Equity and local health systems: a qualitative evaluation of the experiences of local health service leads during the first two years of the NHS Low Calorie Diet programme pilot

DREW, Kevin, HOMER, Catherine <http://orcid.org/0000-0003-2571-6008>, RADLEY, Duncan, FREEMAN, Charlotte, KINSELLA, Karina, MAYNARD, Maria, BAKHAI, Chirag and ELLS, Louisa

Equity and Local Health Systems – a qualitative evaluation of the experiences of Local Health Service Leads during the first two years of the NHS Low Calorie Diet Programme pilot

Kevin J Drew[1]*, Catherine Homer[2], Duncan Radley[3], Charlotte Freeman[4], Karina Kinsella[1], Maria Maynard[1], Chirag Bakhai[5] and Louisa Ells[1]

[1]Obesity Institute, School of Health, Leeds Beckett University, City Campus, Leeds, LS6 3QW

[2]Sport and Physical Activity Research Centre, Sheffield Hallam University, Olympic Legacy Park, 2 Old Hall Road, Sheffield, S9 3TU.

[3]Obesity Institute, School of Sport, Leeds Beckett University, Headingley Campus, Leeds, LS6 3QW.

[4]Northern Care Alliance NHS Foundation Trust, Mayo Building, Stott Lane, Salford, M6 8HD.

[5]Larkside Practice, Churchfield Medical Centre, 322 Crawley Green Road, Luton, Bedfordshire, LU2 9SB

*Correspondence: k.drew@leedsbeckett.ac.uk

Kevin J Drew: https://orcid.org/0000-0003-0149-2521

Abstract

Background: Obesity and type 2 diabetes can both profoundly impact health and wellbeing, and their prevalence largely follows a social gradient. The National Health Service Low Calorie Diet programme in England, aims to support people to achieve type 2 diabetes remission, while also reducing health inequalities. We aimed to explore the experiences of local health service leads and identify barriers and facilitators in relation to the equitable mobilisation of the Low Calorie Diet programme.

Methods: Twenty **s**emi-structured interviews were completed with 24 locality leads across the first two years of the Low Calorie Diet programme. Interviewees were purposively sampled from the ten localities who undertook the Low Calorie Diet programme pilot. Each interview explored a number of topics of interest including referrals, training, communication, incentivisation, governance and engagement, before being subjected to a thematic analysis.

Results: From the data, seven core themes were identified: Covid-19 and primary care capacity and engagement, methods of communication, approaches to training, approaches to incentivisation, approaches to Referrals, barriers to referrals and the importance of collaboration. Covid-19 presented a specific challenge to the mobilisation and delivery of the Low Calorie Diet programme; however, our findings demonstrate the large variation and differences in the approaches taken when delivering the programme across ten geographically and demographically distinct pilot sites. We also identified a lack of a recognised approach or strategy to mobilisation and delivery support for the Low Calorie Diet programme, such as proportionate universalism, which is a social policy response to tackling health inequalities by ensuring service delivery is equitable.

Conclusions: Health inequalities remain a significant challenge, and health service leads have the potential to adopt an equity perspective from the start of programme mobilisation. In doing so resources at their disposal can be managed equitably and can therefore contribute to efforts to reduce the potential occurrence of intervention generated inequalities.

Keywords: Type 2 Diabetes, Obesity, Low Calorie Diet, Equity, Inequalities, Proportionate Universalism, Re:Mission study.

Introduction

Obesity and type 2 diabetes (T2D) are both prevalent non-communicable diseases, which can profoundly impact health and wellbeing (1). In England, 64% of adults live with overweight, of which 26% live with obesity (2). It is estimated that 3.8 million adults (≥16 years) in England have diabetes, and modelled projections indicate that the National Health Service (NHS) and wider societal costs associated with obesity and diabetes, will escalate unless urgent action is taken (3).

Health outcomes largely follow a social gradient, with prevalence of both obesity and T2D increasing with age and area-level deprivation, and amongst people of Black and South Asian ethnicity (1, 2, 4, 5). Inequalities, the unjust and avoidable differences in people's health outcomes, have been further exacerbated by the COVID-19 pandemic (6-8), and also exist in access to healthcare. For example, amongst people of Black and South Asian ethnicity, and also shaped by wider determinants, inequalities in diabetes treatment and metabolic control have been evidenced in the UK (9). Although addressing inequalities is a public health priority (10), many interventions aimed at improving health across the entire population can be markedly more beneficial for individuals of higher socio-economic status, and of White ethnicity (11-14). This has been referred to as an inequality paradox – the occurrence of intervention generated inequalities in interventions that aim to reduce them (15).

The NHS Low Calorie Diet Programme

Recent systematic reviews (16-20) and clinical trials (21-23) show that for some people living with, or at risk of obesity and T2D, a Low Calorie Diet (LCD) achieved by Total Diet Replacement (TDR), can lead to clinically significant weight loss, support remission of T2D, and improve quality of life. The

NHS Long-Term Plan (24) therefore made a commitment to pilot a LCD programme, for people living with excess weight and T2D. This commitment aims to significantly improve health, while reducing health inequalities and associated future costs to the NHS. NHS England, partnered with Diabetes UK, commissioned the programme delivered by commercial providers across ten geographically diverse pilot areas (integrated care systems[1] (25)), where each area tested one of three different delivery models (group, 1:1 and digital) (see Additional file 1). The programme was available to adults (18-65 years) with a BMI ≥27kg/m² (adjusted to ≥25kg/m² for Black, Asian and other ethnic groups) and a T2D diagnosis within the last 6 years (full eligibility criteria (26)), and aims to significantly improve health by reducing glycaemic parameters, diabetes-related medication, and weight, as well as achieving remission.

