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Public Health Wales

# Developing the Intervention for the All Wales Diabetes Prevention Programme

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# Executive Summary

## Background

Following Welsh Government's funding commitment in March 2021, the All Wales Diabetes Prevention Programme (AWDPP) was established to begin the roll out, with in-built evaluation, of a national type 2 diabetes prevention programme, based on Prudent healthcare principles and delivered through Primary Care Clusters (hereafter referred to as 'Clusters').

The AWDPP builds on the approaches piloted and evaluated in two separate Clusters, Afan Valley and North Ceredigion.

In these pilots, patients with non-diabetic hyperglycaemia [HbA1c 42-47 mmol/mol] received a single, face-to-face 30-minute brief intervention with a trained healthcare professional, focused on understanding the risk of developing diabetes, dietary changes and increasing levels of physical activity. Patients were then reviewed after a year, to measure any changes in their HbA1c.

Independent evaluations of both pilot interventions suggested that the approach has promise in terms of both effectiveness in reducing the risk of diabetes and value for money.

## Developing the AWDPP Intervention

Led by Public Health Wales, multidisciplinary professionals from across Wales have worked together to review each element of the piloted models, to refine and better align the intervention with NICE guidance, the All Wales Weight Management Pathway, Prudent health care principles and behavioural science.

This paper describes:

- The AWDPP Intervention design, in particular: the inclusion and exclusion criteria, equitable access to the intervention and the minimum dataset needed. It is recognised that a single intervention design cannot meet the needs of all, and that for some people, a more intensive or tailored intervention, or an alternative clinical pathway, will be required to enable them to benefit most equitably.

- The key elements of work which underpinned and informed the final AWDPP intervention design and promote its robustness. These include: an intervention logic model; a theory of change; completion of the TIDieR Framework (Template for Intervention Description and Replication); an Equalities Impact Assessment (EqIA).

- The key decisions made in the AWDPP intervention design and the rationale for these decisions. By demonstrating the process involved in the intervention design, the intention of this paper is to promote confidence in the design, encourage its adoption and support a move towards an effective, systematic, equitable, Wales-wide approach to type 2 diabetes prevention in Primary Care.

## The AWDPP Intervention

**Patient HbA1c tested as per NICE guidance PH38**

**Patient identified on practice database using the following criteria:**

| INCLUSION | EXCLUSION (coded): | EXCLUSION (may not be coded): |
|---|---|---|
| - HbA1c 42-47 mmol/mol *(within the last 3 months)*<br>- Aged 18 years and over | - Ever diagnosed with T1 or T2 diabetes<br>- Current BMI < 20 kg/m2<br>- Currently prescribed metformin or other medications which lower blood glucose | - Receiving palliative care<br>- Pregnancy<br>- Artificially fed |

Where an individual meets the inclusion criteria but it is unclear if a) the intervention would be beneficial and/or harmful, and/or b) the intervention would be appropriate to their needs, the decision to include should be escalated to make a clinical judgement as to whether the AWDPP intervention is appropriate or if an alternative intervention/pathway is required.

**Patient invited to AWDPP Intervention (letter +/- phone call if no response)**

**30 minute brief intervention with a trained healthcare support worker**

| Collection of Minimum Data Set | DISCUSSION: | REFERRAL ROUTES (as per All Wales Weight Management Pathway): |
|---|---|---|
| | - HbA1c result<br>- Risk of Type 2 Diabetes<br>- Motivational interviewing: Dietary/ Physical Activity behaviour change | - Health Board Weight Management Services (e.g. Foodwise for Life)<br>- National Exercise Referral Scheme |

**12 month recall HbA1c test**

**12 month patient follow up with repeat collection of minimum data set**

| HbA1c < 42 mmol/mol – | HbA1c 42-47 mmol/mol – | HbA1c > 47 mmol/mol – |
|---|---|---|
| patient removed from AWDPP | patient receives further AWDPP support | patient transferred to T2 diabetes mellitus pathway |

# Introduction

The aim of the All Wales Diabetes Prevention Programme (AWDPP) is to provide an effective, equitable approach to type 2 diabetes (T2D) prevention delivered through primary care across Wales, based on Prudent healthcare principles[1]. Unlike Scotland and England, Wales has not had a national diabetes prevention programme to date. This paper demonstrates how the AWDPP Intervention was designed and developed, and by whom, to promote transparency and encourage fidelity to the Wales-wide model.

