Establishing UK consensus on the benefits of achieving lower LDL-C levels and why the role of newer treatment options should be realised in the NHS

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Conflicts of Interest
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Abstract:

While statins have long been the gold standard for lipid-lowering therapy, new therapies [such as PCSK9 inhibitors] have also demonstrated LDL-C reduction but with a similar or better safety profile. Conflicting guidance has contributed to a low uptake of these new drugs. More up-to-date, evidence-led guidance supports greater use of newer therapies particularly in combination with statins to reduce LDL-C to lower levels seen to be effective in the randomised controlled trials. The aim of this study was to determine how such guidance can be implemented more effectively in the UK.

Using a modified Delphi approach, a panel of lipid experts developed 27 statements across 4 key themes. These were used to form an online survey that was distributed to lipid specialist HCPs across the UK. Stopping criteria included 100 responses received, a seven-month window for response (September 2021 – March 2022), and 90% of statements passing the predefined consensus threshold of 75%.

A total of 109 responses were analysed with 23 statements achieving consensus (4 statements <75%). Variance was observed across respondent role, and by UK region. From the high degree of consensus, seven recommendations were established as to how evidence-based guidance can be delivered, including a call for personalised therapy strategies and simplification of LDL-C targets, which should be achieved within as short a time period as possible.

Key Terms (MeSH):

Consensus, Statins, Low-density lipoprotein, Cardiovascular diseases, Hypercholesterolemia

Key Messages:

- Despite up-to-date, evidence-led guidance supporting greater use of newer therapies in combination with statins to reduce LDL-C, uptake in the UK is low.

- Using a modified Delphi based methodology, a panel of 109 UK lipid specialists were sampled to determine how evidence-based guidance can be better implemented in the UK through a 27 statement Delphi consensus survey.

- A set of seven recommendations were derived from the results to inform future guideline development, including a call for personalised therapy strategies and simplification of LDL-C targets, which should be achieved within as short a time period as possible.

Introduction:

Statins have long been established as the gold standard for lipid-lowering therapy, based on efficacy in reducing serum low-density lipoprotein cholesterol (LDL-C) and safety & tolerability [1]. Whilst statins have an extensive body of evidence that have shown them to reduce the risk of fatal and non-fatal cardiovascular (CV) events [2, 3], concern around their side effects has led to the development of alternative LDL-C lowering medications. The evidence base concerning statins has noted an increase in cases of treatment-induced comorbidities, such as new onset diabetes mellitus (NODM) [4, 5, 6], which combined with patient and media concerns has led to a reported 50% drop out rate within the first year of treatment [1].

More recently, proprotein convertase subtilisin-kexin type 9 inhibitors (PCSK9i), such as alirocumab and evolocumab, have demonstrated LDL-C reductions of approximately 60% and maximal reduction within 4 weeks [7]. PCSK9i have also been shown to reduce inflammation and associated progression of atherosclerotic disease [8]. Despite inclusion in the Lipid Management - Rapid Uptake Product programme [7], the number of prescriptions issued for PCSK9i remains far below projected levels (Figure 1).

