

**Section SIGN Prevention and remission of type 2 diabetes consultation**

## COMMENTS RECEIVED FROM EXTERNAL REFEREES AND OTHERS

All reviewers submitted declarations of interests which were viewed prior to the addressing of comments.

Invited reviewers			Type of response and declared interests
AR	Andrew Robertson	Consultant Bariatric Surgeon, NHS Lothian, British Obesity and Metabolic Surgery Society Council Member, Royal Infirmary of Edinburgh, NHS Lothian.	<p><i>Individual response.</i></p> <p><u><i>Personal financial interests</i></u> Educational travel grant from Novo-Nordisk</p> <p><u><i>Non-financial personal interests</i></u> I have an ongoing area of research into bariatric surgery including a current paper looking at remission of diabetes from bariatric surgery in a Scottish (Edinburgh) population.</p> <p>How Safe is Bariatric Surgery?- An update in perioperative mortality following bariatric surgery for clinicians and patients. L Huppler, AG Robertson, T Wiggins, M Hollyman, R Welbourn. Clinical Obesity 2022 Jun;12(3):e12515. doi: 10.1111/cob.12515.</p> <p>Intensive pre-operative information course (IPIC) and pre-operative weight loss results in long-term sustained weight loss following bariatric surgery: 11year results from a Tertiary Referral Centre. James Lucocq; Vikram Thakur; Georgios Geropoulos; Daniel Stansfield; Laura Irvine; Mhairi Duxbury; Andrew C de Beaux; Beverley Wallace; Brian Joyce; Lisa Harrow; Gillian Drummond; Peter J Lamb; Andrew G Robertson Surgical Endoscopy (In Press).</p> <p>Patient Pathways to Bariatric Surgery: What Pre-operative Medical Weight Management Programmes Exist Globally; Results of an International Survey. D Clyde, M Boland, G McCabe, W Cambridge, LR Brown, K Aitken, G Drummond, B Joyce, A de Beaux, B Tulloh, O Moussa, W Yang, B Madhok, P J Lamb, K Mahawar, AG Robertson. On behalf of the TUGS (The Upper Gastrointestinal Surgery): Global GI Community. Journal of Bariatric Surgery. 2023.</p>

Young-IFSO Bariatric/Metabolic Surgery Training and Education Survey. Felsenreich DM, Yang W, Taskin HE, Abdelbaki T, Shahabi S, Zakeri R, Talishinskiy T, Gero D, Neimark A, Chiappetta S; Young IFSO Collaborative Group. *Obes Surg.* 2023 Sep;33(9):2816-2830. doi: 10.1007/s11695-023-06751-8. Epub 2023 Jul 28. PMID: 37505341

Handling of the Covid 19 Pandemic and Its Effects on Bariatric Surgical Practice: Analysis of GENEVA Study Database. R Singhal, T Wiggins, S Pouwels, Y Rajeev, B Madhok, W Hanif, AA Tahrani, Y Graham, C Ludwig, K Mahawar, On behalf of GENEVA collaborators. *Obesity Surgery* 2022.

Patient Preparation for and Criteria to Progress to Bariatric Surgery are not Standardized Across the United Kingdom: Results of a National Survey. M Boland, K Aitken, G Drummond, B Joyce, A de Beaux, B Tulloh, PJ Lamb, AGN Robertson. *Obesity Surgery* 2022 Vol 32;937-939.

Portomesenteric vein thrombosis in patients undergoing sleeve gastrectomy: A meta-analysis of 101,865 patients. Giannis D, Geropoulos G, Kakos CD, Lu W, El Hadwe S, Fornasiero M, Robertson A, Parmar C. *Obesity Surgery.* 2023 Jul 31. doi: 10.1007/s11695-023-06714-z.

Systematic Review of Patient and Public Involvement (PPI) in Bariatric Research Trials: The Need for More Work . A Musbahi, D Clyde, P Small, M Courtney, K Mahawar, PJ Lamb, AG Robertson. *Obesity Surgery* 2022.

Peri-operative mortality in bariatric surgery: a meta-analysis. AGN Robertson, T Wiggins, FP Robertson, L Huppler, B Doleman, EM Harrison, M Hollyman, R Welbourn. *British Journal of Surgery* 2021; Vol 108(8):892-897.

Submitted

Long Term Weight Loss and Comorbidity Resolution of Laparoscopic Sleeve Gastrectomy and Laparoscopic Roux-en-Y Gastric Bypass and the Impact of Pre-operative Weight Loss on Overall Outcome. James Lucocq, Kate Homyer, Georgios Geropoulos, Vikram Thakur, Daniel Stansfield, Mhairi

			<p>Duxbury, Lisa Harrow, Andrew de Beaux, Bruce Tulloh, Beverley Wallace, Brian Joyce, Gillian Drummond, Peter J Lamb, Andrew G Robertson</p> <p>Predicting Weight Loss Failure after Bariatric Surgery: Derivation and Validation of a Four Factor Model. James Lucocq, Conor Hughes, Kate Homyer, Georgios Geropoulos, Brian Joyce, Gillian Drummond, Andrew de Beaux, Bruce Tulloh, Peter J Lamb, Andrew G Robertson</p> <p>Others in progress.</p> <p>Also</p> <p>BOMSS Council Member</p> <p>TUGS Bariatric Committee Member</p>
<b>AS</b>	Andrew Steele	Senior Pharmacist for Medicine, NHS Fife	<p><i>Individual response.</i></p> <p>Nothing declared.</p>
<b>BK</b>	Brian Kennon	Professor/ Consultant Diabetes and Endocrinology/ CMO Specialty Adviser Diabetes & Endocrinology/ National Lead Diabetes, Scottish Diabetes Group, NHS Greater Glasgow and Clyde	<p><i>Individual response.</i></p> <p><u><i>Personal financial interests</i></u></p> <p>Speaker at national DSN conference (speaker topic: deprivation in Scotland) - funded by Lilly (September 2023)</p> <p><u><i>Non-financial personal interests</i></u></p> <p>Chair and National Lead for Diabetes. Lead author in Diabetes Improvement Plan 2021 - Scottish Diabetes Group, Scottish Government.</p> <p>Chair of group - Scottish Diabetes Innovation and Technologies Group</p> <p>Wife is Health Systems Engagement Manager for Diabetes Scotland – personal.</p> <p><u><i>Any other interests of relevance</i></u></p> <p><u>Non-Financial</u></p> <p>Member of the group who has produced publications relevant to type 1 diabetes - Scottish Diabetes Research Network Epidemiology group – topic specific.</p>

<b>CW</b>	Anna Bell-Higgs	NHS Implementation and Training Lead, submitting comments on behalf of Counterweight	<p><i>Group response.</i></p> <p><u><i>Nature and purpose of your group or organisation</i></u> Weight management and Diabetes Prevention and Remission provider</p>
<b>DK</b>	Dorothy Kirkwood	Person with lived experience, Bellshill	<p><i>Individual response.</i></p> <p>Nothing declared.</p>
<b>HD</b>	Hannah Dale	Health Psychologist, NHS Tayside and NHS Education for Scotland	<p><i>Individual response.</i></p> <p>Nothing declared.</p>
<b>JH</b>	Jennifer Hynes	Type 2 Diabetes Early Intervention Lead, NHS Forth Valley	<p><u><i>Non-financial personal interests</i></u> I am employed to deliver the NHS Forth Valley prevention and remission of type 2 diabetes pathway and have a programme of work relating to person centred care and health inequality included in the CMO Annual Report, due for publication in May 2024.</p>
<b>KF</b>	Kevin Fernando	GP Partner, North Berwick Health Centre	<p><i>Individual response.</i></p> <p><u><i>Personal financial interests</i></u> I have received speaker &amp; advisory board fees for educational meetings from Lilly, Boehringer Ingelheim, Novo nordisk, Menarini, Napp, AstraZeneca I work 1 day weekly as content advisor for Medscape Global &amp; UK</p>
<b>MCh</b>	Mandy Christie	Person with lived experience, Dundee	<p><i>Individual response.</i></p> <p>Nothing declared.</p>
<b>JW</b>	Jacqueline Walker	Professional Adviser, Scottish Government, St Andrews House, Edinburgh	<p><i>Individual response.</i></p> <p>Nothing declared.</p>
<b>SW</b>	Sarah Wild	Professor of Epidemiology and Honorary Consultant in Public Health, University of Edinburgh and NHS Lothian/ Public Health Scotland	<p><i>Individual response.</i></p> <p><u><i>Non-personal financial interests</i></u></p>

Lindsay RS, Wild SH, Sattar N, Philip S, Barnett A. Longer term impact of COVID 19 infection people with diabetes, Chief Scientist Office Ref COV/LTE/20/28, 01/02/21-31/01/24 £295,201

Sattar N, Holman N, Khunti K, Dayan C, Pearson E, McCrimmon R, Wild SH, Colhoun HC, Lindsay RS, Gregg E, Young R. Effects of Covid-19 Pandemic on Diabetes Risks and Outcomes In UK. Diabetes UK 01/06/21-20/03/24 £83,398

Wu H, Denniston A, Sudlow C, Liu X, Wild SH. Quantifying and Mitigating Bias affecting and induced by AI in Medicine. MRC/NIHR Ref MR/X030075/1 01/10/23-31/03/25 £649,218

Smith D et al. Hub for Metabolic Psychiatry MRC Ref: APP4419-GTEE-2024 01/04/24-31/03/29 £3,489,248

*Non-financial personal interests*

Holman N, Khunti K, Wild SH, Sattar N, Knighton P, Young B, Gregg EW, Bakhai C, Valabhji J. Care processes in people in remission from type 2 diabetes: A cohort study using the National Diabetes Audit. Diabet Med. 2023 Mar;40(3):e15016. doi: 10.1111/dme.15016. Epub 2022 Dec 15. PMID: 36440921.

Iduye D, Wild S, Ostrishko K, Macdonald M, Helwig M, Iduye S, Jefferies K. Lifestyle interventions for type 2 diabetes prevention in children and adolescents of African descent in OECD countries: a systematic review protocol. JBI Evid Synth. 2022 May 1;20(5):1392-1403. doi: 10.11124/JBIES-21-00179. PMID: 35199655.

Captieux M, Fleetwood K, Kennon B, Sattar N, Lindsay R, Guthrie B, Wild SH on behalf of the Scottish Diabetes Research Network epidemiology group. Epidemiology of type 2 diabetes remission in Scotland in 2019: a cross-sectional population-based study. PLoS Med. 2021 Nov 2;18(11):e1003828. doi: 10.1371/journal.pmed.1003828. PMID: 34727107.