The original business case to Welsh Government for an equitable approach to T2D prevention in primary care in Wales is referenced, including findings from the independent evaluations of the pilots undertaken in Afan Valley and North Ceredigion, which showed promising outcomes.

There is a clear case for developing a systematic, Wales-wide approach to T2D prevention. As of 2020, 8% of the population of Wales aged 17 years and over live with diabetes, of which around 90% have T2D. The majority of T2D diagnoses are preventable, with the most significant modifiable risk factors being overweight and obesity. This is a concern given the rising prevalence of obesity in Wales, with current estimations suggesting that as many as 580,000 people in Wales could be at risk of developing T2D[2]. Managing diabetes and its complications puts a considerable burden on healthcare services and accounts for 10% of the annual NHS Wales budget, approximately 500 million pounds per annum[3].

# Background to the All Wales Diabetes Prevention Programme (AWDPP)

## Afan Valley and North Ceredigion Cluster Pilot Work

Of particular interest to diabetes prevention in Wales are the pilot interventions undertaken and independently evaluated in two separate Clusters – Afan Valley and North Ceredigion. The evaluations examined the impact of a brief intervention on HbA1c in people identified as being at increased risk of developing diabetes[4]. The pilot interventions in both Clusters involved patients with non-diabetic hyperglycaemia [HbA1c 42-47 mmol/mol] who received a single, face-to-face, 15 to 30-minute consultation with an appropriately trained health care professional to discuss their risk of developing T2D and health behaviour modifications to reduce their risk: making dietary changes and increasing levels of physical activity.

Both interventions also referred patients (if appropriate and where local provision allowed) to services including the National Exercise Referral Scheme (NERS) and the *Foodwise for Life* community weight management programme. Patients were then reviewed after one year to measure any changes in their HbA1c. Data from both Clusters were later combined and demonstrated a mean decrease in HbA1c of 2.22 mmol/mol in those who received the intervention. Of the 16 practices involved in the pilot work, 14 demonstrated statistically significant decreases in HbA1c.

## All Wales Weight Management Pathway

There is clear synergy between the design of the AWDPP intervention and other weight management approaches in Wales. The AWDPP is aligned with and complementary to the All Wales Weight Management Pathway[5], published in 2021, which focusses similarly on individualised obesity prevention initiatives. Primary prevention interventions (e.g. social, environmental, etc.) are however out of scope of this Pathway.

## Business Case and Funding

Whilst there is a clear need for a systematic and equitable T2D prevention programme for Wales, scaling up the pilot work in Afan Valley and North Ceredigion to a national programme requires a phased rollout, with robust embedded evaluation in order to scale these approaches effectively.

Building on this position, and in line with Welsh Government's high level strategic priorities, the All Wales Diabetes Implementation Group (AWDIG) submitted a business case to Welsh Government to fund a systematic approach to T2D prevention in Primary Care based on the models used in the pilot areas. This resulted in the initial commitment of £1 million per year, for a two year period (2021-22, 2022-23) for this purpose, which was subsequently extended by Welsh Government to 2023-2024. The funding comes from the Healthy Weight, Healthy Wales programme in Welsh Government.

## Establishing the AWDPP

The development of the AWDPP is being led by Public Health Wales, supported by a steering group and four workstreams comprised of multidisciplinary professionals. At the start of the programme, a baseline review of T2D prevention activity in primary care settings in Wales was undertaken and this showed that there is currently wide variation in the support offered to prevent T2D.