The delivery of the NHS LCD programme gave due regard to the reduction of health inequalities by ensuring compliance with the NHS Act 2006 and the Equality Act 2010 (27, 28). The promotion of equal access by all service users, and the tailoring of a programme to support those with the greatest need through a proportionate universalism approach, was also mandated in the service specification (29). Thus, health equity (the state in which people have a fair and just opportunity, irrespective of their social position, to attain their full health and welling from social conditions that seek to promote and support good health (30)), is crucial to the delivery of the NHS LCD programme. Although the programme is delivered by commercial service providers, the local health system (primary care) is responsible for referring eligible patients to the programme. The obligations set out in the service specification, and specifically the due regard to reduce inequalities is therefore incumbent, in part, on local health service leads who have responsibility for the mobilisation of the

[1] Integrated care systems are partnerships between NHS bodies, local authorities, and local organisations which work together on health and care services to improve the lives of people locally

programme. This paper, therefore, aims to explore the experiences of local health service leads, and identify barriers and facilitators in relation to the equitable mobilisation of the service.

Methods

This study received ethical approval from the Health Research Authority (REF 21/WM/0136), and is reported using COREQ guidelines (see Additional File 2)(31). Participants from each of the first ten Integrated Care Systems (referred to hereon in as 'localities') who undertook the pilot programme across England were sampled. Twenty four health service leads (referred to hereon in as 'locality leads') (20 females and 4 males) with responsibility for the mobilisation of the NHS LCD programme and employed by local integrated care systems (local commissioning lead, project manager, and clinical lead) were interviewed across 20 interviews (see Additional file 1). Semi-structured interviews (MS Teams) lasting between 60 and 90 minutes were completed between July and September 2021 (n=10), with follow up interviews completed in July 2022 (n=10).

In 2021, interviews were carried out by two researchers (KD and CF) each conducting five interviews, whilst all follow up interviews (2022) were conducted by KD. The interviews were semi-structured in nature, giving the interviewer control over the interview, and designed to elicit discussion on specific topics of interest. Topics were communicated to interviewees prior to interview, and included: referrals, training, communication, incentivisation, governance and engagement. These topics were pre-empted by initial programme theory (32), developed through the overarching realist informed Re:Mission evaluation (33), which this study contributes to. Fieldnotes were recorded after each interview.

Interviews were audio recorded, transcribed verbatim, and then subjected to a thematic analysis as described by Braun, Clarke (34). KD and CF familiarised themselves with the data, by undertaking multiple readings of the interview transcripts from the interviews they conducted. Transcripts were coded using a latent coding method and the interview guide as a deductive

framework for analysis. This involved abductive reasoning, or the mixing of inductive and deductive reasoning which facilitated movement between participant accounts and researcher defined topics of interest. Following initial coding, KD, CF and KK read through a sample of transcripts as second coders, to search for alternative meanings in the data not previously tagged. Differing interpretations of the data were subsequently discussed. NVivo software (QS International Pty Ltd. Version 12) was used to assist this process of storing and organising textual data and initial coding.

The use of thematic analysis allowed for the identification of patterns ('themes') in the data. The identification, reviewing, defining, and naming of themes was conducted by KD, who used inequalities as a theoretical lens for interpretation. This involved the organisation of codes by clustering them to identify what Braun et al. call 'higher-level' patterns in the data. Twelve and ten themes emerged from the data collected in 2021 and 2022, respectively. These themes were then subjected to a further interrogation by KD to consolidate themes into clusters that represented broader patterns in the data. A fourth researcher (CH) provided a greater depth of meaning in the analysis, which led to the refinement and consolidation of themes and the development of recommendations.

Findings

Upon completion of the analysis, seven core themes were constructed out of the data from both years of data collection. The following section presents these core themes, along with exemplar quotes. Further supporting quotations can be found in Additional file 3.

Covid-19 and, Primary Care Capacity and Engagement of (theme 1)

The NHS LCD programme was mobilised when primary care was experiencing Covid-19 related pressures, such as the pausing of governance processes, the vaccine rollout, and the deferral and

alteration of annual diabetes reviews. By year two of the programme, interviewees discussed Covid-19 related backlogs, and staffing challenges.

> *"We've not got back to pre-pandemic levels at all. I think it is still very much a barrier, you know from a workforce perspective, from a backlog perspective*" (LL10 – Y2).

In this context of Covid pressures, the engagement of GP practices was mixed and variably defined. Engagement was discussed in relation to the generation of referrals in the healthcare system, where, by year two, percentages of referring practices fell between 42% and 85%. Engagement was also deduced from the number of practices that had taken part in LCD training.

> *"187 practices in [area], 87 of whom have referred. So that's 46.5% have referred"* (LL6 – Y2).

Interviewees also discussed referrals being generated by a small number of practices, or even single referrers. Specifically, the capacity of referrers, and their interest and passion for the NHS LCD programme were important aspects of engagement.

> *"But this practice that's done 56 is a single referrer"* (LL20 – Y2).

> *"it seems to be that you have one particular referrer who just gets the programme, sees the benefits of the programme and is passionate about it"* (LL10 – Y2).

The engagement of practices was not only dependent on referral staff, such as GPs, practice nurses or pharmacists. Interviewees discussed the important contributions of other colleagues from the wider community, including nurse or diabetes champions, dietitians, clinical leads, and care coordinators. Thus, the engagement of practices was dependent on the wider team across the whole health system.

Methods of Communication (theme 2)

Interviewees discussed a multitude of methods used to communicate information about the NHS LCD programme to the local health system. These methods included internal communication

channels, which typically relied on written communication, such as bulletins, newsletters, or emails. It was, however, ubiquitous across all interviews that these more formal means of written communication did not always reach their intended audience, either because the right gatekeepers in GP practices had not been identified, the information wasn't passed on, or primary care staff often suffered from "Bulletin blindness" (LL3 – Y1).

> "*it's every other month for the GP bulletin. Again, we want to avoid like sending out too many and people just sort of then just skimming over it, I don't know, bulletin blindness*" (LL3 – Y1).

Methods of communication also included synchronous information sessions, either, via means of attendance at existing forums, such as practice or health system meetings, or LCD specific sessions, such as drop in sessions or diabetes education events. Information sessions were predominantly delivered remotely via video conferencing, with in person sessions starting to be utilised by July 2022. Furthermore, the use of existing forums was seen as the most successful method of communication.

> "*Newsletters, e-mail circulars, they just land in practice inboxes and don't tend to be analysed, read or they're put to the bottom of the pile. I think practices are absolutely bombarded with communications, be it from the CCG [Clinical Commissioning Group], from NHS, from lots and lots of other sources. They just don't have the time or the capacity to wade through. Whereas if we can get ourselves a brief slot on a session that's delivered by senior stakeholder like the CMO [Chief Medical Officer], practices will tend to engage with that*" (LL15 – Y2).