			<p>Captieux M, Prigge R, Wild S, Guthrie B. Defining remission of type 2 diabetes in research studies: A systematic scoping review. PLoS Med 2020 Oct; 17(10): e1003396. Published online 2020 Oct 28. doi: 10.1371/journal.pmed.1003396 PMID: 33112845</p> <p>Member of NICE Programme Development Group for Type 2 diabetes: preventing pre-diabetes <a href="https://www.nice.org.uk/guidance/ph38">https://www.nice.org.uk/guidance/ph38</a> 2009-2011</p>
Open consultation			Type of response and declared interests
<b>AG</b>	Ann Gold	Consultant in Diabetes, Aberdeen Royal Infirmary, NHS Grampian	<p><i>Individual response.</i></p> <p>Nothing declared.</p>
<b>CC</b>	Clara Carr	Specialist Dietitian, NHS Grampian	<p><i>Individual response.</i></p> <p><u><i>Non-financial personal interests</i></u> Right Decision Service Preventing the Progress of Diabetes (Jan to June 2024)</p>
<b>CH</b>	Conrad Harvey	Clinical Lead, North Enhanced Intermediate Care Team, GPwSI in Intermediate & Anticipatory Care. Ayrshire Central Hospital, NHS Ayrshire & Arran	<p><i>Individual response.</i></p> <p>Nothing declared.</p>
<b>DM</b>	David Munro	Senior Planning Manager, NHS Forth Valley	<p><i>Individual response.</i></p> <p><i>Nothing declared.</i></p>
<b>DS</b>	Doug Stewart	Team Lead - Adult Weight Management / Specialist Weight Management Dietitian, NHS Ayrshire and Arran	<p><i>Individual response.</i></p> <p><u><i>Any other interests of relevance</i></u> I have worked within a Diabetes Prevention service at NHS Ayrshire and Arran.</p>
<b>ED</b>	Emma Darling	Adv. PH Practitioner, NHS Grampian	<p><i>Individual response.</i></p> <p>Nothing declared.</p>

<b>ELC</b>		Anant Bansal, Pricing, Reimbursement and Access Manager submitting comments on behalf of Eli Lilly and Company	<p><i>Group response.</i></p> <p><u><i>Nature and purpose of your group or organisation</i></u>  <i>Pharmaceutical Manufacturer</i></p>
<b>JMF</b>	Jessica May Fletcher	Specialist Dietitian (Diabetes), NHS Highland	<p><i>Individual response.</i></p> <p><u><i>Non-personal financial interests</i></u>  No, T2D prevention framework and adult healthy weight outcomes framework monies</p>
<b>JR</b>	Joanna Rose	GP, Murieston Medical Practice, Livingston	<p><i>Individual response.</i></p> <p><u><i>Any other interest of relevance</i></u>  Diabetes Lead - sit on East Region Formulary Committee</p>
<b>KS</b>	Kiran Sodha	GP, NHS (London UK)	<p><i>Individual response.</i></p> <p>Nothing declared.</p>
<b>MC</b>	Morven Clark	General Practice Nurse, St Serf's Medical Practice, Lochleven Medical Centre, Kinross	<p><i>Individual response.</i></p> <p>Nothing declared.</p>
<b>MS</b>	Mark Strachan	Consultant Diabetologist, NHS Lothian	<p><i>Individual response.</i></p> <p>Nothing declared.</p>
<b>NN</b>		Catherine Brant, Advocacy and Engagement Lead submitting comments on behalf of Novo Nordisk	<p><i>Group response.</i></p> <p><u><i>Nature and purpose of your group or organisation</i></u>  Pharmaceutical Manufacturer</p>
<b>RCN</b>		Callum Metcalfe O'Shea, UK Professional Lead for Long Term Conditions submitting comments on behalf of the Royal College of Nursing	<p><i>Group response.</i></p> <p><u><i>Nature and purpose of your group or organisation</i></u>  Trade Union and Professional body.</p>

<b>SF</b>	Simon Farrell	Stakeholder GP South Ayrshire HSCP, Cathcart Street Practice, Ayr	<p><i>Individual response.</i></p> <p><u><i>Personal financial interest</i></u> GP in South Ayrshire.</p> <p><u><i>Non-financial personal interest</i></u> I am in Ayrshire and Arran LMC and as stakeholder GP for south ayrshire involved in developing GP services.</p>
<b>TD</b>	Thomas Donaldson	Service Development Lead - Diabetes Prevention, NHS GG & C	<p><i>Individual response.</i></p> <p><i>Nothing declared.</i></p>
<b>TR</b>	Tracy Russell	Weight Management Dietitian - Type 2 Diabetes Remission, NHS Lothian	<p><i>Individual response.</i></p> <p>Nothing declared.</p>
<b>YI</b>	Yuka Ishida	Specialist Diabetes Dietitian, NHS GG & C	<p><i>Individual response.</i></p> <p>Nothing declared.</p>

REVIEWER	COMMENT	DEVELOPMENT GROUP RESPONSE
<b>Section 1: Introduction</b>		
AR	Bariatric surgery should be replaced with bariatric and metabolic surgery through the manuscript (minor point)	This has been amended throughout the document to bariatric and metabolic surgery.
AS	Scope and remit of the guideline clear	Thank you
BK	Excellent introduction. Very clear and well presented. Delighted to see the inclusion of the Social Determinants of Health and the focus on a person centred approach.	Thank you
DM	A very well written introduction. Clear and concise. Useful background information.	Thank you
CC	Comprehensive - no more info needed here	Thank you
CH	In terms of real-world efficacy, sustained engagement with lifestyle behaviour modification (diet, exercise and weight loss) in a population already at risk of prediabetes and T2DM would seem to be the priority for this Guideline? The Evidence Base for, and efficacy of, the "Newcastle diet" and weight reduction strategies, to reverse T2DM and prevent progression from prediabetes into T2DM, are robust. For this guideline to have more impact, the focus on which behavioral modification interventions actually work with patients in Scotland, will be key to population impact. As such the authors and reviewers would be advised to define the specific characteristics of services that have delivered successful interventions, and (in an age when most patients will have smartphones) if a motivational free App may consistently facilitate better outcomes than periodic traditional meetings with clinicians/healthcare staff? The "Couch to 4K" App supports patients with a some motivation, but who need encouragement. Similarly the Hollyhealth app works with patients' habits in the real world, to achieve sufficient discipline to facilitate the desired health benefits.	<p>Within the section on preventing progression we have added more detail about the most effective way in which to design and deliver interventions for optimal outcome, including appropriate behavioural approaches to effect change. There is also reference to digital programmes where they are found to have evidence of outcomes in line with the traditional in person delivery format, therefore supporting remote and virtual interventions.</p> <p>We have added a link to the NHS Lose Weight website which includes links to a range of useful apps such as the Couch to 5K in the sources of further information.</p>
CW	Great to see person first language being used throughout the introduction.	This has been amended to a more formal style at editorial.

	<p>This sentence clearly sets the scene for the reader on what is known from the evidence base "We now know that prevention and remission are possible with clinically effective interventions, notably intensive weight loss" which I assume will be thread through the guideline. As this is applicable to a Scottish population, I would make reference to the Latest publication on Weight Management services.</p> <p>chrome-extension://efaidnbnmnnibpcajpcglclefindmkaj/https://publichealthscotland.scot/media/26286/2024-03-26-weight-management-report-adult.pdf</p> <p>Notably this paragraph which demonstrates levels of weight loss being achieved in current weight management and diabetes remission programmes:</p> <p>'For Tier 2 services the average (mean) weight loss was 3% in the year October 2019-September 2020, 1% in the year October 2020-September 2021 and 2% in the year October 2021-September 2022. In Tier 3 service the average (mean) weight loss was 5% in all three years. For the intensive weight management and remission programmes within Tier 3, the average (mean) weight loss was much higher at a consistent level of 12% in each of the three years.'</p>	<p>The outcomes and data relating to weight management services in Scotland are relevant for only a snapshot in time and would quickly be out of date as services continue to evolve and expand. We felt that the guideline should have longevity therefore including data that would soon be out of date would not be in keeping with the group intentions.</p>
DK	<p><b>1.1</b> Para 2 uses the phrase "population health loss". Does this mean an overall reduction in general health of the population or is it a rather clumsy euphemism for death? I feel it needs to be clearer.</p> <p>The health inequalities information is striking but, sadly, all too true. I hope that the flagging up of these has some effect and agree that the "potential to improve and standardise the approach " and "there is potential to ensure more equitable access to services" but for that potential to be realised the underlying support services need to be in place equally and that does not seem to be the case.</p> <p><b>1.4</b> I find it disappointing that the Guidelines are not considered to be a "standard of care". If they are not that then what are they</p>	<p>This has been amended to update to newer data (2024) and also worded more factually in terms of overall projected increase in people living with diabetes.</p> <p>We are in agreement with your concerns and have highlighted this in the implementation section which refers to the need to undertake equality impact assessments in the design of services.</p> <p>The guidelines provide recommendations for good practice but cannot be mandatory, as care should take into account the needs and wishes of the individual. It provides evidence-based recommendations for best practice for the majority of patients, while allowing for adaptation</p>

	<p>for. Tailoring to the needs of the individual patient are surely a constituent part of that standard. It is difficult to achieve equity and access and almost impossible to evaluate success if there is no baseline standard to measure against.</p>	<p>under clinical judgement over each individual's conditions and settings. This section includes the agreed wording on the status of SIGN guidelines.</p>
TD	<p>Content of the introduction could be strengthened by reference to the recent NESTA study, in addition to Burden of Disease study.</p> <p>1.3.2 Says useful to maternity services – but GDM not mentioned/covered and separate guidance for GDM being developed</p>	<p>The advice on prevalence in NESTA is taken from the Scottish Health Survey, which we have cited directly.</p> <p>GDM is discussed in the section on identifying people at high risk. We have included recommendations from, and a link to, the GDM guideline.</p>
ELC	<p><b>1.4.3</b> Health technology assessment advice for NHS Scotland</p> <p>To ensure the Prevention and Remission of Type 2 Diabetes SIGN Guidelines contain the latest information and provide guidance on relevant newly-licensed medicines, we request that the publication of this guidance is delayed to incorporate the latest SMC Guidance (SMC2653) for tirzepatide for weight management. SMC2653 will be published on 10 June 2024.</p> <p>We believe the advice provided in SMC2653 will be directly applicable to Section 4, Section 5, and Section 6 of the Prevention and remission of type 2 diabetes SIGN Guidelines and may be indirectly applicable to other sections.</p>	<p>Tirzepatide advice issued by SMC has been incorporated into the section on pharmacological interventions.</p> <p>We have incorporated the SMC advice in all relevant areas of the guideline.</p>
HD	<p>Good brief overview.</p>	<p>Thank you</p>
JH	<p>The presentation, structure, language and content of the introduction is excellent. There is a good summary of incidence and prevalence data, with projected consequential social, health and financial burden outlined.</p> <p>The introduction makes reference to obesity and type 2 diabetes stigma, and nicely summarises the inequity in risk of developing the disease, based on the social determinants of health.</p> <p>The introduction mentions "good conversations", which are key to identifying whether or not someone feels they are in a position to make health change. I don't think this paragraph makes it clear that the healthcare professional needs also to be trauma informed, understand when it is not the right time to push to</p>	<p>We have added further information and links to the training for good conversations.</p>

	<p>support health behaviour change, and understand how to manage a conversation where social context and resources don't support health change. A "good conversation" will not automatically include these - as suggested in the text.</p> <p>For each weight management or diabetes prevention intervention to be preceded by a "good conversation", the culture regarding the way we interact with patients would need to change across every person working for NHS Scotland, to prevent stigma or unintentional disengaging language and intervention. The first conversation might be with any practitioner who is able to refer to a digital programme or who supports health change in any way. This is currently not feasible in Scotland, but could be implementable with a focus on reporting which prioritises person centred care, and increased availability of training which can promote and build confidence in using these skills, alongside stigma awareness and trauma informed skills. This good practice is applicable to all long term conditions and many acute conditions, so is not the sole responsibility of diabetes prevention practitioners and policy.</p>	
JMF	Well written introduction setting the scene. Info re financial impact and growth of T2D will be particularly helpful if / when making a case locally for service funding etc.	Thank you
JW	<p>The introduction is clear and concise. The T2D Remission intervention is intensive weight loss but moderate weight loss using non-intensive weight loss methods can stop the onset of T2D in people who are at high risk/ pre-DM or history of GDM. Sometimes the introduction reads as if it is the same intervention for prevention and remission. Could this be altered?</p> <p>The introduction describes the causative effect of deprivation in the development of T2D due to overweight and obesity but little is made of the inequalities during interventions eg higher drop out rates from SIMD 1&amp;2; local home grown interventions not catering for people where English is not their first language. There is much we can do to reduce health inequalities within our services and more should be made of this as this is within our gift to alter.</p>	<p>We have amended the sentence from intensive weight loss to cover both:</p> <p>We now know that prevention and remission are possible with clinically effective interventions, notably weight loss.</p> <p>We have added in the following sentence:</p> <p>Uptake and completion of structured education and weight management programmes is poorer in SIMD areas 1 and 2 despite around 50% of all referrals originating from people living in those areas.</p>

