HEALTH AND SPORT COMMITTEE

WHAT SHOULD PRIMARY CARE LOOK LIKE FOR THE NEXT GENERATION?

SUBMISSION FROM: Ascensia Diabetes Care

Submission of a digital health intervention for patient group T2 diabetes, Prediabetes and Obesity. This platform addresses and supports priorities outlined in the Health and Sport committee’s report:

Use of technology

- Use of technology /wearables to monitor health e.g. blood pressure, diabetes and sharing information with relevant professionals.

Patient-centred approach

- Supports greater engagement where triaging to service most appropriate.

Prevention

- Encouragement and education for healthy behaviour e.g. healthy eating and physical activity.
- Use of technology for prevention

Of those surveyed over two thirds of respondents would be willing to take part in on-line education, with over 82% content to use digital resources to access information.

Challenges within Scotland:

- Spend on Type 1 and Type 2 diabetes medicine makes up 8% of total Primary care spend in Scotland £93,452,065.
- 4.8% of the Scottish Population have T2 diabetes with an increase of 39% from 2007 and 2016
- T2 patients with a recorded BMI 87.3% are either overweight or obese. (SDS2017)
- Average attendance of structure education across Scotland in 2017 was 3.7% (9,918)

Overview of programme: Low Carb Program (LCP) - https://www.lowcarbprogram.com

The LCP is a behaviour change programme of structured education in type 2 diabetes, facilitated in primary care by Ascensia Diabetes Care who can provide an implementation programme for training at practice level to ensure high levels of patient engagement. The service includes an online application and implementation support.
Programme details:

The Low Carb Program is an award-winning, evidence based, patient-centred behaviour change platform that facilitates sustainable weight loss and blood glucose control through education, resources and, most importantly, support for people living with type 2 diabetes, prediabetes and obesity. It is available on both mobile and desktop devices; web, iOS and Android. The Low Carb Program is clinically validated and delivers an extensive range of clinical and health economic outcomes including HbA1c, weight loss, and reduction in patient medication use.

The Low Carb Program has been developed with Dr David Unwin in 2015 (Senior Medical Advisor; NHS Innovator of the Year 2016; and RCGP National Champion for Collaborative Care in Obesity and Diabetes), and the feedback of over 20,000 people with type 2 and prediabetes.

Healthcare Professional Education and Support:

To ensure that full implementation is successful the programme delivered by Ascensia Diabetes Care includes service support to ensure that HCPs in primary care are equipped and confident to use the programme with their patients.

A major component of this is to provide comprehensive training for healthcare professionals according to their requirements and the needs of their patient population.

Extensive training, support materials and healthcare professional community are also available through the LCP HCP Platform.

Ascensia Diabetes Care will also work with the HBs to develop a suitable programme of direct patient engagement using appropriate communication channels for the local community.

Support for Patients: Structured Education

Members participate in an initial 12-16-week structured therapeutic nutrition and wellness education program. Education is personalised to disease type for people with type 2 diabetes and prediabetes. Participants receive data-led education on additional modifiable risk factors including sleep, stress, mental health, smoking cessation and blood glucose testing.

Education is approved by the Quality Institute for Self-Management Education and Training (QISMET) to meet Quality Standards: QIS2015, DSME and SS2Q (QISMET 2018). The platform is QISMET approved for T2 diabetes, Obesity and NAFLD.

Community peer support

Participants receive support from a community of over 420,000 members from 190 countries. This includes program champions (graduate members) and is moderated by a team of community members, and program staff.
Behaviour change mentoring

Participants have access to behaviour change mentors to keep them accountable to their goals and check-in on habits and motivation.

Goal identification and setting

Guided goal setting during personalisation and check-in and feedback on goal progress is provided within the digital architecture at regular intervals.

Resources

Participants receive a personalised library of resources including personalised budget-specific meal plans tailored to dietary preferences, over 1,000 searchable recipes, food swap lists, guides, and over 170 frequently asked questions. Identified demographics receive culturally relevant and engaging resources.

Behaviour change maintenance

Participants are placed on an infinite behaviour change maintenance pathway which includes AI-recommended (or curated) education, support and resources once the implementation phase is complete. Participants have access to Lifestyle, a daily-updated area of the app dedicated to health and lifestyle medicine, including expert interviews, weekly cookery videos, seasonal features, recipes, guides, conference highlights, expert interviews and presentations all aligned with the latest evidence-base.