A targeted, standardised brief intervention with an embedded national evaluation will be at the heart of the AWDPP approach. This will enable rigorous assessment of: the fidelity of intervention delivery; effectiveness against a core set of patient and clinical outcomes; the value of the intervention; and will explore the factors for successful implementation across Wales. The roll-out of the AWDPP is envisaged to take place in three phases:

i. **The 'Design' Phase (2021/22):** to determine the intervention design (in line with value-based healthcare principles), eligibility criteria, initial delivery model and approach to scaling the rollout of the Programme, and evaluation approach.
ii. **The 'Implementation' Phase (2022/-)** which will see the phased rollout of the intervention to 'waves' of selected Clusters across all Health Boards in Wales.
iii. **The 'Maintenance' Phase,** characterised by the sustained delivery of the AWDPP across all Clusters in Wales.

# Developing the AWDPP intervention

## The Intervention Design Workstream

Four interdependent workstreams have contributed to the development of the AWDPP and report to the AWDPP Steering Group. These include:

- **Intervention design [task and finish(T&F)]**
- Stakeholder engagement and communication
- Delivery and distribution of funding
- Evaluation design

Membership for the Intervention Design (T&F) workstream comprises multidisciplinary professionals from across Wales as well as relevant members of the AWDPP Steering Group. The Senior Responsible Owner for the AWDPP Intervention Design (T&F) workstream is the Consultant in Public Health Medicine, Primary Care Division, Public Health Wales. The workstream is Co-Chaired by the National Clinical Lead for Primary Care, Strategic Programme for Primary Care and a Consultant in Public Health Medicine (Local Public Health Team). Membership for this workstream reflects the specific expertise required to develop the intervention and includes:

- General Practitioners (including Afan Valley pilot lead)
- Local Health Board: Deputy Head of Nutrition and Dietetics

- National Nursing Lead for Primary & Community Care
- Public Health Wales: Deputy Head of Research and Evaluation
- Public Health Wales: Director of Health Improvement
- Public Health Wales: Principal Public Health Practitioner

The Intervention Design (T&F) workstream is supported by the AWDPP Programme team. The Programme also brought together a Clinical Reference Group, to inform decisions, where specialist knowledge was required.

The role of the Intervention Design (T&F) workstream was to develop and agree the intervention design and full intervention protocols based on:

- The AWDIG business case to Welsh Government
- Learning from independent evaluations of pilot diabetes prevention interventions
- NICE Guidance PH38
- Behaviour change theory

The workstream also agreed:

- Inclusion and exclusion criteria for the target population
- Data requirements to enable programme monitoring and evaluation
- To adopt Prudent healthcare principles to guide the equitable development of the intervention whilst also recognising the need for alternative pathways for people with specific needs or in certain circumstances

## NICE Guidance PH38: T2D - Prevention in people at high risk

For people with pre-diabetes (HbA1c 42 - 47 mmol/mol) and therefore at high risk of developing T2D, NICE recommends the following:

- Inform the person that they are currently at high risk of T2D but that this does not necessarily mean they will progress to T2D
- Explain that the risk can be reduced
- Briefly discuss their particular risk factors, identify which ones can be modified and discuss how they can achieve this by changing their lifestyle
- Offer them a referral to a local, evidence-based, quality-assured intensive lifestyle-change programme

It is notable that NICE Guidance[6] advocates a more complex intervention for individuals identified to be at increased risk of T2D than might at first be seen as the offer from the pilots in Wales. This approach is in keeping with England's NHS Diabetes Prevention Programme (NHS DPP), which has multiple contact points over a number of months. It is recognised that the NHS DPP however operates separately and in parallel to the offer of weight management services in England.

The pilots in Wales had similar inclusion criteria and outcome measures to those of the NHS DPP, and whilst they were each based on a single brief intervention, referral to related services was considered within the offer, based on local provision. The context of local provision is evolving in Wales following the recent publication of the All Wales Weight

Management Pathway (AWWMP) 2021 and the subsequent developments happening to support implementation of the AWWMP.

Through a person-centred lens, it is therefore evident that the overlap in prevalence between obesity and pre-diabetes will result in many patients ultimately receiving a complex package of interventions, as per the AWWMP and depending on the availability of services locally. This suggests that the diabetes prevention approach in the pilots in Wales is a value-based approach in line with Prudent healthcare principles.