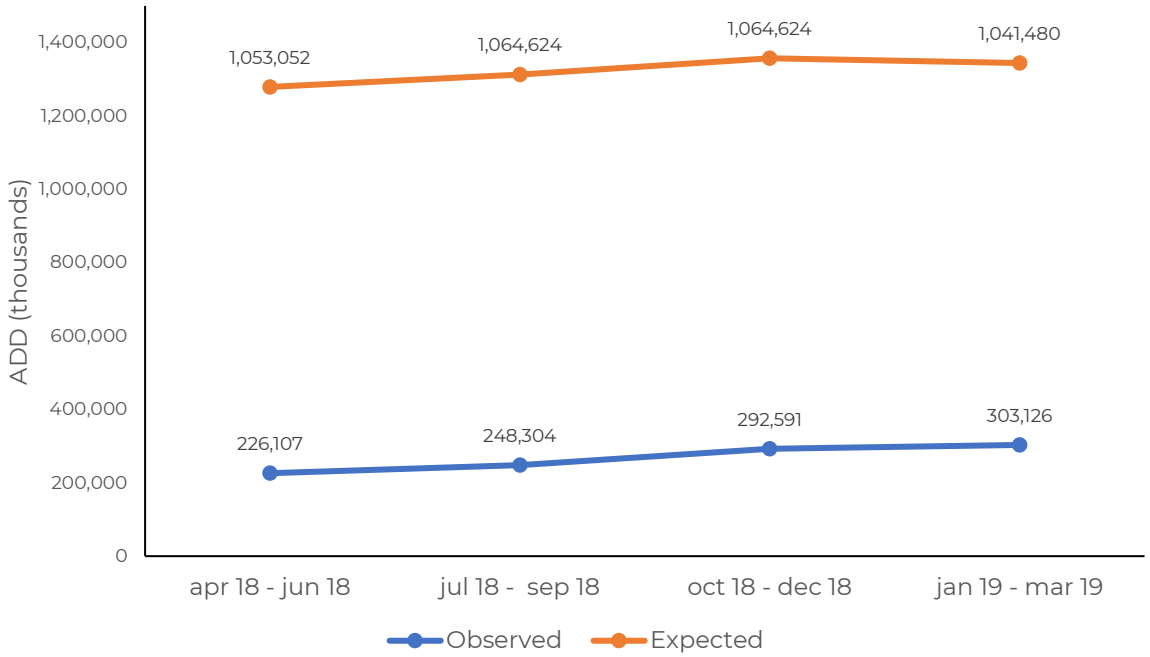

Figure 1: Observed use and range of expected use of PCSK9i (combined alirocumab and evolocumab) in primary and secondary care prescribing from April 2018 to March 2019 (adapted from NHS Digital [9]). ADD = Actual Daily Doses

NICE recommends starting PCSK9i for patients at high/very high risk of cardiovascular disease (CVD) in patients with LDL-C concentrations persistently above 4.0/3.5 mmol/L respectively despite maximally tolerated lipid-lowering therapy (including statins, high intensity statins, and combination therapy with ezetimibe) [10]. This is problematic as NICE guidelines for CVD specify a 40% reduction in serum non-high density lipoprotein cholesterol (non-HDL-C) as a treatment target rather than a specific LDL level to aim for [11] In contrast, European Society of Cardiology (ESC) guidelines focus on LDL-C as a marker for CVD risk [12].

These issues are further compounded when considering patients with familial hypercholesterolemia (FH). This is a relatively common genetic disorder with a prevalence of 1 in 500, with an estimated 120,000 individuals affected in the UK [13]; untreated men are at a 50% risk of a fatal or non-fatal coronary event before 50 years of age with women at a 30% risk before the age of 60 [14]. Though evidence suggests that PCSK9i are effective in getting FH patients to LDL-C targets [15], the current provision within NICE guidelines state that PCSK9i can only be prescribed in those individuals who's LDL-C levels are not controlled or do not reach a 50% reduction from baseline [16]. NICE further recommends starting FH patients without CVD and at high/very high risk of CVD only if LDL-C concentration is persistently above 5.0/3.5 mmol/L respectively [10].

Confusion regarding lipid parameters to measure (LDL-C vs Non-HDLC) may result in hesitance amongst NHS prescribers to escalate treatment (e.g. to include PCSK9i and novel treatments such as Inclisiran and bempedoic acid), resulting in UK patients receiving sub-optimal treatment.

Given these points, the intent of this projecct was to determine the strength of opinion held by UK healthcare professionals (HCPs) involved in lipid care as to how evidence-based guidance can be better implemented, and what role newer therapies can have in delivering these guidelines.

Methods:

A panel of experts in the management of CVD from across the UK convened in July 2021 to discuss current challenges to LDL-C reduction and how additional treatment options could be utilised to meet these targets. Using a modified Delphi methodology guided by an independent facilitator, the panellists identified 4 main topics of focus:

A. Why do we need to address current practice in lipid management?
B. Defining a treatment target
C. Best practice principles
D. Considerations (targets) for other populations

These topics were each discussed further, from which 27 statements were developed.