Interviewees were unanimous about the need to find as many methods of communication as possible, while three localities discussed using more informal and unstructured methods of communication, such as an MS Teams channel, WhatsApp group or lunch and learn session. These methods of communication were seen as successful because they dealt with the issues of "bulletin blindness" while providing a means of reaching referral staff via more unstructured and informal means.

"So, every time we sort of have an opportunity, we will raise it to just try and drive the numbers up really" (LL23 – Y2).

"We also have a WhatsApp group for [area] with 140 GPs, practice nurses and practice pharmacists" (LL11 – Y1).

During mobilisation, communication was focused on practices, however, in year two, five localities reported communicating directly to patients, including via Facebook, press releases, audio visuals in GP waiting rooms, diabetes events and at the end of structured education for diabetes.

Approaches to Training (theme 3)

Interviewees discussed their localised approach to the adoption of training to support the mobilisation and delivery of the NHS LCD programme. Nine localities made training available - defined as a resource more than just the dissemination of written information – by providing synchronous webinars, and their recordings for asynchronous viewing. One locality did not make training available on the account of it not being necessary from their perspective.

"*That works on it's a sort of a 2 minute introduction from me to the programme itself, a 5 minute introduction from [provider] […] on how they operate. And then the rest of the session is delivered by the GP going through the referral process, going through the medication changes with Q&A time. And as I say, we record those sessions and then make them available as well*" (LL21 – Y2).

"*I think from our perspective, it was fairly cut and dry. You have a new service with a set of criteria, you have a mechanism whereby practices can identify and refer patients into that, as I say those parameters are fairly set in stone, we provide the supporting information. I guess we trust our clinicians to a certain degree to read and absorb that, and we didn't, I guess we didn't really feel that there was a need for formal training*" (LL12 – Y1).

Training was typically delivered by a team, including locality leads, IT support staff, providers, and clinical leads, with an emphasis on the latter being important for addressing the concerns of referral staff. The frequency of training varied but was overall provided infrequently across both years of data collection, with fewer synchronous sessions provided in year two.

> "*We did, we did all the bulk of the referrer training [at the start]. So, we haven't done anything since then up until this last couple of weeks where what we've done is, we've started to create more recordings*" (LL10 – Y1).

The aim of training varied between localities. It was made mandatory by four localities because it was perceived to lead to a higher proportion of eligible referrals and thought to be better for referral staff and account for patient safety. Conversely, training was made optional by five localities because participation in the programme was voluntary, and because mandatory training was seen as a barrier to generating referral numbers. However, the need for training overall coalesced around the need to address referrals barriers, ineligible referrals, and the need to improve engagement amongst GP practices.

> "*we were seeing quite a high proportion of inappropriate or ineligible referrals either because the patient didn't meet the eligibility criteria or the medication changes simply hadn't been filled in, either appropriately or indeed at all. So, what we wanted to do was go back out to practices and stress one, raising the awareness, but two, taking them through and giving them the opportunity to see how to go through the referral properly and make those medication changes appropriately*" (LL21 – Y2).

There were no national requirements on the use of training, and therefore training was managed based on local resource (time of key stakeholders), the views and experiences of locality leads and clinical leads, and in line with local approaches to training more broadly. Moreover, any training that was put in place and described by locality leads did not address inequalities.

Approaches to Incentivisation (theme 4)

Reimbursement systems are meant to create incentives to achieve policy objectives, or health-related targets (35). During mobilisation of the NHS LCD programme, four localities deployed incentivisation while a further two had their plans to incentivise delayed by Covid-19. As a result, by the second year of data collection, six localities were offering localised incentivisation, which varied in the amount and the time of payment. For example, one locality paid £200 per practice for attendance at LCD training. Three localities paid between £10.30 and £75 for each referral, of which one locality also paid £41.20 for patients starting TDR while a second paid an additional £10 for programme completion. A fifth locality paid £90 for starting TDR. A sixth locality introduced a local improvement scheme and paid GP practices a one off sum of £150 for making a referral to the programme, as well as £20 at 6- and 12-month for the completion of GP reviews.

> "*We released a local improvement scheme that incentivises practices. But they have to follow certain steps before they get a payment, they have to do the search, review the […] numbers that the search throws up, contact the patients, do the consultation, do the medication review and generate at least one eligible referral before we pay them £150*" (LL19 – Y2).

There was also variation in the reasons for incentivising. For some localities, incentivisation was deployed as a means of increasing the number and eligibility of referrals. Other interviewees discussed incentivising as a means of just remittance for the increased work of referral to the programme. Further still, there was an element of opportunism to incentivisation locally, and plans were devised in line with other services, or because the money was available.

> "*What we're trying to say is we recognise these consultations will take longer. We want to make sure that they're high quality, and therefore we will remunerate you in this pilot phase for this*" (LL13 – Y1).

The remaining four localities reasoned that incentivisation did not increase the number, or improve the quality of referrals, or stated that they did not have sufficient funds to incentivise.

> "*unless it's something that's really significant, the same practices that will refer anyway will refer whether they are incentivised or not. And the lower referring practices […] whether or not you're incentivised, they'll still be the lower referring practices. I don't think that any previous project has proven that incentivisation generates more referrals*" (LL8 - Y1).

During the second year of the programme, the NHS added the NHS LCD programme to the national weight management incentivisation scheme[2] (36), thus, all ten localities had a form of incentivisation, as well as their localised approaches to incentivisation.

Approaches to Referrals (theme 5)

Five localities staggered the rollout of participating practices over a period of 1 to 12-months (i.e., not all parts of each pilot area were encouraged to refer at the same time), due to capacity issues and the need to provide training before practices could refer. Yet, despite these differing approaches taken during mobilisation, all localities were required to adopt an open referral policy, i.e., any eligible patients could be referred within the referral limits at any time. The main reasons given for this approach were that an open referral policy facilitates high referral numbers and is considered fair or provides an equality of opportunity.