	<p>The use of digital interventions can be advantageous to reduce the need for in person interventions and allow greater reach and supporting reductions in health inequalities.</p> <p>The impact and cost of type two diabetes is well described. The recent NHSE digital type two diabetes prevention program has been able to demonstrate increased reach, effectiveness prevention at good value. I think more needs to be made of digital interventions in the discussion because the level of need is so great that we will never be able to deliver care at this scale in person. This would balance the in-person intervention points.</p>	<p>We have added a suggestion to the implementation section around equalities and resources for people where English is not their first language.</p> <p>We have added further information about the development of digital interventions for a Once for Scotland approach in the section Implementation: Digital innovation</p> <p>We have referenced the importance of digital interventions in the section on Preventing progression from prediabetes to type 2 diabetes, as an evidence-based treatment with parity of outcomes with traditional in-person treatments to acknowledge the utility of digital modes of intervention.</p>
KF	<p>Additional information to consider adding:</p> <p>BMJ 2020 meta-analysis (&gt;10million participants) suggested that pre-diabetes is associated with an increased risk of all-cause death and CVD in both the general population and in those with established ASCVD</p> <p>JAMA Network OPen cohort study 2023 that demonstrated that prediabetes is more than just dysglycaemia. Reversion to normoglycaemia was associated with a lower risk of death only in those who remained physically active. Additionally risk of death was higher in those living with obesity and reversion to normoglycaemia. Finally normoglycaemia did not offset the risks of smoking.</p>	<p>This has been added to the introduction to the section Identifying people at high risk of type 2 diabetes:</p> <p>Prediabetes is more than just dysglycaemia; it is associated with an increased risk of all-cause death and CVD in both the general population and in those with established atherosclerotic CVD. Risk of death in those with prediabetes, even when glucose levels are normalised, remains higher for those with obesity and lower for those who are physically active, evidence that supports the role of intensive lifestyle behaviour-change programmes in the treatment of this condition.</p>
MC	Comprehensive and provides good background data	Thank you
MCh	<p>Could be shorter and more focused on issues to be considered.</p> <p>Can graph / table be used to highlight increases over time, numbers affected, etc?</p>	On balance this was not the overall opinion of the group nor of the majority of reviewers so we have retained the detail and narrative of the introduction as feel it fully sets the scene.
SF	Sets the scene well and makes this impending public health crisis we are facing very clear.	Thank you
SW	Suggest replace: "Owing to recent ...." with " Owing to recent scientific breakthroughs,1,2 type 2 diabetes may not be a progressive and irreversible disease in some people. We now know that prevention and remission are possible with clinically	The group felt that the evidence is such that the scientific understanding of diabetes as a progressive disease has changed warranted the more strongly worded statement that we have retained.

effective interventions, notably intensive and sustained weight loss”.

Suggest replace: “The rate of growth ....” with “The number of people living with type 2 diabetes in Scotland has increased by a third between 2011 and 2021 and further increases are expected over the next decade.”

The statement “ A diagnosis of type 2 diabetes reduces life expectancy by around 10 years, driven by the increased risk of cardiovascular disease (CVD)” needs a reference and further explanation – it is not appropriate to quote a single figure for reduction in life expectancy as it varies by attained age/age at diagnosis of diabetes/ duration of diabetes, sex and SIMD.

Suggest replace: “Diabetes is a key driver of health inequalities” with “Diabetes is a key component of health inequalities”

Suggest replace: “We know that people living with ...” with “We know that people living with obesity and overweight are more likely to develop type 2 diabetes than those with a body mass index (BMI) in the healthy weight range. This is reflected in Scottish data, with 87% of people with type 2 diabetes living with overweight and obesity (while 67% of adult participants in the Scottish Health Survey in 2021 were in this group ref <https://www.gov.scot/publications/scottish-health-survey-2021-volume-1-main-report/pages/10/>).3”

I strongly recommend that a summary of the 2018 Scottish Government Framework for diabetes prevention is added to section 1.1 to provide some policy context and an explanation that much of the work, particularly that taking a whole systems approach, has either moved very slowly or stalled due to a variety of factors including the Covid-19 pandemic.

Thank you, we have amended with your change.

Thank you. We have added a reference and amended to say:

The average age at which people are diagnosed is also decreasing, and is associated with a poorer prognosis. A diagnosis of type 2 diabetes at age 40 reduces life expectancy by around 10 years, driven by the increased risk of cardiovascular disease (CVD)

Amended to: Type 2 diabetes does not affect our population equally. In Scotland, people living in the most deprived communities having a 77% greater chance of developing diabetes than those in the most affluent areas.

Paragraph made more concise:

In Scotland 87% of people with type 2 diabetes are living with overweight or obesity, with 67% of the overall Scottish adult population living with a body mass index (BMI) over 25 kg/m<sup>2</sup>. While healthcare professionals are unable to change the social determinants of health or non-modifiable risk factors, there is an opportunity to support some people to live healthier lives, in ways appropriate to their circumstances which might include weight loss.

Whilst understanding the importance of this strategy in the context of the Scottish landscape, the introductory section needs to be succinct. Discussion of the framework has been added to the section on implementation.

### Section 3: Identifying people at high risk of type 2 diabetes

For **figure 1**: suggest change title to Figure 1: Risk identification and HbA1c testing

In the third box that currently reads: "likely to be type 2 diabetes" suggest change to "possible type 2 diabetes, requires repeat testing"

For the **first R** suggest replace "Second, for those with.." to "Second, for those with high risk scores, a blood test should be offered to investigate whether people might have type 2 diabetes or prediabetes."

For the first paragraph in the section labelled "Record-keeping supports following up and reassessing risk."

Suggest replace relevant sentence with "Where risk assessment is conducted by health professionals in NHS venues outside general practice (for example, in community pharmacies) and the individual has a high risk score, the professionals involved should ensure the results are shared with the individual and their GP practice or added to the person's health record by the professional and that a blood test for glucose or HbA1c is offered".

Suggest reword sentence to : "GP practices should record diabetes risk scores and ensure appropriate follow-up and continuity of care, with consent from the individual". Also suggest adding recommended Read/SNOMED codes to implementation section and a reference to them here.

Suggest reword to: "Where self-assessment is offered in community venues, health professionals and community practitioners in those venues should ensure people with a high risk score are offered a subsequent blood test and an informed discussion on how to manage their risk. Those at high risk should have blood test arranged at their GP practice or appropriate primary care provider."

With reference to "GP practices should maintain a register for patients with prediabetes and annually review their weight and risk factors" my understanding is that a "register" is automatically created if primary care records include complete and accurate

Agree. The title has been changed and is now figure 2: Risk identification and HbA1c testing

Amended as suggested.

Preference is to leave this as it is. Introducing additional work for GPs to record all risk scores without rationale for doing so is not evidenced. The key aspect is to focus on testing and record those with high risk.

This has been amended to:

Where risk assessment is conducted by health professionals in NHS settings outside general practice (for example, in community pharmacies) and the individual is scored as high risk, the professionals involved should work to ensure the results are shared with the person and their GP practice (with permission).

Blood testing is discussed in the section: Testing for diabetes.

We agree that a register may be automatically created if complete and accurate diagnostic codes are recorded, however at the moment there is inconsistency with coding. A new section on coding has been added to encourage more accurate recording.

This should prompt annual review.

The following amendments have been made to the good practice points:

Primary care providers should consider maintaining a register of patients with prediabetes and annually review and record their weight and risk factors. If the patient has comorbid cardiometabolic conditions these checks could be captured in the same annual review.

	<p>diagnostic codes (see relevant comments above and below)? It might be helpful to clarify the recommendation that weight and risk factors be recorded as well as reviewed.</p>	<p>On diagnosis use a single READ code for prediabetes (C11y500 – pre-diabetes’), which is inclusive of prediabetes, impaired glucose tolerance, impaired fasting glycaemia and non-diabetic hyperglycaemia. In Vision use #C11y5 to locate the correct code. The additional recall code should be used to ensure patients with prediabetes are followed up appropriately (66Az - high risk of diabetes annual review).</p>
AG	<p>Why is the word "eligible" needed - do you mean to risk score everyone over 40 if so just say that - I have no idea what eligible means ?</p> <p>Also suggest list conditions which are associated with Type 2 or reference document for completeness.</p> <p>Glucose levels in this guideline determining level of risk of progression to T2 (5.5-6.9) are inconsistent with the pregnancy guideline which says 6-6.9. It is very confusing have different information being presented without explanation if there is a valid explanation.</p>	<p>Agree, the word ‘eligible’ has been removed.</p> <p>We agree that the different population diagnostic cut offs can cause confusion and have amended the cut off used in the guideline to 6.1.</p>
CW	<p>Risk Assessment: I think it is in the Scottish populations best interest to be offering risk assessments to all eligible adults 18+ especially in relation to the context in the introduction: "The average age at which people are being diagnosed is also becoming younger, which leads to a poorer prognosis. A diagnosis of type 2 diabetes reduces life expectancy by around 10 years, driven by the increased risk of cardiovascular disease (CVD)." By not identifying the risk of younger adults as early as possible, this has the potential to have a serious impact on our workforce and the NHS spend.</p> <p><a href="https://digital.nhs.uk/data-and-information/publications/statistical/national-diabetes-audit-2021-22/young-people-with-type-2-diabetes-2021-22">https://digital.nhs.uk/data-and-information/publications/statistical/national-diabetes-audit-2021-22/young-people-with-type-2-diabetes-2021-22</a></p> <p>chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.diabetesinscotland.org.uk/wp-content/uploads/2023/10/Scottish-Diabetes-Survey-2022.pdf</p>	<p>There is no evidence that a population wide, all adult screening programme delivers more benefit than harm (UK National Screening Committee, 2019) so at this time, a targeted approach is recommended as per the evidence base.</p>

AS	Clear who is at risk, who should be offered a risk assessment and how often risk should be reassessed.	Thank you
BK	Clearly laid out and flows well. The recommendations seem appropriate and the supporting Good Practice Points are helpful. I am mindful that there are 8 GPP in this section alone, over and above the recommendations. There is the risk of GPP overload and maybe streamlining it to 2 or 3 key GPP may be helpful.	Group felt that each of the good practice points were important and preferred to retain them.
CC	People at higher risk include those with "mental health problems" is this for those on antipsychotic drugs only?	<p>This was taken directly from the NICE guideline, which includes mental health problems (we have amended to mental health conditions). We have removed the sentence about antipsychotic drugs as this was not part of the NICE evidence on which the recommendation is based.</p> <p>We have added a link to the Lester Positive Cardiometabolic Health Resources which provides a pathway for assessment and care for people with psychosis and schizophrenia</p>
CH	In an age of AI, anticipatory algorithms should be able to identify patient at risk characteristics from EMIS/Vision (every patient in Scotland has had a digital IT record since 2004); which records BMI, PMHx, diabetogenic medications. Anticipatory, not reactive, Medicine is the solution here.	The group agree with this comment. No change to the guideline needed.
DK	Given that section 1 identifies the scale and potential cost to the NHS of the future care of people with Type 2 diabetes, I was astonished by the statement that "The UKNSC does not recommend whole population level screening for Type 2 diabetes because there is no evidence of benefit" . This statement reads extremely dismissively. If there is evidence of dis-benefit of the projections then it would stand to reason that wide scale prevention measures must be beneficial. It also means, and this is a concern for me in general about the guidelines, that the focus is on people presenting with comorbidities, and risks missing many preventable cases where there are no "obvious" risk factors or symptoms. It is NOT unusual for apparently healthy, non "high risk" people diagnosed with Type 2 to have received their diagnosis after going to the doctor about something totally unrelated.	The comment has been reworded to better explain the UKNSC outcome but please note that this guideline remit was not to review the evidence for a national diabetes screening programme. At present the evidence for screening all adults does not show overall benefit or cost effectiveness. We would recommend reading the UKNSC report for further detail on how they reached this decision.