## The AWDPP Intervention: Underpinning Work

An intervention flow chart has been developed which charts the process of the intervention from initial patient identification through to annual patient follow up. Included in the flowchart are the eligibility criteria which have been agreed by the AWDPP intervention work stream. Work underpinning the intervention design also included:

- An Intervention Logic Model
- A Theory of Change
- TIDieR Framework (Template for Intervention Description and Replication)
- An Equality Impact Assessment (EqIA)

All documents are available upon request by contacting PHW.AWDPP@wales.nhs.uk

## Behavioural Science

The AWDPP has been developed with considerations made to the principles of behavioural science. Along the AWDPP pathway, there are multiple points at which behaviour change techniques can be implemented to support patients to both engage with the intervention and to achieve positive outcomes. The focus of the discussion between the patient and healthcare support worker (HCSW) will be based on motivational interviewing techniques in line with NICE guidance PH49[7], 'Behaviour change: individual approaches', recommending targeting discussions around a patient's capability, opportunity and motivation to change health related behaviours (COM-B model; Mitchie et al. 2011[8]). By taking this approach, the patient's physical and psychological capabilities to take necessary action, barriers to change and motivation to adopt new behaviours can all be understood and can assist in setting goals relating to improved physical activity and dietary behaviour.

# AWDPP Intervention

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| **HbA1c < 42 mmol/mol** – patient removed from AWDPP | **HbA1c 42-47 mmol/mol** – patient receives further AWDPP support | **HbA1c > 47 mmol/mol** – patient transferred to T2 diabetes mellitus pathway |

The pilot diabetes prevention work in the Afan Valley and North Ceredigion provides the foundation for the approach which the AWDPP development follows. However, all elements of the intervention have been reviewed by the AWDPP Intervention Design (T&F) workstream to consider how best to align to NICE guidelines, the AWWMP, Prudent healthcare principles, the existing evidence base and the potential feasibility for delivery at national level.

## HbA1c Testing

As part of routine practice in primary care, patient HbA1c should be tested in line with NICE guideline PH38[5] which outlines a two-stage strategy for identifying people at high risk of T2D. Stage one of the guideline recommends that risk assessments using validated questionnaires should be offered to the following groups:

- All eligible adults aged 40 and above, except pregnant women
- People aged 25 to 39 of South Asian, Chinese, African-Caribbean, black African and other high-risk black and minority ethnic groups, except pregnant women
- Adults with conditions that increase the risk of T2D

Where risk assessments identify patients at high risk of T2D, a venous blood test should be offered to determine the risk of progression to T2D or to identify possible T2D. NICE consider HbA1c levels between 42-47 mmol/mol to be high risk and HbA1c 48 mmol/mol and above to meet the threshold for diagnosis of T2D.

## Eligibility Criteria: *Safety and Equity*

The eligibility criteria for the AWDPP intervention broadly determine:

- Who would potentially benefit from the intervention (*inclusion*)
- Who would be unlikely to benefit and may be harmed by the intervention (*exclusion*)

Patients will be eligible for the AWDPP intervention if they are aged 18 years and over and have an HbA1c between 42-47 mmol/mol tested within the last three months. The AWDPP recognises that the intervention will not be suitable for some groups and therefore, the following exclusion criteria have been agreed:

- Ever diagnosed with type 1 or 2 diabetes
- Current BMI < 20 kg/m$^2$
- Current prescription of metformin or other medications which lower blood glucose
- Receiving palliative care
- Pregnancy
- Artificially fed

However, in addition to the eligibility criteria above, the EqIA process was pertinent in highlighting that:

- ***For some individuals, the potential for benefit or the risk of harm may be unclear and the HCSW may need to escalate the decision regarding the person's eligibility***. As highlighted in the flowchart, examples of when to escalate

the decision regarding an individual's eligibility include when an individual: has a diagnosis of cancer; could be experiencing frailty; has diminished mental capacity; has safeguarding concerns; or has recently received a similar intervention. This list is not exhaustive and there will be other situations where decisions regarding eligibility require escalation; however these examples demonstrate some important instances where this consideration is needed.