[2] To maximise referrals to weight management services, during the second year, the programme was included in the Weight Management Enhanced Service which enabled practices to claim a payment of £11.50 for each individual referred who was eligible for the Enhanced Service payment, and within an allocation limit of 20% of the number of patients on the practices Obesity Register.

"*You'll get some that will need an awful lot of hand holding. But we didn't have the time and the resource to set out and map out a phased introduction of those practices, so we just went with the big bang once we were happy that everything worked*" (LL6 – Y1).

"*I think it's because there are practices that have been generally quite good at referring in, and then there's always the practices that, that aren't so good, and we just wanted to make sure that there wasn't any inequality in patients being able to access it*" (LL7 – Y1).

In the first year of the programme, five localities allocated referral places at either a practice or area level, thus, putting some caps on referral numbers. These allocations were typically based on diabetes prevalence locally, for example, one locality initially allowed practices to refer 1% of their registered population with T2D. The remaining localities did not allocate referral places on the account that they did not want to add barriers to the generation of referrals. However, all five localities to initially use a referral allocation had removed that cap to encourage increased referral numbers by the second year of the programme.

"*We also thought we didn't necessarily want practices to think that they were restricted in terms of the number of referrals that they could send. So initially we just really wanted to kind of keep it open to encourage practices to refer anybody that they had identified as eligible*" (LL2 -Y1).

"We'd allocated everybody 1%. But actually, what we were finding was a high proportion of non-engaging practices. So therefore, we removed the cap of 1% so that people could refer as many as they found, and they wanted to" (LL20 – Y2).

During the second year of data collection, a greater number of localities subsequently discussed monitoring referrals to see who refers, before taking action to target individuals or areas where the number of referrals were low, or not representative of the population. Given this practice of monitoring referral numbers, inequalities or inequities were not considered or addressed in the

management of referrals by all localities from the start of the programme or were only starting to be considered during the latter stages of the programme. Some localities discussed a focus on inequalities as taking time, not being conducive to referral generation and an aspect to have only been discussed following the first year of the programme.

> "*I have started talking to our engagement officer about actually how are we going to target with that inequalities lens. […] I think as we're kind of going through this year we'll definitely put an inequalities lens on that and that's something I'm really keen to do*" (LL24 – Y2).

> "*what I found quite difficult with the inequalities aspect of this is it, it kind of seems to have raised its head quite recently*" (LL10 – Y2).

Barriers to referrals (theme 6)

By the second year of the programme the majority of locality leads reflected that referral numbers were below their referral trajectories. This resulted in frustrations: it was felt that referral numbers did not reflect the work locality leads were putting into the programme, which in turn resulted in a sense that some localities just did not know what worked to generate increased referrals.

> "*At the moment I'm really struggling to see that we're even gonna get to our figures" (LL10 - Y2).*

> *"It doesn't feel like the referrals are reflecting kind of the effort we are putting in*" (LL17 – Y2)

In this context of low referral numbers, multiple referral barriers were discussed by interviewees, and include process-based barriers, such as: ineligible referrals, the time needed for a referral and the fact that it was considered complicated.

> "W*e were seeing quite a high proportion of inappropriate or ineligible referrals*" (LL21 – Y2).

"*The comment that's often passed from referrers is oh it's complicated, it's a complicated criteria*" (LL6 – Y2).

Referrer-based barriers were also discussed, such as: staff turnover in the local health system and referrer confidence and expertise.

"S*taff turnover is like a really big issue. We worked with our provider to get like time at various forums for practice managers, nurses, you know even with GPs, social prescribers. But the turnover is so high it's almost as if we need to do that on a constant basis*" (LL14 – Y2).

"*I think again this comes down to confidence though, 'cause in my experience of going into practices it's not always that they don't know what they're doing, they just need a reminder of how to do it or you know, obviously it's a live clinical system*" (LL16 – Y2).

Some locality leads also discussed a lack of database searches to identify eligible patients. Instead, and to varying degrees, all localities relied on opportunistic referral touch points, such as annual reviews, to identify eligible patients. However, with Covid-19 related disruption and the reliance on staff engagement in the local health system, localities discussed a lack of opportunistic referral touch points.

"*Some of the barriers would include one, the search function itself is not, not capturing the totality of the patient population, because the information simply isn't up to date or correct. Second is the capacity within practices themselves to run the searches and then act upon them appropriately when there's so much other stuff going on*" (LL21 – Y2).

"*I think the biggest issue for the LCD has been that patients haven't been seeing their clinicians face to face*" (LL18 – Y2).

A number of localities had started to address these barriers, and in doing so made the referral process easier for referral staff. At the time of data collection, at least one locality had developed a referral pop-up and had shared it amongst several other localities. The referral pop-up maximised

opportunistic touch points by prompting referral staff to discuss the programme with eligible patients, whilst also alleviating the need to run searches. Another locality was potentially providing additional staff to run searches, whilst three other localities were trying to increase referral touch points by involving clinical pharmacists, dietitians, and care coordinators in the referral process.

> "*Late last year we started working on a clinical system pop up. So, these pre-runs the searches and caches them in a report. Then when the patient's record is opened by an appropriate clinician […] [LCD] will pop up […][and what] they're presented with is about 95, 98% populated referral form. So, as it's gone along it prepopulates and the only things that they're left to do are any free text that the field needs to go on to support the referral and medication changes*" (LL6 – Y2).

> "*the second approach that we're looking at doing is putting in additional staff to the provider and getting the GP practices to consent to running a search and sharing the eligible participants with the provider. So then then the provider can ring them up and say, would you like to join one of these sessions*" (LL20 – Y2).

The Importance of Collaboration (theme 7)

Locality leads discussed the importance and positive impact of collaboration with fellow public health colleagues in mobilising and supporting the delivery of the NHS LCD programme. Steering groups, and to a degree programme boards, which was protected leadership time, enabled oversight of the programme and brought together a broad representation of people who could share ideas, and converse constructively about the challenges of delivering the programme. Despite some Covid-19 disruption, these governance structures were largely unchanged across the two years of the programme.

