapy initiation, particularly in those with diabetes.<sup>21,22</sup>

The theme of organizational and governance issues builds on findings in previous studies, although they did not specifically explore reasons for this other than reporting high rates of discontinuation.<sup>15,16,19,20</sup> Our study is unique in undertaking a qualitative approach to exploring the organizational and governance issues. Having the prescription of PCSK9 inhibitors limited to hospitals is associated with a significant administrative burden for these centres, and clearly, improvements in the administration and distribution of injectable therapies are needed if wider use is to be achieved. A previous study highlighted the importance of community pharmacists' benefit in improving delivery of these medications and their role in monitoring patients and reducing the barriers.<sup>23</sup> Post COVID-19, there is evidence supporting patients' preferences for local appointments and the ability to collect medications from their local pharmacies rather than have to go to the hospital.<sup>4</sup> A Spanish study undertaken during the pandemic demonstrated that home delivery of medication was advantageous to patients and good

lipid control was maintained.<sup>24</sup> One issue noted a lack of homogeneity in prescriptions between the various Italian regions. However, the national scientific societies are working with the Italian Medicines Agency (AIFA) to reduce some of the differences. A new update from AIFA is expected shortly. Interestingly, cost did not come up as a theme.

It was reassuring that there were existing facilitators identified by the participants that included the clinical benefits of PCSK9 inhibitors in terms of their lipid profile and patients who had prior experience of injectables such as insulin as well as the importance of word of mouth among patients.

Limitations need to be acknowledged: the study was undertaken in two European countries, and other countries may have revealed different themes and contextual barriers. Only HCPs working with the hospital sector were approached to participate in this study, as at the time of the data collection, neither country was prescribing these medications in primary care. It may be that different perceptions would now be observed within the primary care setting where prescribing of PCSK9 prescriptions is in practice. The participants only had experience in PCSK9 inhibitors, which may be seen as a limitation; however, the principles of injectable therapies are similar, and thus, this is not viewed as a major limitation. There still remains a paucity of education on these novel injectable therapies for HCPs.

## Conclusions

The interviews with HCPs identified several themes and provided some suggestions on how the delivery and education could be improved. The development and availability of educational material for both patients and HCPs have the potential to optimize the use of injectable therapies and help reduce the initial fears and reluctance around commencing injectable therapies. The findings could be used to develop educational material that can be implemented into practice and improve uptake and maintenance of injectable therapies.

## Supplementary material

Supplementary material is available at *European Journal of Cardiovascular Nursing* online.

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## Author contributions

G.A.L. and E.V. devised the study. M.K., G.C., and F.D. undertook the interviews. E.E.B., G.A.L., A.D., and R.K. analysed the data. All authors contributed to the writing of the paper.

**Conflict of interest:** none declared.

## Data availability

Due to the nature of the data collected, it is not possible to share it.

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