	<p><b>3.1</b> In the section about record keeping the first Good Practice point "Newer approaches..." reads more like a statement of fact than a pointer to good practice action. Consider rewording.</p> <p><b>3.2</b> I would suggest that para 1, line 2 should read " type 2 diabetes should be followed up" rather than can be followed up.</p> <p>Para 4 seems to have a word missing between "made" and "individuals"</p> <p>I understand that the recommendations have already been set but I would have considered that the second good practice statement here should be a recommendation instead.</p>	<p>This has been reworded to:</p> <p>Robust approaches to follow up and recording (with permission) should be applied in point-of-care pharmacy testing and home blood testing.</p> <p>3.2 (now Testing for diabetes) First sentence. We have changed this to 'should be followed up'.</p> <p>Para 4 sentence amended to: Consideration should also be given to individuals with haemoglobinopathies and anaemia, in whom the measurement of HbA1c may not be accurate or may need adjusted.</p> <p>This is not evidence based but is good practice. If the diagnosis is coded correctly it should also help with prompts for follow up.</p>
DM	<p>Important steps are covered. Need to ensure that this is prioritised for action.</p>	<p>Thank you</p>
DS	<p>It would be helpful to have some elaboration of what conditions increase the risk of T2DM, under the second R that talks about "encourage the following to have a risk assessment." Perhaps including gestational diabetes here as well.</p> <p>In the testing section where it says "Consideration should also be made individuals with haemoglobinopathies and anaemia, in whom the measurement of HbA1c may not be accurate." What is the evidence for this? I would love to know as I have seen instances with patients who have had this and have been unable to locate good evidence to support this myself.</p>	<p>These are covered in the first paragraph of the section: Identifying people at high risk of type 2 diabetes.</p> <p>We have not looked at the evidence for this, but the expert opinion of the guideline group is that this is good practice.</p>
ED	<p>Risk assessments/screening - Major and unmanageable load for an already well overstretched Primary Care system unless consideration to other routes linked in to primary care. Would need considerable HSCP planning/CTAC involvement/robust pathway development.</p>	<p>We appreciate the system pressures and with guidelines the primary aim is to outline the best-evidenced care, for boards and services to consider how they work to meet that. Further consideration is given to this in the implementation section and we have added the following sentence to the introduction to the section identifying people at high risk:</p> <p>Encouraging more people to take a risk assessment and testing may add pressure on services, so support from a variety of access points in primary care and the potential for new approaches, such as, home testing kits is needed (see the section on implementation).</p>

HD	Appears to be a balanced approach to identify those at highest risk without implementing population based testing.	Thank you
JH	<p>As in my comment regarding the introduction, if risk is to be identified in General Practice and by a range of healthcare professionals, the professionals need to have increased access to, and incentive to undertake, "good conversations". Without this we risk increased stigma and disengagement from diabetes prevention and other health services.</p> <p>Whilst I agree with the recommendations and good practice point indicated in this section, these is not currently feasible in Scotland because:</p> <ol style="list-style-type: none"> <li>1. Services are not designed or resourced to allow "good conversations"</li> <li>2. GPs do not currently have a remit for diabetes prevention (or any prevention) included in their contract, and the number of people presenting "at risk" could be prohibitively large, particularly with regards to ongoing testing linked to self management.</li> <li>3. HB funding for diagnostic testing is often insufficient to meet demand, and many GP Practices continue to fund their own additional phlebotomy. Priority will therefore be given to diagnosing and monitoring conditions which are already present.</li> </ol> <p>There are a large number of people with haemoglobinopathies and anaemia, for whom an OGTT is required for diagnosis, but there is insufficient resourcing to action this test for prevention.</p> <p>For these reasons, I don't think that the additional information supports implementation of the recommendations in this section. It would be helpful to have some guidance about identifying people at high risk where there is limited access to General Practice to deliver the pathway.</p> <p>The section is well written, easy to follow and concise.</p>	<p>Thank you</p> <p>The group appreciate that 'good conversations' for all is aspirational however, it is also best practice therefore important we acknowledge that here.</p> <p>The group consider raised blood glucose to be a risk factor for CVD. The patients determined to be at risk of type 2 diabetes are often at risk due to existing long-term conditions for which they are having routine bloods tested in primary care – we do not anticipate that the cohort of people for whom this guideline is aimed to help will be new in terms of requiring routine and annual follow up as part of existing condition/risk factors. The group do acknowledge that there are resource challenges in primary care and that work is required across the system to enable the guideline to be implemented.</p> <p>We have added a section in implementation and a sentence in the introduction to the section on identifying people at high risk to acknowledge this.</p> <p>We have removed the GPP re haemoglobinopathies but retained information about consideration of haemoglobinopathies when interpreting results.</p> <p>Thank you for your comments, the points about impact on General Practice have now been included in the implementation section.</p> <p>Thank you for your feedback.</p>
JR	GP offering risk assessment to all the groups listed is not feasible without significant transfer of funding and workforce to primary care. This is a huge amount of work suggested.	Where appropriate, we have amended the term 'GP' to primary care to accommodate new developments in community services.

		<p>We appreciate the system pressures and acknowledge there are limitations for delivery which we reference in the implementation section. The guideline is designed to describe and outline best clinical practice for boards and services to work towards. We have added a section on implementation in primary care and signposted to it in the assessment section.</p>
	<p>Can we be stronger on coding of high risk, pre-Dm, history of GDM in this section. Can we be stronger to ensure weight, height and BMI are captured and recorded at assessment and on review thereafter. At present there is huge variation in coding in PC. Weight/BMI is not always being undertaken or recorded at risk assessment/ diagnosis or review. As weight loss/diet and lifestyle change is needed then it is imperative that weight/BMI is undertaken so informed patient focused discussions can be had in helping identify level of intervention required.</p> <p>Are we going to state which risk assessment tool at what level we take action?</p>	<p>Section 3.1 (now Risk assessment) We have created a specific section and amended the good practice point to emphasise the use of Read codes.</p> <p>In the other good practice point we have added the need to record weight and risk factors.</p> <p>We have amended the sentence: Validated computer-based self-assessment tools, like <a href="#">QDIABETES-18</a> or Diabetes UK's <a href="#">Know Your Risk</a>, allow people to estimate their risk without a blood test.</p>
MS	<p>Anecdotally the coding of pre-diabetic states in primary care is done inconsistently and not necessarily accurately. There are many different codes for pre-diabetic states - including IFG, IGT, pre-diabetes and 'at risk of future diabetes', which causes confusion and drives the inconsistency Personally, I believe it would be simpler for everyone if these were all considered to be 'pre-diabetes' and that this guideline makes an explicit recommendation that the 'pre-diabetes' code is the favoured code to be used for anyone with a dysglycaemic state identified by glucose or HbA1c testing.</p>	<p>Thank you, we have taken this on board and have advised accordingly that we should use one code for prediabetes that covers all of these dysglycaemic states.</p>
KF	<p>I think a range of validated computer-based self-assessment &amp; risk assessment tools should be included not just the Diabetes UK tool to facilitate use in multiple settings. The DUK tool is good for self assessment but my personal preference in a HCP environment is QDiabetes -2018 which is well validated in UK populations and contains a wide range of clinical risk factors. There is also the Leicester Diabetes Risk Tool.</p>	<p>We have not conducted an evidence review on which is the best tool to recommend, but we have provided two tools as examples: Validated computer-based self-assessment tools, like <a href="#">QDIABETES-18</a> or Diabetes UK's <a href="#">Know Your Risk</a>, allow people to estimate their risk without a blood test.</p>

	<p>Figure 1 I feel is too rudimentary and needs further clarification. I have already shared my own prediabetes flowchart which can be adapted but i suspect the involvement of Medscape may preclude this.</p> <p>2 populations at risk of developing type 2 diabetes which have been neglected are women living with PCOS (1.4x) more likely to develop T2D over their lifetime and importantly this risk is independent of their baseline bodyweight. All women living with PCOS should be accurately coded and under 1-3 year follow-up lifelong irrespective of their weight.</p> <p>Additionally, i was surprised not see a dedicated section to highlighting increased cardiometabolic risk of people living with severe mental illness. T2D is 2-3x more frequent in this group and affects up to 10-15% of people living with severe mental illness. Risk factor management including checking of hba1c needs to be done at point of diagnosis. The well established Lester Positive Cardiometabolic Health Resource updated in 2023 could be signposted here. It is included in NHS England Core20plus5 and has been endorsed by RCPsych, RCGP RCP et al. The mantra of this resource is to intervene and not just screen with early consideration of metformin</p> <p>With respect to testing I strongly feel to keep things simple for primary care HbA1c alone should be used with acknowledgement of its caveats. For the vast majority of individuals this is appropriate</p> <p>Accurate coding and follow-up needs to be highlighted in a separate section/recommendation as this is disparately done in primary care</p>	<p>Figure 1 is intentionally straightforward to show the basic process. We agree that your flowchart is comprehensive and it has been added to the 'further resources' section on RDS.</p> <p>We have added women with PCOS, with a link to NICE advice.</p> <p>Mental health is listed as one of the conditions associated with high risk, so the population covered by the recommendations.</p> <p>We have added a link to the Lester Positive Cardiometabolic Health Resource</p> <p>We have restructured to cite HbA1c before FPG, to indicate that this is the preferred test.</p> <p>We have amended the good practice points for coding and follow up to be more specific, and created a separate section: Clinical coding.</p>
MC	Needs further support and education for HCPs	Thank you. We acknowledge that additional resources and support would be needed for primary care providers to perform this work. This has been added to the implementation section.
MCh	<p>Multiple ways of identifying people at high risk NB not all visit GP regularly.</p> <p>Community workers / practitioners can play a role.</p>	This is outside the remit of the guideline. Whole population screening is not recommended.