"*It was important for us that the steering group wasn't just those that were going to be directly involved in this, so we have dietetics representation, we've had varying clinical inputs, we've got a GP practice based nurse at the moment who's got a particular interest in research and obesity, so she sits on it and gives a really good clinical insight. Our clinical leads on it. We've also got population health and public health representation. So, we've gone quite broad in terms of where those people sit, it's open to all localities […]. We wanted people in that group that, that would constructively challenge*" (LL12 – Y1).

The notion of collaboration also includes the role of the provider and their contributions towards the mobilisation and delivery of the programme. Provider representatives attended LCD engagement events, contributed to the delivery of training, and sat on steering groups. Overwhelmingly, the relationship between the locality leads and providers was discussed positively. These views of the providers are held in a context where the locality lead role has been filled by a number of different staff with different levels of experience, and where those in post have reported having numerous other responsibilities. Overall, locality leads reported having other pressures which limited the time they could spend on the NHS LCD programme, however, the support and time put in from the provider enabled delivery to progress.

"*It's been a really, really good working relationship. Really positive I think right from the outset […]. In terms of how easy the team have been to work with, really kind of positive. I think that has made a huge difference actually, in terms of, you know, working together collaboratively, as a team, I don't think that could have really been any better to be honest*" (LL2 – Y1).

"*It would be a couple of hours per week is the amount of time I'm able to put into LCD*" (LL21 – Y2).

Discussion

In this paper we have provided insights from the evaluation of the NHS LCD programme (which will be renamed NHS Type 2 Diabetes Path to Remission Programme when rolled out nationally in June 2023) by exploring the experiences of NHS staff involved in the mobilisation within the wider local health system. A significant investment for the NHS, the NHS LCD programme is based on outcomes from two recent UK clinical trials (21, 22), however, translating controlled clinical trials into routine service delivery remains a significant challenge. Thus, the data presented in this paper elucidates this challenge by highlighting the approaches and context in which the NHS LCD programme is being delivered, and contributes to a larger programme evaluation (Re:Mission study) (33, 37).

At its most fundamental level, our findings demonstrate the variation and differences in the approaches taken when mobilising the NHS LCD programme. Key aspects of these approaches, such as training, incentivisation and management of referrals (allocation, rollout to practices), and the human and financial resource they depend on, were utilised, and justified differently across the ten pilot localities. Covid-19 presented a specific challenge, which meant the programme was mobilised and delivered in a context that undoubtedly had a constraining influence on the capacity and capability of the local health system. The findings also highlight a lack of focus on proportionate universalism, and although delivery is ultimately the responsibility of the service providers, local health systems could play a more prominent role in driving this agenda through the mobilisation process.

Despite an ongoing debate about the use of targeted and universal strategies to address health inequities (38), proportionate universalism is an example of a policy approach or strategy considered appropriate for tackling the social gradient in health. Calling for a combination of universal and targeted actions, Marmot (5, p.16) defines proportionate universalism as universal actions "with a scale and intensity that is proportionate to the level of disadvantage". Proportionate universalism, therefore, is conceived as a social policy response to inequities – the state in which people do not have a fair and just opportunity to attain health. This is important because it is inequities that create,

perpetuate and exacerbate inequalities, thus, inequalities or the social gradient in health is the manifestation of inequities (10, 30).

An equity perspective from the start

During the first year of data collection, five of the ten localities adopted referral allocations based on the size of eligible populations. While these localities did not explicitly target specific populations, by considering how eligibility was distributed they adopted a 'secondary' level of targeting within their referral policy. This level of targeting is considered secondary because it ensures that areas or practices with the highest need are given more opportunities to refer but does not take measures to ensure that certain groups within these areas or practices subsequently receive referrals.

Our findings show that the targeting, or the equitable distribution of referrals was not something adopted by all localities, and for localities that started with referral allocations, there was a tension between generating referrals and doing so equitably. Specifically, despite the best intentions of some localities, there was a tension between generating referrals equitably and utilising all the places available, and therefore maximising the benefit from the NHS LCD programme for the whole population. Furthermore, while the lack of a referral allocation may result in referrals coming from a small number of practices, it is possible these referrals are generated equitably. Nonetheless, referral allocations adopted in year one, were later changed in order to meet overall referral numbers, which often relied on a small number of practices or referral staff. Similarly, a lack of commitment to concrete action to reduce inequalities in local systems has previously been reported (39). Yet, following the ratification of the Health and Social Care Act 2012, local health systems have had an increased responsibility to address inequalities in access to health and health outcomes (40).

To address inequalities, or achieve equitability, there is a need for a suite of measures at varying levels, including at a national or policy level, organisational or planning level (local health systems), service delivery level and a lifestyle level (41-45). By implication, there is also a need to adopt

443 an equity perspective from the start, as a degree of responsibility for identifying and addressing the
444 inequities in healthcare falls upon those doing public health work (46). Thus, the organisation and
445 planning of resources at a local health systems level can be managed within a proportionate
446 universalism approach. As a result, the decisions locality leads make regarding the organisation and
447 planning of resources at a local health system level has an impact on the equitability of programme
448 delivery and should be duly considered.

449 A health equity impact assessment (HEIA), a process of exploring or mitigating the impacts of
450 decisions on inequalities during decision making, is one such tool that encourages an equity
451 perspective from the start (42). When conducted meaningfully a HEIA can act as a catalyst to equity-
452 focused organisational change and can improve health equity by promoting and encouraging
453 considerations of health equity in policies and programmes, such as the deployment of resources at
454 the disposal of local health systems. The local completion of a HEIA has been recommended by Public
455 Health England (44) who advocated positioning health equity at the heart of all strategies and policies
456 across local health systems. Doing this can reduce the negative impact of policy and programmes that
457 could further widen health inequalities (42).

458

459 ## Managing resources equitably

460 Overall, our findings demonstrate the importance of training for addressing referral barriers
461 and ineligible referrals, as well as improving engagement amongst GP practices. Similarly, the use of
462 information sessions proved effective at communicating information about the programme to the
463 local health system, especially in light of the phenomenon of "bulletin blindness" – where written
464 communications do not always reach referral staff. Therefore, training and/or synchronous
465 information sessions can be considered important in enabling the effective referral of eligible patients
466 to the NHS LCD programme. For example, our findings show that barriers to referrals include referrer-
467 based barriers, many of which can be addressed by providing appropriate training. Indeed, the depth

of knowledge within participating stakeholders in the health system, and the subsequent need for training has been shown to be important for the effective delivery of large diabetes programmes (47).