These statements were then used to create an online questionnaire using Microsoft Forms (ref). The questionnaire was distributed through a convenience sampling method to HCPs working within CVD care across the UK. Stopping criteria were defined as a seven-month time period to collect responses (September 2021 – March 2022), more than 90% of statements exceeding the threshold established for consensus, and a minimum target of 100 responses within the pre-defined time period.

These criteria were agreed to provide the maximum opportunity for HCPs to respond given the prevalent pressures on the NHS from the COVID-19 pandemic. The threshold for consensus agreement was defined as 75%. This was further defined as 'high' at ≥75% and 'very high' at ≥90%. Respondents were offered a 4-point Likert scale ('strongly disagree', 'tend to disagree', 'tend to agree', and 'strongly agree') to indicate their corresponding level of agreement with each statement. The questionnaire also captured some demographic data for further analyses including country of work, role, and time in role.

Completed surveys were anonymously collected and analysed by an independent facilitator to produce an arithmetic agreement score for each statement. This information was then reviewed by the panel of experts and recommendations made accordingly.

As this study only sought the anonymous opinions of HCPs and no patient-specific data were captured, ethical approval was not required.

Results:

A total of 109 responses from across the UK were received between September 2021 and March 2022 (Figure 2).

From this first round, 14/27 statements attained very high agreement (≥90%), 9/27 attained high agreement (<90% and ≥75%), and 4/27 statements did not reach the threshold for consensus (<75%).

Given the high level of agreement displayed to the statements, and that the stopping criteria for the number of responses and time scale had been met, it was decided not to undertake a second round of testing.

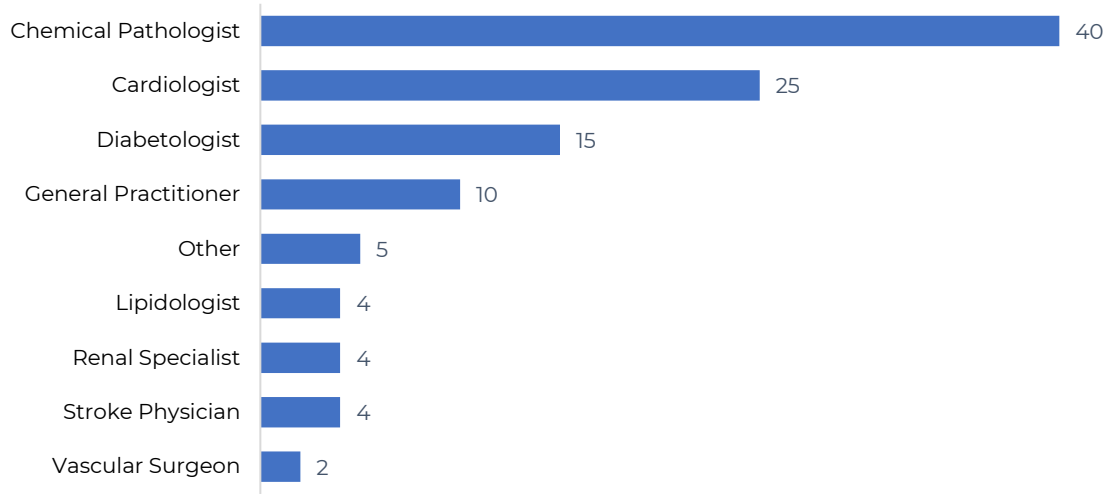

Figure 2: Respondent numbers by role.
Other heading includes Pharmacist, Lipid nurse, Pharmacist – lipid clinic, Advanced Nurse Practitioner (ANP) for lipids, and Cardiac nurse practitioner.

The defined consensus statements and corresponding levels of agreement from 109 responses are shown in table 1.

Table 1: Defined consensus statements and corresponding levels of agreement from 109 responses.