	<p>Use of social media so people can self - identify as being at high risk.</p> <p>TV adverts ? Radio adverts?</p>	
RCN	<p>May want to consider terminology around the word 'pre-diabetes' as can be interchangeable with definitions of 'high risk diabetes' and 'non-diabetic hyperglycaemia'</p>	<p>We have added the code for prediabetes and amended the terminology to prediabetes, where appropriate.</p>
SF	<p>I think this is sensible but I have concerns it will need huge financial investment, particularly in primary care, to deliver on. My impression is practices are struggling to cope with the care burden of exponential rises in Type 2 patients, rising steps and stages to management requiring more interventions in primary care with diminishing secondary care supports in place and rising waiting lists. Already historically agreed enhanced service agreements don't appropriately fund this work and so investment shift to community care is already needed. Huge investment will be needed and perhaps there is more opportunity to expand this in areas like Community pharmacy.</p>	<p>Thank you. We acknowledge that this requires significant additional resources and support for primary care providers to undertake this work. The guideline outlines the best clinical practice, and this is an implementation issue. We have now highlighted this in the implementation section.</p> <p>Where relevant we have changed the term GP to primary care provider, or practice which includes community pharmacies.</p>
SW	<p>In section <b>3.2</b></p> <p>First para suggest replace relevant sentence with: "The aim of blood tests for people with high risk scores is to conduct further risk assessment and to identify people with pre-diabetes or who may have previously undiagnosed type 2 diabetes (subject to confirmation based on the results of a second HbA1c or glucose test in people without symptoms of diabetes such as thirst, polyuria, weight loss)".</p> <p>Later para: suggest replace relevant sentence with: "The 2-hour oral glucose tolerance test (OGTT) assesses the body's ability to process a glucose load. Following a fast of 8–10 hours FPG is measured then the patient is given 75 g of glucose in a solution. A second blood sample is then taken 2 hours later to measure glucose again. A 2 hour glucose of 7.8-11 mmol/l is used to defined impaired glucose tolerance, with a value of <math>\geq 11.1</math> mmol/l indicating possible type 2 diabetes (subject to confirmation based on the results of a second HbA1c or glucose</p>	<p>We prefer to leave these as they are. Essentially both statements are recommending the same thing. The suggestion to include subject to confirmation based on the results of a second is not specifically required here and is covered in recommendations.</p>

	test meeting any of the above criteria in people without symptoms of diabetes)".	
TD	<p>Whilst the aspiration is reasonable, the scale of the 'at risk' population, particularly within larger board areas makes the implementation of this unfeasible and unaffordable. Given that over two thirds of the adult population are overweight or obese and a significant cohort of the population would meet other risk factors, this approach would effectively reflect population-level screening where, as noted, there is no evidence of benefit. Further resource would be required for additional testing and clinical requirements. It is not clear whether a targeted case-finding approach has been considered. Any consideration of this and the evidence base around it should be described in this section to be clear why this approach would or would not be recommended. Local scoping of case-finding approaches in NHSGGC found limitations in their use in relation to the availability of appropriate data however a broader evidence base would be helpful.</p> <p><b>3.1</b> Self-identification of risk should be highlighted at the beginning and at this point they should be fully informed about the consequences of the screening tool and of not screening.</p> <p>Additional information on coding relating to a condition that they may or may not develop could be considered, to support GP practices to adequately warn their patients of the implications of having a diagnosis on their record.</p> <p>Recommendation in relation to self-assessment within community venues requires more clarity. What venues are being described and how does this approach reflect the evidence? There is evidence around the limitations of community based approaches that have identified clinical risk where they are not linked to the appropriate clinical systems.</p> <p>Recommendation 3 – typo - added to the person’s health record by the professional. and that a diagnostic blood test – full stop not needed</p> <p><b>3.2</b> - Identification of T2 DM is very focussed on the GP and does not incorporate the wider primary care team.</p>	<p>The guidelines do not recommend treatment for ‘at risk’ populations, but instead recommend consideration of their risk factors during routine healthcare appointments where there is an opportunity to quantify their risk with a risk assessment tool. We have not conducted primary evidence reviews.</p> <p>We have amended the threshold for prediabetes from FPG 5.5 to FPG 6.1 which will reduce the numbers implied in the consultation draft.</p> <p>3.1 Yes, in the introduction to the section on Risk assessment we have made clear the importance of informed consent which covers this important point about harms and risks.</p> <p>The risk tool should be offered by primary care providers, so they should highlight the risks of delayed diagnosis of prediabetes or diabetes.</p> <p>At this stage it is a tool to estimate risk, rather than screening.</p> <p>This is an implementation issue for the development of community, treatment and care services. We have added a new section under Implementation.</p> <p>Full stop has been removed.</p> <p>We have changed the good practice point from GP consultations to primary care:</p>

	<p><b>3.3</b> Implementation of reassessing risk/ patient recall may be dependent on enhanced patient management systems.</p>	<p>Primary care consultations are important opportunities to identify individuals at elevated risk and an opportunity to make a shared decision on whether or not a diagnostic test is indicated.</p> <p>The other recommendations provide advice for whichever healthcare professional is carrying out testing.</p> <p>3.3 (now Reassessing risk) the recommendation reflects the evidence and should inform the development of patient management systems.</p>
TR	<p>Thank you for developing these guidelines which will be extremely useful . I wanted to comment on this section and ask if it would be possible to consider HIV infection as a condition that can increase the risk of Type 2 Diabetes (Page 7). There is increasing evidence to support the higher incidence of Type 2 Diabetes amongst people living with HIV. Research has reported a 1.39-4 times higher incidence in this group. I have included some references.</p> <p><a href="https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0250676">https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0250676</a></p> <p><a href="https://drc.bmj.com/content/5/1/e000457">https://drc.bmj.com/content/5/1/e000457</a></p> <p><a href="https://www.frontiersin.org/articles/10.3389/fmed.2021.676979/full">https://www.frontiersin.org/articles/10.3389/fmed.2021.676979/full</a></p> <p>On page 10 <b>section 3.2</b>, the recommendation in relation to re-testing for those who are asymptomatic with an HbA1c of 48 or above '• Carry out a second blood test within 3 months of the original test'. Is it possible to recommend a minimum time from the original test for this second test to be repeated? Is it more effective to repeat the test nearer to 3 months or as early from the original test result as possible?</p>	<p>We have listed the conditions covered in the evidence review by NICE. Local health board protocols for HIV include testing for diabetes.</p> <p>We have amended to say 3-6 months, in line with the NICE Type 2 diabetes guideline.</p>
<b>Section 4: Preventing progression from prediabetes to type 2 diabetes</b>		
CC	<p>Why are smoking, alcohol and sleep not included?</p>	<p>We have amended the final sentence to say: While the following risk factors are not covered in the recommendations, advice, signposting or referral to relevant services should be given to people on smoking, alcohol and sleep.</p>

BK	<p>The introduction is very clear. I appreciate the last sentence in the intro outlines what isn't in scope i.e. smoking etc. I do however wonder if it is worth stating that although smoking and alcohol are not considered in this guideline they should be considered as part of the review process with onward referral to support/cessation services where indicated.</p> <p><b>4.1.2</b> Is there any merit in including Figure 1 from the Public Health Scotland Standards for the delivery of tier 2 and tier 3 weight management services in Scotland in the guideline. It ensures that readers at a glance get an understanding of the different tiers of WM service. It also helps break up the text with a figure.</p> <p><b>4.2</b> Clearly very detailed recommendations. It would be useful having a one paragraph update on the provision of these services across Scotland so that the reader can contextualise where we are at present. This covers the implementation in Scotland part of the recommendations. The more we can contextualise the recommendations to the current Scottish context the more we can get the clinical community to review where we are at present and hopefully what we need to do to support further implementation.</p>	<p>The final sentence has been amended to:</p> <p>While the following risk factors are not covered in the recommendations, advice, signposting or referral to relevant services should be given to people on smoking, alcohol and sleep.</p> <p>The figure has been added.</p> <p>Because of the variation in practice across Scotland, and it is constantly changing, this isn't feasible. Users should consult their local pathway.</p> <p>NHS Boards are at different stages of implementing tiers 2 and 3 of the Public Health Scotland standards for weight management (see figure 3).</p>
CH	<p>As noted above, the key is which interventions actually work outside a Trial setting, with real Scots? Countering effectively targeted PR and Advertising influence to consume unhealthy foods, on a fraction of the budget of companies whose profits depend upon continued consumption, requires smarter psychologically-informed strategies (often with a limited budget). Free, recommended motivational Apps may be the key, in the absence of legislation to limit companies profiteering from promoting cheap low quality diets, delivered to the doors of sedentary customers in their own homes?</p>	<p>Agree, this is valuable, but outside remit of the guideline.</p> <p>This is covered by other organisations such as Public Health Scotland.</p>
CW	<p>In those with risk factors, reassess the individual's risk factors at least once a year, and review any changes in behaviour or social circumstances or any practical lifestyle changes people at high risk have made. Use the review to help reinforce engagement in reducing modifiable risk behaviours. The review</p>	<p>Amended to:</p> <p>The review could also provide an opportunity to discuss any barriers and to help motivate people to restart any positive behaviours that may have lapsed.</p>

could also provide an opportunity to discuss any barriers to help motivate people to 'restart'.

What does 'restart' mean? this is not made clear to the reader

#### **4.1 4.1.1 Components of an effective diabetes prevention programme**

In those with risk factors, reassess the individual's risk factors at least once a year, and review any changes in behaviour or social circumstances or any practical lifestyle changes people at high risk have made. Use the review to help reinforce engagement in reducing modifiable risk behaviours. The review could also provide an opportunity to discuss any barriers to help motivate people to 'restart'.

R Lifestyle behaviour change programmes should offer ongoing tailored advice, support and encouragement to help people:

- undertake at least a level of physical activity that is in line with government recommendations
- gradually lose weight towards a healthy body weight

Recommendations should be based upon individuals starting point of their current level of weight or physical activity and tailored to make realistic goals towards increasing activity, less sedentary time and prevention of weight gain and loss if possible. This means that many people may still not meet the PA guidelines or achieve a 'healthy weight' as determined by BMI charts. To avoid weight stigma these conversations should first of all determine what changes may have been implemented in the last 6 months around weight, physical activity and eating behaviours.

You need to define what a healthy weight is.....

#### **4.1.2 Diet and weight management**

Overall the approach is written well with the evidence base available. However it is also important to note that the individual's preference for finding a balanced way of eating for weight loss should encourage finding a dietary approach that they can stick with during the weight loss stage and then support them to find a dietary approach for longer term weight loss maintenance which may be different from the weight loss phase.

Agree. This is linked to realistic medicine.

'healthy' has been changed to 'healthier'.