There is also a need to consider the proportionality of service resourcing and provision when delivering health-based interventions. Time could be distributed differentially at a planning or organisational level, for example, by delivering training amongst GP practices proportionate to their need, judged by the prevalence of T2D in their population, or their level of engagement across multiple programmes. However, our results show that time was not managed equitably by all participating localities, because training and synchronous information sessions were delivered variably.

Specifically, many localities were reactive in allocating additional time and resource to support practices or areas with lower rates of referral. There was less evidence of proactive allocation of time and resource at the initial stages of mobilisation to avoid intervention-generated inequalities in referral rates from potentially developing at the outset. Therefore, many localities did not use resource and time proportionately from the start, thus missing a potential opportunity to adopt an equity perspective in service resourcing and provision. Indeed, where local health systems have allocated resource that is proportionate to need, instead of simply supporting those who are easiest to support, proportionate universalism has been an effective policy approach (44).

The introduction of incentivisation has been associated with an improvement in quality of primary care for people living with diabetes (48). However, we found that economic resource, used as an incentive, missed a potential opportunity to use financial incentives to address inequalities (49). As a consequence, the actions of locality leads run the inherent risk of exacerbating existing inequalities, if patients who are more likely to achieve favourable outcomes are selected (50). However, there is limited evidence to support the use of incentives to address inequalities, and it has been suggested that resource allocation matched to increased needs might have a greater impact on health inequalities than the type of incentivisation (35). Nonetheless, the approaches to incentivisation have the potential to contribute to a more equitable programme and should be considered through an

493 equity lens. This is important, because any programme that does not take due diligence towards
494 equities, runs the risk of becoming an inequality paradox, thus, becoming markedly more beneficial
495 for individuals of higher socio-economic status, and of White ethnicity.

496 The importance of collaboration within the local health system was also demonstrated in this
497 study, for example, a close working relationship with providers (51) and community involvement to
498 identify services users (47) have also been reported by others. Furthermore, the presence of a Steering
499 Group was more often than not discussed as an important part of the NHS LCD programme, which
500 presented an ideal location for the equitable management of resources. Findings from this work help
501 to build a comprehensive picture of the programme mobilisation, which will be further supported by
502 insights from NHS staff responsible for patient referral to the programme.

503

504 ## Limitations

505 This is the first study to explore the experiences of local health service leads with the responsibility for
506 the mobilisation of a national Low Calorie Diet programme of this nature in real-world settings.
507 However, there are a number of limitations to the current study: 1) The programme was mobilised in
508 the middle of the Covid-19 pandemic, which placed significant strain within the health system and will
509 have undoubtedly impacted programme mobilisation. 2) The wider health system, including the
510 position of locality lead, experienced a high turnover of staff during this tumultuous period, meaning
511 follow up interviews were often conducted with different personnel, which will have impacted
512 consistency in the findings between years 1 and 2. 3) These findings alone do not permit us to conclude
513 which approaches and methods are the most successful when judged against their impact on the
514 identification and generation of referrals. Instead, we have attempted to share the perspectives of
515 locality leads, and as we move away from first order constructs, we have shared our interpretations
516 of the data using inequalities as a lens for interpretation. 4) There is also a need to consider the impact
517 on equity at a national or policy level, which in the case of the current study precedes the actions of

locality leads, and therefore has not been considered. This is important as an equity perspective from the start needs to consider policy, which has not always been presented convincingly (52, 53).

Recommendations

Based on our findings the following recommendations may help inform the equitable mobilisation of the NHS LCD (and similar) programmes at a local health system level in the future:

1. Localities could consider an approach to addressing inequalities at the start of programme mobilisation, such as a local HEIA, and review it regularly to ensure it remains fit for purpose.
2. Training and/or information sessions could be delivered equitably, for example, by prioritising delivery to parts of the local health system with a high proportion of eligible patients and/or low engagement.
3. Financial incentivisation can be used to increase the equity of the NHS LCD programme, but should be measured to ensure this is achieved. For example, outcome incentives, whereby practices receive payment for the number of patients referred, have been shown to stimulate more participation (54). However, they could also adopt an equitable perspective, or be proportionate to the prevalence of T2D locally, by paying more to areas with a greater need.
4. Built on the collaboration within the wider health system, a means of regularly monitoring uptake in addition to adopting an equity perspective from the start is reasonable, as is responding to this data in a timely manner to address any emerging inequalities.

Conclusions

Health inequalities remain a significant challenge, and while the healthcare system may not be able to remedy inequalities that transcend healthcare, such as socioeconomic inequalities, we should expect that the healthcare system does not exacerbate existing inequalities. As a result, it is important

that health service leads adopt an equity perspective from the start of any new service mobilisation, and in doing so manage resources equitably. This will help to reduce the potential occurrence of intervention generated inequalities and avoid the possibility of programmes becoming an inequality paradox. Perhaps only when inequities are considered at a planning or organisational level, can we expect to see more favourable outcomes in health and access to healthcare between different socio-demographic groups.

Abbreviations

T2D: Type 2 Diabetes; **NHS**: National Health Service; **TDR**: Total Diet Replacement; **LCD**: Low Calorie Diet Programme; **HEIA**: Health Equity Impact Assessment; **LL**: Locality Lead; **Y**: Year.

Declarations

The views expressed in this paper are those of the authors and not necessarily those of the NHS or the National Institute for Health Research.

Ethics Approval and consent to participate

All methods were carried out in accordance with relevant guidelines and regulations. The Re:Mission study was granted ethical approval by the Health Research Authority (HRA) on 5 July 2021, REC ref: 21/WM/0136. Participants provided both oral and written informed consent to participate in the Re:Mission study, including consent for publication.

Consent for publication

Not applicable

Availability of data and materials

The datasets generated during this current study are not publicly available due to reasons of privacy and confidentiality, and because of the inability to de-identify the data. Additional knowledge of the data can be available from the corresponding author on reasonable request.