Food diary

Participants receive access to a food diary, barcode scanner and a searchable database of foods, brands and units.

Health tracking and wearable/device integration

Participants have the ability to log their weight, blood glucose, medication, blood pressure, cholesterol, ketones, and mood to track their progress. Members can sync with Apple HealthKit, Fitbit, Nokia, Alexa and BG monitors. Patients will obtain this data from the use of their own equipment or as a result of a clinic appointment and enter the data into their program accordingly.

Data insights and AI-led feedback

Participants receive insights based on their data. Insights are provided after 4 weeks of use.

Multi-platform engagement

The Low Carb Program is available on iOS, Android and on the web. Complementary watch apps are available for both the Apple Watch and Android Wear OS.
**Indication of use:** The Low Carb Program is indicated for people living with type 2 diabetes, prediabetes and obesity and it is unsuitable for people with type 1 diabetes. The impact of the LCP is in three areas:

- **Sustainable weight loss** - People with type 2 diabetes or prediabetes who complete the program sustainably lose an average of 7kg at 1-year.

- **Lower HbA1c** - Most people who complete the program improve blood glucose control whilst reducing or eliminating medications and losing weight.

- **Reduced medication dependency** - More than 40% of people with type 2 diabetes who start the program on medication eliminate a medication from their regime at 1-year.

**Technology Assessment**

- The Low Carb Program is QISMET approved, has a CE mark and is an MHRA-regulated Class I Medical Device with peer-reviewed, published outcomes. The platform is GDPR compliant, with all data held and transferred within England, United Kingdom and meets Mobile Application Security Verification Standard (MASVS) Level 2+R compliance.

- The platform is featured in the NHS Apps Library and part of the NHS Innovation Accelerator for 2019-2020.

**Target patient group:** Patients suitable for this programme can include newly diagnosed and people with type 2 diabetes, people with obesity. The programme is also indicated for people with pre-diabetes to provide behaviour and lifestyle change through the use of the digital solution.

**Clinical evidence base**

Research into low carbohydrate diets in people with type 2 diabetes typically show that low-carb diets are at least as good as low-fat diets (Diabetes UK, 2019). Low-carb diets tends to perform significantly better in terms of:

- Improved blood glucose levels (HbA1c)
- Greater rates of remission – able to control diabetes well without the need for medication

Low-carb diets are usually either as effective, or slightly more so, than low-fat diets in terms of:

- Reduced insulin resistance
- Achieving weight loss
- Improving cholesterol levels
- Lowering blood pressure levels
- Improved remission
A 2014 study by the Second University of Naples, showed that a low-carbohydrate Mediterranean diet produced significantly greater remission rates than a low-fat diet (Esposito et al, 2014). The study showed that the low-carb diet led to 14.7% of participants achieving remission in the first year and 5% achieving remission after six years. By comparison, those following the low-fat diet had remission rates of 4.1% after the first year and 0% after six years.

When low-carb and low-fat diets have been directly compared, low-carb diets have typically outperformed the low-fat diets. Rock et al. (2014) compared equal calorie slimming club diets showing the low-carb diet to be more effective in reducing HbA1c, body weight, triglycerides and total cholesterol. Mayer et al. (2013) showed that a low-carb diet outperformed a low-calorie, low-fat diet that was supplemented with the weight loss drug Orlistat. The results showed similar weight loss, whereas the low-carb diet was most effective at reducing HbA1c levels and dependence on medication. Dietary environments are also critically important where access to particular types of food (for example in hospitals, care homes and other institutions as well as family meal choices) as impact on diabetes control (Cradock et al, 2017).

Westman et al. (2008): A low-carb ketogenic diet was compared with a low-glycaemic index diet. The low-carb group had a significantly greater reduction in HbA1c than the low-GI diet group (17 mmol/mol compared with 6 mmol/mol). The low-carb group also showed the greatest improvements in terms of improved cholesterol levels and reduced dependency on diabetes medication.

Diabetes Digital Media (DDM) is conducting a three-year study on a randomly selected cohort of people who joined the Low Carb Program. One-year outcomes have been published in JMIR Diabetes. The first evidenced benefit is a 71% platform retention at 1-year, which is unrivalled for any digital platform. Engagement within the platform is critical as without engaging users, behaviour change is not possible.