No.	Statement	Score %
Topic 1: Why do we need to address current practice in lipid management?		
1	The lifetime burden of LDL-C has significant healthcare consequences	100
2	Current risk calculations are underestimating the lifetime burden of LDL-C and its consequences	94
3	There is conflicting guidance on appropriate lipid targets with NICE vs ESC	97
4	Conflicting guidance on appropriate lipid targets in the UK leads to suboptimal health outcomes	90
5	More intensive lipid management in the UK will lead to improved patient outcomes	94
6	An evidence-based, population-based approach to target setting should be the goal in the UK	89
7	The European Society of Cardiology (ESC) 2019 targets should be adopted in the UK	88
Topic 2: Defining a treatment target		
8	The use of non-HDL-C targets in the UK leads to confusion in the application of clinical guidelines	82
9	Non-HDL-C should no longer be used in routine clinical practice in the UK	69
10	An LDL-C target should be the standard of measurement in future UK guidance	80
11	It is important to get all patients with high LDL-C to the treatment target as quickly as possible	87
12	LDL-C targets should apply equally irrespective of the lipid lowering therapy being used	93
13	For patients with high CV risk, the absolute treatment target for LDL-C should be 1.8mmol/L and a ≥50% reduction from baseline LDL-C	93
14	For patients with very-high CV risk, the absolute treatment target for LDL-C should be 1.4mmol/L and a ≥50% reduction from baseline LDL-C	89
15	Secondary prevention ASCVD patients should be initiated on a combination of a high dose statin and ezetimibe following their initial ASCVD event	72
16	After treatments to reduce LDL-C have been initiated, treatment should be reviewed (and optimised) within 3 months	96
17	The addition of PCSK9i to lipid management improves patient outcomes	95
18	PCSK9 inhibitors should be prescribed in primary care	73
19	In my practice there are barriers to prescribing PCSK9i	74
20	The current NICE guidance for the use of PCSK9i is too restrictive	84
Topic 3: Best practice principles		
21	Combination therapy for lipid management should be recommended, as is the case for hypertension and diabetes	95
22	If patients fit the NICE criteria for a PCSK9i, they should be initiated on this option rather than bempedoic acid (+/- ezetimibe)	87
Topic 4: Considerations (targets) for other populations		
23	The nocebo effect should be considered before patients are considered statin intolerant (the nocebo effect is the opposite of the placebo effect. It describes a situation where a negative outcome occurs due to a belief that the intervention will cause harm)	94
24	Other lipid lowering therapies should always be considered in patients for whom statins cannot be used	99
25	Other lipid lowering treatment options should always be considered in patients that experience side effects	96

26	Patients with known CVD, type 2 diabetes, very high levels of individual risk factors and chronic kidney disease (CKD) are at high or very high-risk total cardiovascular risk and need active management of all risk factors	100
27	Patients with known CVD, type 1 diabetes with microalbuminuria are at high or very high-risk total cardiovascular risk and need active management of all risk factors	100