Additional File 1 presents an overview of pilot areas, delivery models and programme structure. Additional File 2 provides an overview of the COREQ checklist. Additional File 3 provides further quotations from the data.

Competing interests

Dr Chirag Bakhai is a primary care advisor to the national diabetes programme for NHS England and NHS Improvement.

Funding

This work was supported by the National Institute for Health Research, Health Services and Delivery Research [NIHR 132075]. The NHS England Low-Calorie Diet Pilot is funded by NHS England.

Author contributions

LE secured funding for the Re:Mission study, and with CH, DR and KD designed the outline for the current work and managed access with NHS England. KD and CF conducted fieldwork. KD, CF, KK and CH contributed to the analysis of data. All authors contributed to drafts of this paper and have reviewed and agreed this final draft that is submitted for publication.

Acknowledgements

The authors would like to acknowledge Clare Helm from NHS England, who has worked on the coproduction of this study; identification of study aims, gatekeeper to participants who were previously unknown to the interviewers and provided feedback on an earlier draft of this manuscript.

The authors would also like to acknowledge the Patient and Public Involvement team that have worked on the coproduction of the Re:Mission study, including Ken Clare, Abimbola Ojo, Jennifer Teke, Mike Willis, Gulsoom Akhtar, Beth Clegg and Clair Goddard.

Members of the steering and oversight groups are also acknowledged by the authors for their input and involvement in the Re:Mission study, including the clinical leads Dr Mark Ashton and Dr Chirag Bakhai.

The Re:Mission study includes a multidisciplinary team of academics from across the North of England. The authors would like to acknowledge all members of the team including Dr Jamie Matu, Prof Jim McKenna, Dr Susan Jones, Pat Watson, Dr Simon Rowlands, Dr Tanefa Apekay, Dr Stuart Flint, Prof Janet Cade, Dr Adam Martin, Dr Maria Bryant, Dr Jordan Marwood, Dr Tamara Brown, Dr Wendy Burton, Mick Martson, Pooja Dhir and Tamla Evans.

References

1. Gatineau M, Hancock C, Holman N, et al. Adult obesity and type 2 diabetes. London: Public Health England; 2014.
2. NHS Digital. Health Survey for England, 2021 part 1. London: National Statistics; 2022.
3. Public Health England. Diabetes prevalance model. London: Public Health England; 2016.
4. Marmot M. The Health Gap: the challenge of an Unequal World. London: Bloomsbury; 2015.
5. Marmot M. The Marmot review: Fair society, healthy lives. The Strategic Review of Health Inequalities in England Post-2010. London: The Marmot Review; 2010.
6. Green H, Fernandez R, MacPhail C. The social determinants of health and health outcomes among adults during the COVID-19 pandemic: A systematic review. Public Health Nursing. 2021;38(6):942-52.

615 7. Marmot M, Allen J, Goldblatt P, et al. Build Back Fairer - The COVID-19 Marmot Review. The
616 Pandemic, Socioeconomic and Health Inequalities in England. London: Institute of Health Equity; 2020.
617 8. Khunti K, Feldman EL, Laiteerapong N, et al. The impact of the COVID-19 pandemic on ethnic
618 minority groups with diabetes. Diabetes care. 2023;46(2):228-36.
619 9. Ricci-Cabello I, Ruiz-Perez I, De Labry-Lima AO, et al. Do social inequalities exist in terms of the
620 prevention, diagnosis, treatment, control and monitoring of diabetes? A systematic review. Health &
621 social care in the community. 2010;18(6):572-87.
622 10. Bleich SN, Jarlenski MP, Bell CN, et al. Health inequalities: trends, progress, and policy. Annual
623 review of public health. 2012;33:7-40.
624 11. Cleland CL, Tully MA, Kee F, et al. The effectiveness of physical activity interventions in socio-
625 economically disadvantaged communities: a systematic review. Preventive Medicine. 2012;54(6):371-
626 80.
627 12. Lorenc T, Oliver K. Adverse effects of public health interventions: a conceptual framework.
628 Journal of Epidemiology and Community Health. 2014;68(3):288-90.
629 13. Alvaro C, Jackson L, Kirk S, et al. Moving Canadian governmental policies beyond a focus on
630 individual lifestyle: some insights from complexity and critical theories. Health Promotion International.
631 2010;26(1):91-9.
632 14. Whyte MB, Hinton W, McGovern A, et al. Disparities in glycaemic control, monitoring, and
633 treatment of type 2 diabetes in England: a retrospective cohort analysis. PLoS medicine.
634 2019;16(10):e1002942.
635 15. Frohlich KL, Potvin L. Transcending the known in public health practice: the inequality paradox:
636 the population approach and vulnerable populations. American Journal of Public Health.
637 2008;98(2):216-21.
638 16. Castellana M, Conte E, Cignarelli A, et al. Efficacy and safety of very low calorie ketogenic diet
639 (VLCKD) in patients with overweight and obesity: A systematic review and meta-analysis. Reviews in
640 Endocrine and Metabolic Disorders. 2020;21(1):5-16.
641 17. Sellahewa L, Khan C, Lakkunarajah S, et al. A systematic review of evidence on the use of very
642 low calorie diets in people with diabetes. Current diabetes reviews. 2017;13(1):35-46.
643 18. Caprio M, Infante M, Moriconi E, et al. Very-low-calorie ketogenic diet (VLCKD) in the
644 management of metabolic diseases: systematic review and consensus statement from the Italian
645 Society of Endocrinology (SIE). Journal of endocrinological investigation. 2019;42(11):1365-86.
646 19. Rehackova L, Arnott B, Araujo-Soares V, et al. Efficacy and acceptability of very low energy diets
647 in overweight and obese people with Type 2 diabetes mellitus: a systematic review with meta-analyses.
648 Diabetic medicine. 2016;33(5):580-91.