Discussion around the person's personal circumstances are covered in the introduction of the section on Preventing progression from prediabetes to type 2 diabetes. We have created a new section in the introduction 'Person-centred communication' which includes links to training for conducting good conversations in section the introduction

	<p>Evidence shows that macronutrient distribution is not the overriding factor in achieving successful weight loss but the diet that they can stick to taking into account their cultural and social scenarios and affordability.</p> <p>Comment on recommendation: A variety of weight loss dietary regimes can be adhered to but neither high nor low carbohydrate (ketogenic) diets are recommended.</p> <p>Some people living with type 2 diabetes choose to follow a low carbohydrate plan (&gt;50g - &lt;120g day). This is not ketogenic and should be supported for my reasons listed above.</p> <p>Very low carbohydrate diets (ketogenic) are diets consisting of &lt;50g carbohydrates per day.</p> <p>I would make this clear in the recommendations that you are referring to Very Low Carb diets but also to acknowledge that some individuals will choose to follow this to manage their pre diabetes and should be supported to ensure that the nutritional quality of their diet is as balanced as it can be in all other nutrients.</p> <p>People are going to follow low carb diets to manage T2D even though the guideline does not support this, maybe this needs to acknowledge that and that if they are doing low carb to ensure diet is nutritionally adequate and not deficient.</p> <p>Recommendation: Offer people with a BMI of 30 kg/m<sup>2</sup> or more (27.5 kg/m<sup>2</sup> or more if heritage includes South Asian, Chinese, other Asian, Middle Eastern, Black African or African-Caribbean family background) a structured weight-loss programme. Or, if more appropriate, offer them a referral to a dietitian or another appropriately trained health professional.</p> <p>I would make it more clear what is meant by 'if more appropriate' - what examples are there to guide reader in making this decision?</p>	<p>We think changing the term 'healthy' to 'healthier' allows people to set manageable targets, rather than determining what their health weight.</p> <p>We did not conduct an evidence review to determine whether one diet was superior to another. We have therefore removed the statement regarding high or low carbohydrate diets.</p> <p>The focus of the guidance is that the individual should find a diet that suits their lifestyle, culture and values.</p> <p>This is covered by the statement: Dietary guidance should promote self-management and always consider an individual's treatment goals alongside practical challenges, values, cultural appropriateness, preferences, social circumstances and income.</p> <p>We have signposted to advice on a range of foods and dietary patterns available, and listed the range of foods required for a balanced diet.</p> <p>This recommendation has been replaced with advice to follow the weight loss programme recommended in the Public Health Scotland standards for weight management.</p>
ELC	<p>Lilly agrees that “upon receiving a diagnosis of prediabetes....it may be possible to prevent or delay progression to type 2 diabetes by addressing modifiable risk factors”, with a primary modifiable risk factor being excess weight.</p>	<p>The sections have been revised to provide further information on the SMC advice.</p>

	<p>Lilly recommends the SIGN Guideline should consider all options, including cost-effective pharmacological interventions, for patients with excess weight to support them in reversing their prediabetes. Among the patients in the SURMOUNT-1 clinical trial with prediabetes at baseline (N = 1032), 95.3% patients treated with tirzepatide reverted to normoglycemia at week 72, as compared with 61.9% of patients in the placebo group.</p> <p><b>4.1.2 Diet and Weight Management</b></p> <p>Within section 4.1.2, a recommendation or amendment to the “structured weight-loss programme recommendation”, should include pharmacological treatments that are cost-effective for weight management in people with a BMI≥30 (27.5 kg/m<sup>2</sup> or more if heritage includes South Asian, Chinese, other Asian, Middle Eastern, Black African or African-Caribbean family background) and at least one weight-related comorbidity, including prediabetes.</p> <p>Furthermore, Lilly would like to highlight the recent NICE HTE14 early value assessment on digital technologies for delivering weight-management services. These digital technologies may enable more patients to access support while on pharmacological interventions to prevent the development or progression of their prediabetes.</p>	<p>We have added this to the introduction to the section.</p>
DK	<p><b>4.1.3</b> Second good practice point. I would suggest adding "and disabilities" after other conditions.</p>	<p>Changed to: In shared decision-making discussions about someone’s options for physical activity, be sensitive to any individual barriers such as health conditions, physical disabilities or eating disorders (see <a href="#">SIGN 164: Eating disorders</a>).</p>
DK	<p><b>4.2</b> Again, the second good practice point reads like a statement of fact rather than something action based. needs rewording.</p>	<p>Second GPP has been removed as it is covered in the section on Supporting behavioural change.</p>
DM	<p>Supporting behaviour change is key. Is there an economic evaluation to cover the cost effectiveness of these interventions?</p>	<p>The recommendations are taken from NICE who conducted an economic evaluation as part of their evidence review.</p> <p>We have amended the threshold for prediabetes from FPG 5.5 to FPG 6.1 which will reduce the numbers and resources implied in the consultation draft.</p>

DS	Sorry to be pedantic, but please capitalize Dietitian on page 15, and throughout the document.	It is house style to use lower case with job titles.
HD	<p>The supporting behaviour change section, details some evidence-based techniques. However, given that the ethos of the guideline is trying to recognise social and environmental influences, it would be beneficial to at least include changing the environment and prompts/cues.</p> <p>Good to see recommendations for training and inclusion of health professionals including health psychologists and dietitians, as well as engagement with community leaders.</p>	<p>Social environment is one of the barriers that the recommendations advise discussing with the individual, eg. support individuals to identify and problem-solve barriers to maintaining healthful eating habits and physical activity. No further recommendations on environmental influences were in the NICE guideline that we have adopted..</p> <p>We have added links to the NES MAP training in the section on supporting behavioural change</p>
JH	<p>The recommendations in the guideline regarding type 2 diabetes prevention programmes are feasible in Scotland. They do suggest that these programmes are deliverable in a wide range of settings, many of which suggest face to face contact with minority groups. Although evidence based and impactful for these groups, this would require more investment in community care, due to the time it takes to travel, cost of venue hire, specific targeted resource development, and the involvement of interpreters or other support services.</p> <p>Onward referral to activity on referral is beneficial to many people, as is including activity within programme sessions. Certainly locally to me, these Local Authority services are not sufficiently well enough funded to meet demand, and public buildings offering leisure services and community space are closing in areas of health inequality.</p> <p>Current funding structures do not support implementation at a level sufficient to impact the number of people we need to reach to reduce national prevalence, incidence and burden.</p> <p>The supporting information does support implementation of the guideline, if there is sufficient multi-organisational resource to be able to deliver on this at whole systems level.</p> <p>It is well set out and easy to understand.</p>	<p>Agree this is an issue. SIGN is about recommending best practice with the aim that local boards and primary care to work towards meeting the recommendations.</p> <p>The recommendation focuses on the need to adapt to the needs of the individual, including their cultural or religious beliefs. It does not necessarily need to be face to face. We have added a good practice point to consider use of technology which is accessible to people whose first language is not English.</p> <p>A new section on implementation has been added which highlights the need for wider community services.</p>

<p>JW</p>	<p>See above section 3 response.</p> <p>Can we be clear on what we mean about digital/remote interventions.</p> <p>Digital/remote enabled in-person service can be nhs group NearMe. 1:1 Near me. Remote only - tel remote 1:1. All the above are synchronous. Digital can also be a procured digital service such as Oviva prevent or Second Nature prevention. Procured digital services use a range of digital support and tools - video/ asynchronous chat/ synchronous contact/ remote health pathways support etc. NHSE identified some key aspects of digital services that were key to ensure effective digital interventions. Should we mention these as we may procure a digital prevention service for Scotland and Boards are currently procuring these digital services currently.</p> <p>Are we strong enough on ensuring that those identified as high risk are given supported effective conversations onto appropriate diet/lifestyle/weight management interventions to reduce risk?</p>	<p>In this paragraph we have added a sentence to clarify what the digital programmes included:</p> <p>The programmes assessed delivered information, advice and support using a combination of digital technologies, such as smartphone apps, websites, videoconferencing, and wearable devices such as smartwatches.</p> <p>We have added further information on holding good conversations to the introduction.</p>
<p>KS</p>	<p>feasible and implementable - yes, based on the guidance you have provided. but....</p> <p>Many thanks for the opportunity for feedback.</p> <p>Considering that type 2 diabetes strong crossover with metabolic associated conditions including fatty liver disease and obesity, it is useful to see the determinants of health - however this significantly downplays the role of nutrition.</p> <p>The specific guidance you have provided around low fat, reduced saturated fat are specific to cardiovascular risk, and not to type 2 diabetes.</p> <p>The only way you've put in more detail about inducing remission is by rapid calorie weight loss, but there is evidence to show that this can impact the body's ability to keep weight off in the future, and this is essentially a short to medium term measure - where going deeper and looking at the root cause of diets, and also looking at the hormonal level is largely ignored in this guideline.</p>	<p>We have removed the paragraphs describing different diets. The recommendations encourage a long-term change in dietary habits.</p> <p>This may be due to other factors. It is not necessarily because the eatwell guide is incorrect.</p>

	<p>There is reference to the eatwell plate which I'm sure that NHS England do not endorse as a management for type 2 diabetes - and encouraging people to eat healthy with the eatwell plate will not help at a population level - we've had this plate for 10 years + and we still have significantly rising rates of diabetes and obesity - so this is not a strategy to move people towards.</p> <p>I believe you have missed out all cultural sensitivity with ethnic groups being at higher risk of developing DM at lower levels of weight/BMI, and more at risk of central adiposity.</p> <p>There also a lack of mention of strategies and support for dietary plans outside of reduction in calorie, many which have evidence base including mediterranean, low carb, and reducing processed food.</p> <p>Unfortunately the guideline does not go into detail on the treatments of diabetes and prediabetes which really do need to focus on this nutrition, exercise, wellbeing, sleep and stress.</p> <p>I commend the input on how to run a diabetes and lifestyle intervention program - but I do feel here that more options need to be offered on how to do this - as these interventions are where medical teams (GP/Dietetic) can meet with health &amp; wellbeing practitioners (health coaches) (non medical) to deliver effective interventions, which are cost effective.</p>	<p>The guideline has not covered evidence for specific diets, as people's needs vary. This is covered by the introduction in the section Diet and weight management:</p> <p>Dietary guidance should promote self-management and always consider an individual's treatment goals alongside practical challenges, values, cultural appropriateness, preferences, social circumstances and income.</p> <p>A range of foods and dietary patterns that are suitable for weight management", and the recommendation.</p> <p>No recommendations were identified for education interventions or psychological wellbeing interventions.</p> <p>For other risk factors we have added the following sentence to the introduction of the section Identifying people at high risk of type 2 diabetes:</p> <p>Other risk factors that are not included are smoking, alcohol and sleep, although referral or signposting to relevant services to address these factors is encouraged.</p>
MC	<p>Are there resources within practices to implement annual reviews alongside all the existing reviews such as CVD, HTN, asthma/copd, diagnosed diabetes, etc?</p>	<p>Some of the people with prediabetes will have comorbid conditions such as CVD so checking weight and risk factors will be covered in that health check. We have added a sentence to the good practice point to make this clearer:</p> <p>If the patient has comorbid cardiometabolic conditions these checks could be captured in the same annual review.</p> <p>We have amended the threshold for prediabetes from FPG 5.5 to FPG 6.1 which will reduce the numbers implied in the consultation draft.</p>
MCh	<p>Clarify blood glucose levels which are normal/ pre- diabetes/ diabetes. - could a table be used instead of plain text?</p> <p>Gold standard = HbA1c - listed first as a test?</p>	<p>We have restructured the paragraphs in the section Testing for prediabetes, so that HbA1c is the test that is prioritised</p>

	How will patients be followed up by General Practice? Whose responsibility?	We have made recommendations and good practice points in the guideline that set out the required follow up parameters and where this should be done.
SF	Again treating patients with pre diabetes sounds appropriate but will constitute huge additional workload so will need resourced. Perhaps training and utilisation of community link practitioners at this stage to link with local 3rd sector and 'green' activity groups might help.	We have updated the implementation section to highlight the need for a whole systems approach to obesity and type 2 diabetes prevention which includes utilising community assets.
SW	First sentence suggest replace "Upon receiving" with "Following"	Amended. (1 <sup>st</sup> sentence, introduction to section on Preventing progression).
TD	<p>In the current climate, it could be challenging for boards to implement a bespoke diabetes prevention programme, in addition to other lifestyle services which already meet much of the criteria described and are struggling to meet existing demand. This could raise an expectation of care that could be difficult to achieve without additional resource. Recognition should be given to the fact that the specific recommendations for the content of a diabetes prevention programme could be packaged and delivered through a range of initiatives e.g. tier 2 WM, physical activity referral schemes etc.</p> <p>This section should be strengthened with clear evidence outlined for the impact of all topics e.g. diet, weight management, physical activity. The evidence base to support the effectiveness of T2 weight management is far more robust than acknowledged here. The section could then be re-structured to clearly describe the evidence for all topics before moving on to the specific recommendations. The evidence-based role of prediabetes education should also be detailed here.</p> <p>There are multiple mentions of achieving and maintaining a healthy weight. It may be more appropriate to describe progressing towards a healthy BMI or towards a healthier BMI (not everyone will be able to achieve a healthy weight.) Similarly, recommendations to undertake at least a level of physical activity in line with government recommendations may not be immediately practicable for many individuals. Could be better to describe aiming or working towards government</p>	<p>We have added a figure showing the tiered approach to weight management programmes and added that NHS boards should take account of these.</p> <p>The recommendations are taken from the NICE guideline. We have added hyperlinks to their evidence reviews.</p> <p>We have amended the recommendation to state that people should aim towards a <b>healthier</b> weight: Lifestyle behaviour change programmes should offer ongoing tailored advice, support and encouragement to help people:</p> <ul style="list-style-type: none"> <li>• gradually lose weight towards a healthier body weight</li> <li>• encourage regular eating, developing and maintaining healthy eating behaviours</li> </ul>