For people with type 2 diabetes who complete the platform, outcomes were:
- 7.4kg weight loss
- 13mmol/mol HbA1c reduction
- 39% place HbA1c under type 2 diabetes threshold
- 26% place type 2 diabetes in remission

Remission is defined as an HbA1c under type 2 diabetes threshold and on no medication or metformin-only. In addition, to this:
- 40% of people on medication eliminate at least one treatment from their regime
- 60% of people on insulin eliminate or reduce it from their regime

The retention and health outcomes evidenced by the Low Carb Program are pioneering for a digital platform.
Primary care reference site

DDM have clinical evidence of the Low Carb Program in practice, where it is being used by patients with type 2 diabetes through NHS Symphony Healthcare health coaches. Clinical data demonstrates for the 73 patients referred into the programme at 6 months:

- 97% uptake of the programme from referral
- 86% completion of all modules of the programme
- 8.7% body weight loss

Pilot: Wincanton Health Centre aim to support 50 patients with type 2 diabetes to achieve type 2 diabetes remission in 12 months.

Metrics:
- Outcome measures: HbA1c, Weight
- Process measures for Low Carb Program: Number of patients enrolled, percentage completing program
- Balancing measures: Adverse events, medication usage

Settings: Wincanton Health Centre is a general practice in the South West of England with a patient population of 8,800. There are 452 patients with type 2 diabetes within this population. Wincanton Health Centre is part of the larger primary care organisation; Symphony Healthcare Services. The practice employs health coaches whose role includes supporting person-centred care, including providing behaviour change support.

The Low Carb Program pilot was introduced as a quality improvement project. This would ensure a continuous improvement process was followed, contributing to knowledge on effective implementation of technology into primary care. More support for people with type 2 diabetes in primary care is necessary.

The National Diabetes Audit found that less than 1 in 10 patients attended structured education, and only 67% of patients achieved a HbA1c below the target of 58mmol/mol. Additionally, with increasing awareness of type 2 diabetes remission, primary care could be setting ‘stretch aims’ for type 2 diabetes remission to raise the expectation and achievement of improved patient outcomes, and reduced burden on the healthcare system.

What happened?

1. Meeting of clinical leads from all Symphony Health Services practices and objective determined.
2. Wincanton Health Centre agreed to pilot first.
3. Meeting with Wincanton Health Centre Quality Improvement lead and GP.
4. Aim statement clarified, and driver diagram produced.
5. Meeting with Wincanton Health Centre healthcare team to cover; Quality Improvement project detail and educational event on type 2 diabetes remission.
6. Agreement to utilise the Low Carb Program to provide the technology for patient knowledge and behaviour change support.
7. Patient awareness event held at practice covering type 2 diabetes remission. Patients were actively invited to the event if they had type 2 diabetes and no contraindications to a low carbohydrate approach. At the event patients were offered the opportunity to participate in the Low Carb Program.
8. Additionally during normal practice clinics patients could be directly ‘prescribed’ the Low Carb Program, with enrolment support from health coaches if required. Patients could also be signposted to the health coaches who could assist in signing them up to the Low Carb Program.

Primary care can successfully implement behaviour change technology and achieve; rapid patient benefit in weight and prescription cost savings. Combining behaviour change technology with primary care-based health coaching can support patient enrolment of behaviour change technology, and those without access to technology at home.

**Long-term benefits** The LCP license provides access to patients over a three-year period. This means that longer term benefits such as on-going weight reduction and HbA1c control over that period for selected patients

**Monitoring**

Ascensia Diabetes care will work with the HCPs network to agree the implementation plan which would include provision of KPIs related to practice level and patient level engagement, information will be provided in an agreed dashboard format. KPIs will enable the HCP to have the ability to track progress of licence activation and performance of patients against agreed health biomarkers.

**Additional comments** This programme aligns with strategic objectives and commissioning intentions in diabetes to provide choice in management of the condition along with improvement in the non-medicines' interventions that clinicians in Scotland can offer their patients. Implementing the LCP will provide greater patient activation and empowerment in managing their condition, potentially reducing the demands on primary and secondary care services.

**To support this submission please find attached** clinical outcomes of the Low Carb Program, a Primary Care pilot study of The Low Carb Program, recent publications on support for HCPs in Primary Care on demedication and an observational study of Insulin resistant patients in Primary Care.

**References**

Scottish Diabetes Data Group (2017) Scottish Diabetes Survey 2017

Scottish Government and NHS Scotland Quality Prescribing for Diabetes: A guide for improvement 2018-20121