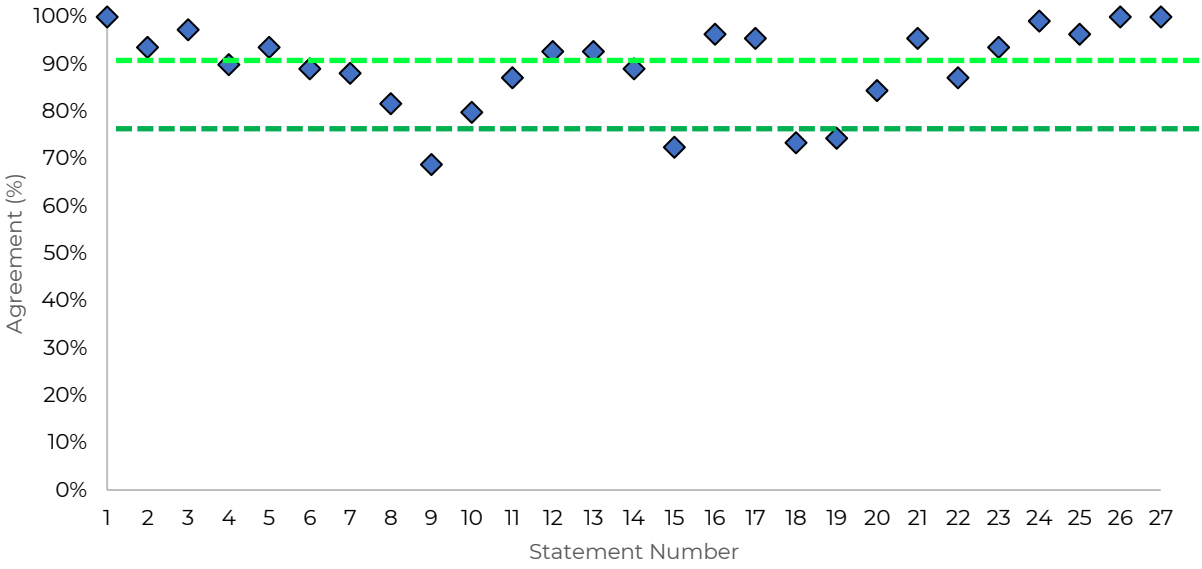

Figure 3: Combined consensus agreement scores.
Note: The dark green line represents consensus threshold of 75%, and the light green line represents the threshold for very high consensus (90%)

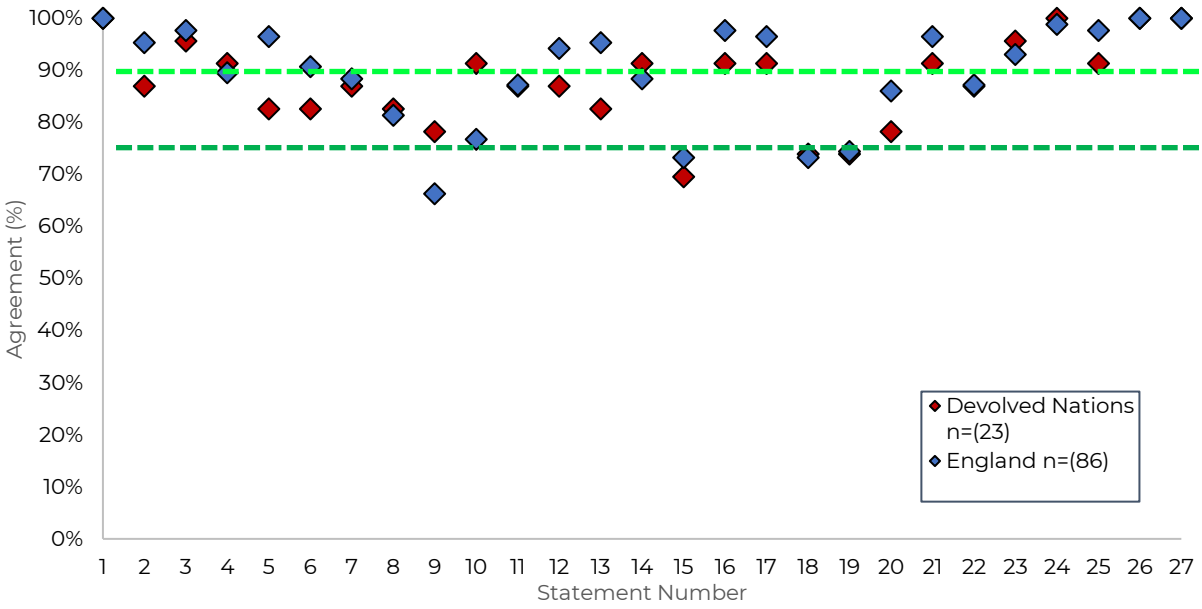

Figure 4: Consensus agreement scores by UK nation. Devolved nation includes Scotland (5), Wales (16), and Northern Ireland (2).
Note: The dark green line represents consensus threshold of 75%, and the light green line represents the threshold for very high consensus (90%).

Does there need to be a bit more text in the results? Much of the discussion could be included here?

Discussion:

The results indicate strong levels of support amongst HCPs to refine current guidelines to support better provision of lipid care within the UK.