<p>recommendations. The recommendations could be included as appendix.</p> <p>Section 4, Paragraph 2 - “Evidence-based behavioural changes may not be feasible for some people; for example, their social and financial circumstances may make certain eating patterns or food choices difficult.” - May be challenging but definitely feasible and evidence based behaviour change techniques which are person centred should be adapted to reflect individual’s circumstances .</p> <p>Recommendation 3 - “Briefly discuss their particular risk factors, identify which ones can be modified and discuss how they can achieve this.” – This is not a brief discussion and should be structured around evidence based behaviour change.</p> <p><b>4.1.1</b> “Action planning: support individuals to develop a plan focusing on a physical activity or eating behaviour they intend to change – including when, where and how they will do this.” – Why does this have to be “or” – can’t both activity and eating behaviour be supported?</p> <p>Incorporate psychological wellbeing support into all aspects of prevention and early management of type 2 diabetes. – Not clear what is meant by psychological wellbeing support and clarity regarding the evidence base to support this. This would be a specific area where feasible given current capacity challenges would require significant investment to support implementation.</p> <p><b>4.1.2</b> “People living with overweight or obesity are at increased risk of developing prediabetes and type 2 diabetes. Dietary guidance including healthy eating, nutrition therapy...” – What is nutrition therapy? Is this from the Canadian guidance?</p> <p>Dietary advice should include advice on all contributory aspect of diet and their impact e.g. sugar, salt intake.</p> <p>Paragraph 3 – should read “Eatwell Guide” not “Eatwell Plate”</p> <p>Paragraph 6 - What parameters are used to define a low/ high CHO diet? Generally when individuals reduce their kcal intake they reduce their overall intake of CHO – particularly refined</p>	<ul style="list-style-type: none"> <li>• undertake at least a level of physical activity that is in line with government recommendations.</li> </ul> <p>Agree. This sentence has been changed to:</p> <p>Evidence-based behavioural changes may be very challenging for some people, for example, their social and financial circumstances may make certain eating patterns or food choices difficult.</p> <p>At this point it would be a brief discussion, with more indepth tailored discussion occurring once the person is on the programme.</p> <p>This relates to a behaviour change technique to focus on one behaviour initially to increase confidence in ability to make changes. We have amended to ‘specific physical activity or eating behaviour’ to make this clearer.</p> <p>General psychological wellbeing support should be a feature of all prevention and care. The statement references the role of all healthcare professionals in promoting psychological health rather than being a call for more mental health resource. We have amended the sentence in the section Underlying principles, to clarify this:</p> <p>Positive interactions are likely to improve psychological wellbeing be more effective in developing knowledge, skills and confidence to support behaviour change.</p> <p>The background information on dietary advice has been removed as this was not part of the evidence review. Readers should refer to the NICE guideline, from which the recommendations are taken.</p> <p>Changed to eatwell guide</p>
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	<p>CHO – e.g. sweets, biscuits cakes, chocolate, crisps drinks high in CHO etc.</p> <p>“Low glycaemic index or low glycaemic load diets can be recommended when fibre, protein, saturated fat and sugar recommendations are being adhered to.” - Links used do not explain glycaemic index/load – this would need to be explained further or omitted. Should document focus on something so specific – this is a T2D guidance not dietetic guidance.</p>	<p>The advice on specific diets has been removed.</p>
<p><b>Section 5: Drug treatments to prevent type 2 diabetes (now section 4)</b></p>		
<p>AS</p>	<p>I know there is not a lot of information on this out there but I don't think it is clear when GLP1's should be considered as a drug treatment in relation to the other options, is this if lifestyle modification hasn't worked or can it support lifestyle modification.</p> <p>In the order I do wonder if metformin should come first as this has clear guidance on when it should be used.</p> <p>I also do worry about the wording of the recommendations for GLP-1's. In 5.1 it implies that GLP1's are licensed as an adjunct in a reduced calorie controlled diet but I don't believe all of them are.</p> <p>The recommendation in <b>5.1.1</b> should be updated to include the brands of semaglutide and liraglutide that are licensed and SMC approved. I think without clarity on the wording of GLP-1's we are opening them up to being widely prescribed on the NHS which if it is not appropriate will create an additional cost pressure.</p> <p>I think the statement in <b>5.1.2</b> is reflective of this worry where it calls GLP-1's anti obesity medications which is not their primary use on the NHS and what we are proposing.</p> <p>I think the section on orlistat has to be expanded as the recommendation comes from a NICE 2012 paper when there are less options and I can't really see a lot of current evidence either published or from practice that supports it's use. I think</p>	<p>We have stated that these therapies can be used as an adjunct to lifestyle changes. We have also added information from the national consensus statement which aims to help prescribers prioritise patients (see the Implementation section). We have also referenced SMC criteria and the licenced indication criteria for completeness.</p> <p>It would not be accurate to choose to place metformin first as it is not a direct comparator – the indications for metformin are for glycaemic control/prediabetes when the indications for GLP1s are weight loss, obesity in the presence of associated condition like prediabetes. One class of drug attempts to control symptoms, another addresses root cause. This can be clarified in the section.</p> <p>GLP-1s for the indication of obesity ARE all licenced as an adjunct to a reduced calorie diet.</p> <p>This statement is incorrect – in this context, GLP-1s ARE anti-obesity medications so this is accurate.</p> <p>Orlistat is not a direct comparator to the other medications so there is no defined/evidence-based sequence in which to use these.</p>

	<p>this could be made clearer and also as above, making it clearer where each treatment comes in practice.</p> <p>Add in sick day rules for metformin as it is essential patients are counselled on these</p>	<p>A good practice point has been added: Individuals should be advised to withhold metformin if they have nausea, vomiting or dehydration (using Medication Sick Day guidance).</p>
BK	<p>Very useful to see the up to date guidance on pharmacotherapy and in particular the comments detailing the current situation in Scotland. The comment that their use should not be restricted to specialist WM services is also welcome.</p>	<p>Thank you</p>
CC	<p>This is clear</p> <p>It says the drugs should be prescribed in addition to lower calorie diet and physical activity - but think this may not be done in practice.</p>	<p>Yes, we acknowledge that work is required on implementation to ensure that wrap around care for obesity medications is in place.</p>
CH	<p>Cost-benefit analysis will be the key here of bariatric surgery. It should be a competent investment/ health benefit return analysis over 5 to 10 years as the private sector would deploy before making any decision to invest.</p>	<p>Excellent data exists in relation to cost effectiveness of bariatric surgery as a treatment and SMC have now determined that the approved obesity medications demonstrate cost-effectiveness to the Scottish NHS.</p>
JR	<p><b>5.1.1</b> - GLP1s currently limited to use in tier 3 weight management services. Guideline proposes to extend this to all NHS settings. Not feasible without significant transfer of funding and workforce to primary care. This would absolutely open floodgates. Impossible to implement - even if there was supply in the NHS....</p>	<p>The recommendations have been revised to reflect the advice issued by the Scottish Medicines Consortium. The implementation section signposts to the Scottish Government consensus statement which suggests a phased approach to implementation of the advice, starting with people with a BMI <math>\geq 38\text{kg/m}^2</math>.</p>
DK	<p><b>5.2</b> 4th Recommendation. I would suggest that this say "carry out" rather than "consider" an annual review, especially as it is related to a side effect of a prescribed drug.</p>	<p>The use of consider effects the strength of the supporting evidence.</p>
DK	<p><b>5.3</b> I do not have a problem with the recommendation but we are all aware that it is proving well nigh impossible for those who have been prescribed Orlistat to actually get it from the pharmacy!</p>	<p>We appreciate sometimes there may be challenges with implementation, but it is the role of the guideline to make recommendations for best practice.</p>
DM	<p>Important section to include as it is a fast paced area (and will continue to be so). Again, is there a link to the economic evaluation/ SMC recommendations. These recommendations</p>	<p>We have added more detail and provided links to the relevant SMC advice.</p>

	need to give simple advice to NHS Boards as to the cost effectiveness of a range of interventions.	
DS	Interesting that Metformin could be considered for people with a lower BMI who have pre-diabetes. It would be helpful to know what a "lower" BMI means. Is it <30, <27, and does this vary with ethnicity?	Statement has been removed as it was not part of the NICE evidence review on which the recommendations are based.
SW	Important to clarify what is meant by lower by giving comparison group in "Metformin improves insulin resistance and is therefore a common treatment for type 2 diabetes. Metformin may also be suitable for individuals with prediabetes who have a lower BMI to prevent progression to type 2 diabetes."	Statement has been removed from the guideline.
ED	<p>Pharmacological management in pre-diabetes including metformin and GLP-1 agonists via primary care rather than specialist weight management services has the potential to open the floodgates. Concerns expressed around both demand and prescribing costs being unmanageable, with Grampian HSCPs currently sitting with £10 million projected prescribing overspend already. Would need a model that protected from risk of overwhelming the system.</p> <p>Unlike current practice, where medications are administered as part of a Tier 3 service which offers the necessary psychological and dietetic support, will the proposed delivery within Primary Care sufficiently support the patients needs and wellbeing.</p>	<p>The guideline provides advice on the effectiveness of treatments. The information should be used to inform models for implementation.</p> <p>This is a point being considered by the national working group for obesity medications, with current evidence suggesting that wrap around support in primary care would be sufficient for most patients.</p>
ELC	<p>We are aligned with SIGN's assessment that recent scientific developments in obesity pharmacotherapy create new possibilities for using medications in conjunction with diet and physical activity for the prevention of type 2 diabetes, and that incretin-based therapies demonstrate significant potential to effectively treat obesity, type 2 diabetes, and reduce cardiovascular disease risk. We understand that a consensus statement for NHS Scotland advises that these medications do not need to be restricted to use within specialist weight management services.</p> <p>We believe that allowing the wider use of new obesity medicines outside of specialist weight management services is a step forward in the effective care of patients with this condition. In doing so, we believe that SMC's recommendations should also</p>	We have added advice on the consensus statement to the implementation section.