- ***In certain circumstances or for specific groups of people, either a tailored version of the intervention or an alternative intervention or pathway may be indicated.*** For example, the EqIA process raised potential issues around the suitability of the standard intervention for: people with a physical disability; women in the post-partum period; and those with a BMI 20-24.9 kg/m$^2$. Potentially individuals from these groups may require a degree of tailoring of the intervention or an alternative pathway. Issues surrounding patients with diminished capacity and hearing and visual impairments were also identified, however requirements outlined in the General Medical Services contract provide mitigations for these issues. Similarly, access to the intervention for minority groups including the travelling community and asylum seekers, refugees and migrants are also mitigated by Welsh Government policies which provide guidance to primary care services in offering an equitable service to these groups. Again this list is not exhaustive but these examples demonstrate the complexity in considering equitable access to support all people in Wales with diabetes prevention. These considerations will be reviewed by the Programme during the initial implementation of the AWDPP to ensure equitable access is maintained.

All decisions made regarding the inclusion and exclusion criteria and conditions for review (see Figure 1) have been discussed and formally agreed by the Intervention Design (T&F) Workstream. Prudent healthcare principles, which highlight the need to prioritise both equitable approaches, reducing variation and caring for those with the greatest health need first, as well as safe practices, 'doing no harm' and doing only what is needed, were recognised by the Intervention Design (T&F) workstream to be important in guiding the eligibility criteria. A document outlining the decisions made and justification for each is available upon request by contacting PHW.AWDPP@wales.nhs.uk.

## Patient Invitation

Eligible patients will be invited to participate via a letter sent by the team responsible for local delivery of the AWDPP and will contain contact information which patients can use to book an appointment. In instances where the patient does not respond to the letter, a follow up phone call from a healthcare support worker will be made to the patient to enhance engagement with the intervention. Declining an invitation to the AWDPP will not affect a patient's statutory right to care from the NHS.

## 30 Minute Brief Intervention

The 30 minute, one-to-one/face-to-face, brief intervention[i] will be formed of two distinct stages, a data collection stage followed by a behaviour-change based conversation between

[i] We recognise the implications of providing care during the Covid-19 pandemic and the need to offer the 30 minute, one to one, brief intervention virtually depending on the policies in primary care. If the intervention needs to be delivered in a virtual format, the HCSW should be aware of the implications this may have on the ability to collect data as part of the MDS and mitigate this where possible.

the HCSW and patient regarding: the patient's HbA1c result, the risks of T2D and the benefits of healthy eating and physical activity in reducing T2D risk. The HCSW, trained and accredited in Agored Cymru Nutrition skills training, will collect all information as part of the minimum data set (MDS). The MDS is in development and will be available when the Programme launches. All data needs to be recorded electronically at the point of collection.

## Referral to Weight Management Services

In line with the All Wales Weight Management Pathway, and with agreement from the patient, referral/signposting should be undertaken to the appropriate weight management programme e.g. the *Foodwise for Life* Programme or other Health Board-led programme. Alternatively, patients may be referred to the National Exercise Referral Scheme (NERS). For patients already involved in a weight management programme, or NERS, who are subsequently found to have an HbA1c in the pre-diabetic range, the AWDPP intervention would serve as an adjunct.

## Patient Follow Up

Patients will be invited to attend a follow up appointment approximately one year after their initial consultation and following a repeat HbA1c test. During this appointment, collection of the MDS will be repeated. Depending on the HbA1c result, the patient will either be:

- Removed from the AWDPP pathway (if HbA1c < 42 mmol/mol)
- Offered a follow up consultation (if HbA1c 42 – 47 mmol/mol)
- Transferred to the T2D mellitus pathway (if HbA1c > 47 mmol/mol)

## Resources

Staff and patient resources to be used in the AWDPP intervention are being developed and will be aligned to those used in previous pilot areas. Patient resources will include the Diabetes UK 'Know Your Risk' booklet and the NHS Eatwell guide. Staff resources will build on existing resources used in the Afan Valley pilot area with additional behavioural science input.

# References

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