Research-led guidelines with a focus to personalised treatment goals should become the gold standard within the UK

All respondents, regardless of their role, recognised that the lifetime burden of LDL-C is currently underestimated (S1, 100%). This has considerable impact for patients, as delaying treatment through a misconception of lipids being a 'slow-burning' condition will in fact lead to greater consequences for the individual if their lipids are left unoptimised. This is compounded by the lack of provision to support personalised LDL-C targets within NICE guidelines [11], contrary to recent research findings [17].

Given the levels of agreement in statements 3 & 7 (97%, 88%), it is clear that HCPs 'specialising' ('managing' – GPs and renal physicians wouldn't see themselves as 'specialising in lipds') in lipid care recognise that the ESC guidelines are more appropriate to manage the needs of the individual patient. This is in part due to the stratification of targets according to risk category alongside the personalisation of LDL-C goals for each patient [12, 18]. As these guidelines are also frequently updated in line with current research, the authors suggest that ESC guidelines should be adopted within the UK.

Focus on LDL-C rather and non-HDL-C

The use of non-HDL-C targets within the UK are driving the confusion around patient lipid goals. A sub analysis of agreement against respondent role (appendix 1) demonstrates the differences in opinion between lipid specialists and other roles, with the other specialist disciplines demonstrating a marked lower level of agreement to statement 9. Education for all HCPs should therefore be improved in future to reduce variation in understanding of lipid targets. However, current NICE guidance uses both non-HDL-C and LDL-C targets [11, 19], the agreement for statement 10 demonstrates that HCPs recognise that LDL-C should be the standard unit of measurement in future guidance, as currently supported by the ESC [12].

The urgency of treatment is as important as the treatment used

As discussed above, the lifetime burden of LDL-C is recognised as a key issue amongst the respondents (S1, 100%). What is also clear from the responses analysed is that the respondents are aware of the need to bring the LDL-C levels of the individual down as fast as possible (S11, 87%). This result corresponds to the wider viewpoint in the field that 'lower is better' as it has been shown that a 1.0 mmol/L reduction in LDL-C corresponds to a 22% reduction in relative risk [15, 20].

Statin monotherapy is no longer the only treatment for lipid management

Since the introduction of statins, more treatments have been approved and there are now five main available therapies for use, with different combinations and approaches available. It is important that these options are employed in an evidence-based approach to therapy.

While respondents agreed that there should be one LDL-C target regardless of the therapy used (S12, 93%), care should be taken to employ the most efficacious combinations. Recent data shows that a combination of statins and bempedoic acid (is this a licenced combo in the UK?)is only 16% effective in reducing LDL-C compared to other methods [21]. Within high-risk groups, statin monotherapy is often less effective in reducing LDL-C to target, therefore a combination therapy approach is often warranted. Recent research supports the need to provide additional non-statin therapies for these patients [17, 18, 22], even to the point at which those most at risk are immediately started on statin/non-statin combination therapy [18].

Further to this, the respondents agree that it is vital to ensure that patients treatments are reviewed and optimised within 3 months to ensure that the individual meets their LDL-C targets (S16, 96%).

Combination therapies are key to getting patients to target

Respondents indicated very strong agreement (S21, 95%) that combination therapies [23] should be developed and become used for lipid therapy, as is the case for other conditions, for example hypertension and glucose lowering in type 2 diabetes. This would allow patients to reach their goals more rapidly, while allowing for greater optimisation of treatment.

As a first step towards the use of combination therapies, widening the usage of PCSK9i would be the logical approach. The utility of PCSK9i is recognised by HCPs as shown by the degree of support shown to statements 17, 20, and 22 (95%, 84%, 87% respectively). However, as NICE guidance around the use of PCSK9i monoclonal antibodies is recognised to be too restrictive (S20, 84%), the authors suggest that addressing the barriers inhibiting the use of PCSK9i monoclonal antibodies would increase uptake. Potential barriers may include:

- a lack of a multidisciplinary approach
- confusion around targets for implementation and requirements to measure LDL-C

- a lack of experience and knowledge of PCSK9i
- a need to improve patient knowledge and engagement of this class of treatment

Recommendations:

Based on the levels of agreement from 109 respondents, the authors offer the following set of recommendations:

1. The tools for managing the lifetime risk of LDL-C should be better implemented in clinical practice.
2. Lipid-lowering therapies should always be personalised for the individual patient, optimised within as short a time period as possible, and all patients should be brought to their targets as quickly as possible.
3. Targets for lipid lowering therapies should be the same across all therapeutic classes and reflect the evidence-based LDL-C targets set by the ESC guidelines (1.4-3.0 mmol/L for very high risk to low risk patients).
4. LDL-C should be the standard unit of measurement in future UK guidance.
5. Use of combination therapy should become the norm and treatments made as widely accessible as is possible.
6. Should we be mention ezetimibe combo with statins at this point??
7. Awareness around the advantages of PCSK9i monoclonal antibodies, inclisiran and bempedoic acid should be raised for both appropriate patients and for HCPs.
8. There needs to be recognition of intensive treatment options for high-risk populations.

This study is strengthened by the nature of the results, in that they are the opinions of a representative sample of practicing professionals within the field in response to questions generated by a panel of experts.

The results provide a reflective grounding towards the current state of CVD care as practised in primary and secondary care settings. Given that this study utilised convenience sampling methods, the results may have been affected by motivation bias, however this was mitigated by including the seven-month time frame within the study design. As most results originated from England, this may have weighted the results.

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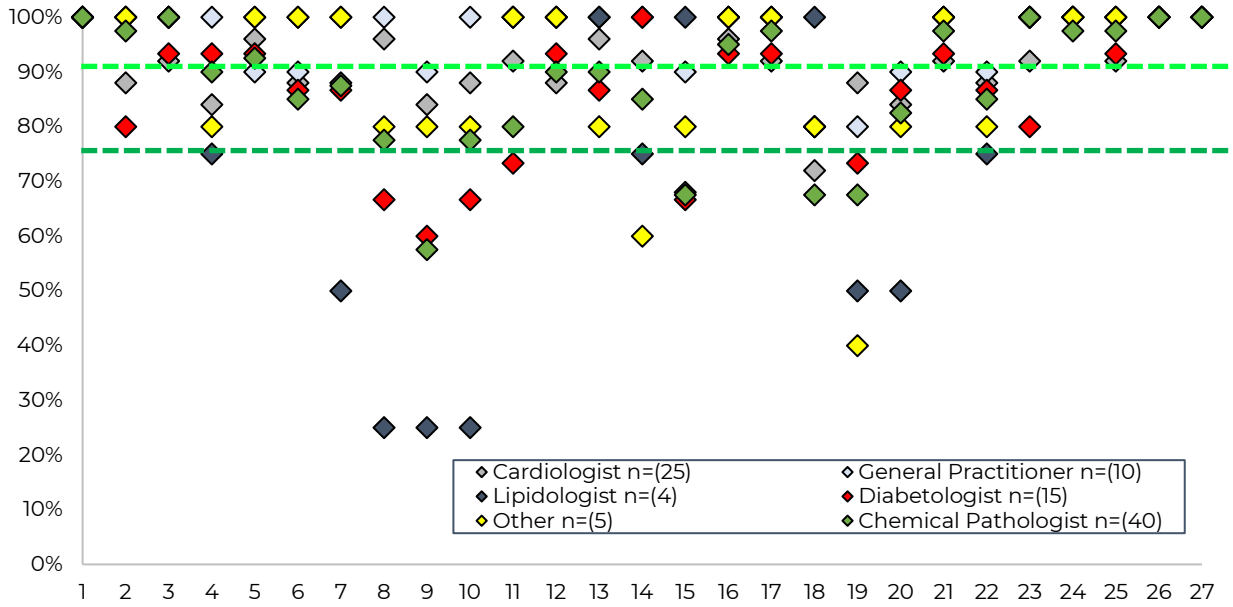
Appendix:



Appendix 1: Consensus agreement scores by respondent role.
Note: The dark green line represents consensus threshold of 75%, and the light green line represents the threshold for very high consensus (90%)