649 20. Astbury NM, Piernas C, Hartmann-Boyce J, et al. A systematic review and meta-analysis of the
650 effectiveness of meal replacements for weight loss. Obesity reviews. 2019;20(4):569-87.
651 21. Lean ME, Leslie WS, Barnes AC, et al. Durability of a primary care-led weight-management
652 intervention for remission of type 2 diabetes: 2-year results of the DiRECT open-label, cluster-
653 randomised trial. The lancet Diabetes & endocrinology. 2019;7(5):344-55.
654 22. Astbury NM, Aveyard P, Nickless A, et al. Doctor Referral of Overweight People to Low Energy
655 total diet replacement Treatment (DROPLET): pragmatic randomised controlled trial. bmj. 2018;362.
656 23. Ard JD, Lewis KH, Rothberg A, et al. Effectiveness of a Total Meal Replacement Program
657 (OPTIFAST Program) on weight loss: results from the OPTIWIN Study. Obesity. 2019;27(1):22-9.
658 24. NHS England. The NHS Long Term Plan. NHS; 2019.
659 25. Bhat K, Easwarathasan R, Jacob M, et al. Identifying and understanding the factors that
660 influence the functioning of integrated healthcare systems in the NHS: a systematic literature review.
661 BMJ open. 2022;12(4):e049296.
662 26. NHS. Low calorie diets to treat obesity and Type 2 diabetes. 2019 [Available from:
663 https://www.england.nhs.uk/diabetes/treatment-care/low-calorie-diets/.
664 27. National Health Service Act 2006, Stat. c41 (2006).
665 28. Equality Act 2010, Stat. c15 (2010).
666 29. NHS England and NHS Improvement. NHS Low Calorie Diet Programme – face to face [one to
667 one/group] delivery model - Service Specification. England2019.
668 30. Williams O, Coen SE, Gibson K. Comment on: "Equity in Physical Activity: A Misguided Goal".
669 Sports Medicine. 2019;49:637-9.
670 31. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a
671 32-item checklist for interviews and focus groups. International journal for quality in health care.
672 2007;19(6):349-57.
673 32. Pawson R. The science of evaluation: a realist manifesto: sage; 2013.
674 33. Ells L, Radley, D., Homer, C. A coproduced mixed method evaluation of the NHS England Low-
675 Calorie Diet implementation pilot. Protocol. 2021 12th March 2021.
676 34. Braun V, Clarke V, Weate P. Using thematic analysis in sport and exercise research. In: Smith B,
677 Sparkes AC, editors. Routledge Handbook of Qualitative Research in Sport and Exercise. London:
678 Routledge; 2016. p. 191-205.
679 35. Tao W, Agerholm J, Burström B. The impact of reimbursement systems on equity in access and
680 quality of primary care: a systematic literature review. BMC health services research. 2016;16(1):1-10.
681 36. NHS England. Enhanced Service Specification Weight management 2022/23 - Version 1. NHS;
682 2022.

683 37. Re:Mission. Re:Mission - An Evaluation of the NHS Low Calorie Diet Programme 2020 [Available
684 from: https://www.remission.study/.
685 38. Fisher M, Harris P, Freeman T, et al. Implementing universal and targeted policies for health
686 equity: lessons from Australia. International Journal of Health Policy and Management.
687 2022;11(10):2308-18.
688 39. Olivera JN, Ford J, Sowden S, et al. Conceptualisation of health inequalities by local healthcare
689 systems: A document analysis. Health & Social Care in the Community. 2022.
690 40. Health and Social Care Act 2012. [Available from:
691 www.legislation.gov.uk/ukpga/2012/7/contents/enacted.
692 41. Ford J, Sowden S, Olivera J, et al. Transforming health systems to reduce health inequalities.
693 Future Healthcare Journal. 2021;8(2):e204.
694 42. Sadare O, Williams M, Simon L. Implementation of the Health Equity Impact Assessment (HEIA)
695 tool in a local public health setting: challenges, facilitators, and impacts. Canadian Journal of Public
696 Health. 2020;111(2):212-9.
697 43. Peeters A, Backholer K. How to influence the obesity landscape using health policies.
698 International Journal of Obesity. 2017;41(6):835.
699 44. Public Health England. Local action on health inequalities: Tackling health inequalities through
700 action on the social determinants of health: lessons from experience. London: Public Health England;
701 2014.
702 45. Mackenzie M, Hastings A, Babbel B, et al. Proportionate Universalism as a Route to Mitigating
703 Health Inequalities? Exploring Political, Policy and Practice Uncertainties in Times of Austerity. In: Fee
704 D, Kober-smith A, editors. Inequalities in the UK. Bingley: Emerald Publishing Limited; 2017.
705 46. Brassolotto J, Raphael D, Baldeo N. Epistemological barriers to addressing the social
706 determinants of health among public health professionals in Ontario, Canada: a qualitative inquiry.
707 Critical Public Health. 2014;24(3):321-36.
708 47. Rodrigues AM, Haste A, Penn L, et al. Stakeholders' perceptions and experiences of the National
709 Health Service diabetes prevention programme in England: qualitative study with service users,
710 intervention providers and deliverers, commissioners and referrers. BMC health services research.
711 2020;20:1-13.
712 48. Kontopantelis E, Reeves D, Valderas JM, et al. Recorded quality of primary care for patients
713 with diabetes in England before and after the introduction of a financial incentive scheme: a
714 longitudinal observational study. BMJ quality & safety. 2013;22(1):53-64.
715 49. Oliver A, Brown LD. A consideration of user financial incentives to address health inequalities.
716 Journal of health politics, policy and law. 2012;37(2):201-26.

50. Koshy E, Millett C. The 'Quality and Outcomes Framework': improving care, but are all patients benefiting? : SAGE Publications Sage UK: London, England; 2008. p. 432-3.
51. Shaw SE, Smith JA, Porter A, et al. The work of commissioning: a multisite case study of healthcare commissioning in England's NHS. BMJ open. 2013;3(9):e003341.
52. Carey G, Crammond B, De Leeuw EJ. Towards health equity: a framework for the application of proportionate universalism. International Journal for Equity in Health. 2015;14(1):81.
53. Coggon J, Adams J. 'Let them choose not to eat cake...': Public health ethics, effectiveness and equity in government obesity strategy. Future Healthcare Journal. 2021;8(1):49.
54. McManus E, Elliott J, Meacock R, et al. The effects of structure, process and outcome incentives on primary care referrals to a national prevention programme. Health Economics. 2021;30(6):1393-416.