HSD8

A Case-study On The Implementation Of The First Population Health Agreement in England

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Background

The growing prevalence of non-communicable diseases (NCDs) has been placing an increasingly large financial and operational burden on the United Kingdom's (UK) healthcare system. This strain is reflected in the healthcare spending, with NCDs costing the UK more than £130 billion annually [1]. Among these diseases, cardiovascular disease (CVD) remains a particularly pressing concern, affecting an estimated 6.4 million people in England as of 2020 [2].

To begin addressing this challenge, NHS England (NHSE) launched the Long-Term Plan in 2019. It identified CVD as a priority due to its high mortality rate and potential for significant cost savings through prevention and early intervention. One of the plan's main objectives is to prevent 150,000 major cardiovascular events by 2029[3].

Aligned with the Long-Term Plan and the broader strategy of Population Health Management (PHM), NHSE established the first Population Health Agreement (PHA) with Novartis in 2021[4]. This innovative agreement aimed to "identify and treat over 300,000 patients at high risk of a second cardiovascular event in a three-year period" by enabling access to Inclisiran in primary care settings. Inclisiran is a first-in-class small interfering RNA (siRNA) therapy indicated for adults with primary hypercholesterolemia who are inadequately responsive to statins. It is recommended for secondary prevention and functions by significantly lowering levels of low-density lipoprotein cholesterol (LDL-C) [5].

Methodology

This study, conducted between June 2024 and March 2025, employed a mixed-methods research design that combined an analysis of prescription data, a literature review and stakeholder interviews. Quantitative data was obtained from OpenPrescribing.net, capturing the number of inclisiran items dispensed monthly by Integrated Care Boards (ICBs) between October 2021 and September 2024. A targeted rapid review was undertaken to examine clinical trial evidence for Inclisiran, alongside guidance from the National Institute for Health and Care Excellence (NICE). This was supplemented by a review of NHS guidelines on lipid management and opinion pieces concerning the adoption of Inclisiran in primary care. To gain an understanding of Inclisiran's rollout, semi-structured interviews were conducted with stakeholders directly involved in implementing the Population Health Agreement (PHA), exploring the key barriers and enablers. Seven stakeholders participated in the interviews. Novartis was also invited to contribute an industry perspective; however, they declined to participate.

The interview data were analysed using thematic analysis, applying a deductive approach to identify key patterns and recurring themes.

Results

Analysis revealed that only **approximately 45,000** doses of inclisiran were administered between October 2021 and September 2024, falling significantly short of the original target to treat **300,000** high-risk patients within three years.
This considerable gap between expected and actual uptake highlights major challenges in the implementation and scale-up of Inclisiran in primary care settings.

Some of the reasons behind this discrepancy are explored here.

1. There was no effective and consistent strategy to identify and reach target patients

The Health Innovation Network has developed a digital search tool designed to flag patients at high risk of cardiovascular disease (CVD). This tool allows for the filtering of patients who may benefit from lipid-lowering therapies. Despite its potential, GPs appear to be largely unaware of the tool's existence, suggesting that its use is not widespread.

Currently, patients eligible for Inclisiran are identified manually during routine appointments. Correct identification relies on the prescriber's knowledge of clinical guidelines. Given the several conditions imposed by NICE, potentially eligible patients may not be always identified. This manual screening process slows the uptake of Inclisiran.

2. **Doctors and local healthcare leaders were frustrated with the 'top-down' approach to the implementation of the agreement**

A local formulary is the "result of processes to support the managed introduction, utilization or withdrawal of treatments within a local healthcare system" (6). Local Area Prescribing Committees (LAPCs) are responsible for assessing drugs before including them in the local formulary. Each drug is assigned a code: Green (safe for use in both primary and secondary care), Amber (requiring shared care with a specialist), or Red (for use in secondary care only). General Practitioners (GPs) are not obligated to prescribe non-formulary drugs. Although the codes are advisory, they carry significant weight in prescribing decisions.

NHS England uniquely advised LAPCs to designate Inclisiran as Green, bypassing the usual assessment process. However, several LAPCs refused to comply, classifying Inclisiran as Amber for several months. This classification meant that treatment would typically not be initiated in primary care, leading to delays in treatment for patients and fostering distrust between primary physicians and NHS England.

3. Concerns about the safety of Inclisiran

Inclisiran is a first-in-class drug, which means it is subject to enhanced monitoring for five years by the Medicines and Healthcare products Regulatory Agency (MHRA) as part of the Black Triangle scheme. The Black Triangle scheme mandates the reporting of side effects of novel drugs to the MHRA through the Yellow Card scheme.

It is uncommon for Black Triangle drugs to be prescribed in primary care. Some General Practitioners were hesitant to prescribe Inclisiran due to a lack of awareness of the drug's benefits and potential side effects. Additionally, the trials provided in the NICE submission had a short follow-up period of 18 months, which many experts considered insufficient to establish the long-term side effects of this new molecule.

4. **Inadequate financial incentives delayed the adoption of inclisiran in primary care**

GPs are not commissioned to deliver Inclisiran as it is not included in the General or Personal Medical Services Contracts. Therefore, funding for Inclisiran should be made available through alternative mechanisms, such as a Locally Enhanced Services (LES). However, fewer than five Integrated Care Boards (ICBs) have established a full or partial LES for this purpose. The £5 fee reimbursed to GP practices, in addition to the nominal charge, is insufficient to cover the overhead costs associated with Inclisiran. Once the cost of nurse training, the NHS clawback, patient identification, and additional monitoring, practices incur a substantial loss for each dose dispensed. Notably, practices receive little to no discount on Inclisiran from the wholesaler, yet the clawback is still applied. This leads to a nominal loss for each dose dispensed.

Recommendations

The first Population Health Agreement (PHA) between NHS England and Novartis fell short of the ambitious expectations initially set, with a lower uptake than anticipated. For future agreements to be more successful, it is recommended that greater consideration be given to factors influencing physicians' willingness to prescribe novel therapies. These include a standard appraisal for inclusion in local formularies, an assessment of their confidence with new treatments with unknown side effects and familiarity with clinical guidelines. Additionally, ensuring that adequate financial incentives and support are in place for primary care providers will be essential to encourage engagement and facilitate broader adoption of innovative therapies.

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