	<p>be an important consideration to ensure both the clinical- and cost-effectiveness of treatments is taken into account. Eligible patient population and treatment setting are key inputs in the cost-effectiveness recommendations from the SMC, which ensures that the most cost-effective treatments (that have been evaluated in the relevant population and/or setting) are used initially/first.</p> <p><b>5.1.1</b> Glucagon-like peptide-1 receptor agonists</p> <p>Within section 5.1.1, we would suggest that the SIGN Guidelines state the SMC Advice in full, including any applicable restrictions, for the pharmacological interventions in addition to their indication. Using the indication alone may lead to confusion for readers, including the Health Boards, as this broader population may not have been assessed to be the cost-effective population by SMC.</p> <p><b>5.1.2</b> Glucose-dependent insulintropic polypeptide dual receptor agonists (GLP-1/GIP RAs)</p> <p>We are aligned with SIGN's assessment that GLP-1/GIP RAs should be included and considered in the prevention of type 2 diabetes. To ensure section <b>5.1.2</b> contains relevant information and recommendations, we request that the publication of this SIGN Guideline is delayed to incorporate the latest SMC Guidance (SMC2653) for tirzepatide for weight management. SMC2653 will be published on 10 June 2024.</p>	<p>The SMC advice has been amended to reflect the restrictions, and a link to the full SMC advice provided.</p> <p>Advice for tirzepatide has been added.</p>
JH	<p>The guideline for drug treatment is very clearly written and includes the additional information required to support implementation. It would be helpful to have a table which states prescribing considerations.</p> <p>(e.g. Drug name and class; HbA1c benefit; hypo risk; cardiovascular risk, renal considerations; CKD considerations)</p> <p>The structure, presentation, language and content was easy to read and understand.</p> <p>The supporting information doesn't address the issue of establishing local pathways or funding for these drugs, which are likely to be in huge demand.</p>	<p>Thank you for your suggestion but it is not within the remit of this guideline to create a detailed prescribing guide.</p> <p>We are aware of the challenges of implementation, however many of which are outwith the scope of a clinical practice guideline. Areas that can be addressed have been highlighted in the section on Implementation.</p>

KF	I feel there is no need to check renal function 6 monthly after starting metformin for prediabetes especially if baseline renal function is normal. This is also challenging given sparsity of resources in primary care. I think an annual check is adequate	Amended to annual check up.
MC	This is new to me and needs rolled out via local MCNs	The guideline will be distributed to MCNs.
MCh	Surprised at focus on pharmaceutical means. In particular, focus on modern expensive drugs. Metformin has a long established safety record in treatment of T2 Diabetes. Many people can make changes to diet, exercise, etc.	We have been led by the evidence, which demonstrates highly effective outcome from new incretin-based therapies for the treatment of obesity, the main modifiable risk factor for prediabetes and type 2 diabetes.
NN	We have one small factual query in relation to clinical trials: To our knowledge there is no available data comparing the Novo Nordisk GLP-1RA treatments for obesity (liraglutide 3mg and semaglutide 2.4mg) with diet and exercise versus these treatments on their own. We propose amending this to 'Clinical trials demonstrated that when used in conjunction with non-pharmacological therapies, incretin-based therapies were more effective than when non-pharmacological therapies were used alone'. Thank you.	Second paragraph of the introduction in the section on Achieving remission has been amended to reflect this change:  Clinical trials demonstrated that when used as an adjunct to non-pharmacological therapies, incretin-based therapies were more effective for weight loss than when non-pharmacological therapies were used alone.
RCN	Limited availability of GLP-1s and whilst the ones listed can be used for weight management, need to consider availability and appropriateness compared to those with type 2 diabetes as stocks may be limited	The guideline provides recommendations based on the clinical evidence. Advice around implementation of the SMC advice is included in the implementation section.
SF	Again treating patients with pre diabetes sounds appropriate but will constitute huge additional workload so will need resourced.	The guideline group acknowledge the system pressures around this, but the guideline provides advice practice for services to work towards. We have added further information to the implementation section
TD	The section on medication has no monitoring requirements mentioned and no guidance on when to discontinue.	We have added advice from NICE on when to discontinue orlistat. Monitoring is part of weight management services, and we have included more information on digital tools that can help with remote monitoring.

## Section 6: Achieving remission

AR	<p>Some comments re the bariatric and metabolic surgery section</p> <p>Bariatric surgery should be referred to as bariatric and metabolic surgery (BMS) in the guideline.</p> <p>The effects of BMS are through altered gut hormones as well as reducing the size of the stomach.</p> <p>BMS is a safe and effective treatment for obesity and type 2 diabetes with a reported mortality of 0.08%. Over 480,000 bariatric procedures are reported in the latest yearly IFSO registry.</p> <p>Bariatric and metabolic surgery may improve life expectancy for patients with type 2 diabetes for up to 9 years. It is unfortunately remains a limited resource. For type 2 diabetes remission it remains the gold standard treatment.</p> <p>In the UK about a third of patients undergoing BMS have type 2 diabetes and this has been replicated in our data (Edinburgh). Patients in the UK with type 2 diabetes present later, at an older age, with more advanced diabetes and with a higher BMI than in other countries.</p> <p>The two main procedures performed are gastric bypass (Roux en Y gastric bypass and one anastomosis gastric bypass) and sleeve gastrectomy. Gastric bypass would be the recommended/preferred procedure for patients with type 2 diabetes if all things equal but sleeve gastrectomy still produces a high rate of remission and improvement of type 2 diabetes. Patients may be recommended for sleeve gastrectomy if they are on complex medications, smoke or have had complex abdominal surgery.</p> <p>With gastric bypass approximately 50% of patients will achieve remission of diabetes (our data 46%) and around a further 25% of patients will get an improvement in type 2 diabetes.</p> <p>The mechanism for improvement in type 2 diabetes involves bypassing the proximal gut and GLP-1. Although results are related to weight loss, especially with gastric bypass there are</p>	<p>Agree. We have changed this throughout the guideline.</p> <p>introduction: Sentence amended to: Bariatric and metabolic surgery (BMS), also referred to as weight loss surgery, aims to help people lose significant weight by reducing the size of their stomach and altering gut hormones to make them feel less hungry and full more quickly.</p> <p>Whilst this information is factual and relevant, this guideline is not specific for BMS and the group felt it was a level of detail not required within the scope of this guidance.</p> <p>We have made reference elsewhere in the guideline about the need to intervene early in the disease progress with effective treatments which would include BMS.</p>
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	<p>independent factors and results can be maintained even with weight regain.</p> <p>Bariatric and metabolic surgery has been shown to be cost effective for the NHS with reducing diabetes costs over a 5 year period.</p> <p>Future work should be aimed at targeting patients earlier in their disease pathway to consider BMS.</p>	
AS	Should there/could there be information on what to do with drug therapy if remission is achieved	This was not covered in the evidence review on which the recommendations are based.
JMF	Sentence in <b>6.1</b> states "Reversing the disease", think we need to be careful how we communicate remission to health professionals / public. Suggest removing "reverse the disease" and replacing with sentence around achieving remission.	All reference to 'reverse' has been amended to align with agreed language 'in remission'
DK	<b>6.1</b> First good practice point. I feel that this should be a recommendation rather than just good practice.	We have not reviewed the evidence so cannot present this as a recommendation, but felt it was important to highlight, hence we have included it as good practice.
BK	<p>It may be useful at the end of section 6.1 to again provide a one or two sentence update on the provision of remission services in Scotland so the reader can contextualise the current situation. A lot of good work has been done in this area and emphasising that will be helpful. It may be that a case study would also be useful to highlight to the reader what is achievable i.e. the progress made by the East region.</p> <p><b>6.2</b> The GPP mentions the use of a validated holistic tool. Providing an example of this would be helpful to support implementation of the guideline.</p> <p>Again a one to two sentence update on the current provision of bariatric surgery in Scotland would be useful to help highlight that this isn't just generic guidance and demonstrates how it is applicable to NHS Scotland.</p>	<p>A statement has been added: Health boards across the NHS in Scotland currently deliver the Counterweight Plus structured type 2 diabetes remission programme, which was implemented as part of the Framework and underpinned by guidance in the PHS standards</p> <p>GPP has been removed. We are unaware of any peer reviewed, validated tools so a sentence has been added under 'recommendations for research' to acknowledge this.</p> <p>At this stage we are unclear as to the national picture with bariatric surgery and there are no longer nationally available guidelines for bariatric surgery so we can't currently accurately state the position unfortunately.</p>
CH	See above. Rather than an optimistic aspirational goal, upscaling all the specific service characteristics of successful interventions elsewhere in the UK or Europe, to our relatively	Further information about the framework and other initiatives has been added to the implementation section.

	<p>small population in Scotland will be key. This has the potential to circumvent the inevitable variance guaranteed by local HSCP or Health Board level delivery which already predictably delivers postcode lotteries across Scotland. Identify the specific characteristics and staffing of a model that works, and don't allow a HSCP or Health Board to deviate from it, under the banner of "local decision making". The QOF worked because it set the same specific standards for supporting all patients with a specific long term condition everywhere in Scotland.</p>	
<p>CW</p>	<p>Correct terminology for the intervention used in the DiRECT trial - it was a formula low energy diet NOT a Very Low calorie diet.</p> <p>Need to acknowledge all of the studies in this area, e.g. both RCT and RWE</p> <p>RCTs: STANDBY DiRECT, DiADEM, PREVIEW, DROPLET, DiRECT-Aust, and RWE: Hackney Groups (adrian brown), Direct Australia</p> <p>"The aim is to achieve remission as soon as possible after diagnosis. Many people can achieve remission without a formal evidence-based programme (signpost to effective methods of weight loss); however, it may help some."w</p> <p>See weight loss achieved in Scottish Weight Management services in my response to the introduction. To achieve remission significant weight loss is required and the evidence from DiRECT and other publications where Counterweight Plus* has been used, consistently achieves &gt;10kg or &gt;10% weight loss. This is not achieved in Scotland's Tier 2 ( 3%) or Tier 3 (5%) services except where an intensive programme such as Counterweight Plus is used (12%)</p> <p>For individuals to make an informed choice about the approach they are most likely to be successful with, they should be provided with the most up to date evidence on what different non-surgical weight management programmes can achieve:</p> <p>10-20% Pharmacotherapy</p> <p>10 - 15%</p>	<p>We are citing the recommendation from the Canadian guideline which clearly describes the type of diet. Low energy diet is not terminology that is commonly used.</p> <p>The recommendation by Diabetes Canada references the aim to achieve &gt;15kg of weight loss for remission. A further statement has been added in the narrative above to ensure readers are clear that this means a more intensive approach.</p> <p>We did not undertake a full evidence review for this section so we can't add this level of data, however there are other publications and research that readers can easily access on remission that would provide this level of detail.</p>

## Total Diet Replacements

5 – 7%

## Meal Replacements

3 – 5%

## Food Based Approaches

e.g. Low Carbohydrate, Low Fat etc.

DiRECT: Lean ME et al. Lancet 2018.

\*Groups: Marples et al, Nutrients 2022.

\*STANby: Sattar et al, The Lancet Regional Health: SE Asia 2022.

## 6.2. Bariatric surgery

“Patient care should be optimised while waiting for surgery in the tier 4 bariatric surgery pathway. Optimisation could include drug treatments to maintain or reduce weight”.

If optimisation has not included an attempt at a Total Diet Replacement or Meal Replacement programme, this should also be considered as an option to maintain or reduce weight whilst waiting on the surgery. In a study looking at pre op optimisation for patients living with osteoarthritis of the knee, 10% of those who followed a Total Diet Replacement did not require surgery after achieving significant weight loss. Currently total diet replacement approaches are offered for those with an early diagnosis of diabetes but not for those who are living with obesity and prediabetes.

\*Opportunity Trial.

[https://www.thelancet.com/journals/lanrhe/article/PIIS2665-9913\(23\)00337-5/fulltext](https://www.thelancet.com/journals/lanrhe/article/PIIS2665-9913(23)00337-5/fulltext)

It is not in the scope of this guideline to go into detail of what the optimisation should involve, our suggestion is that this is something for a specific BMS guideline. We have added a recommendation for research

DM	Also a critical step. How does this compare to the recommendations in the other sections? More important?	Group didn't know what this referred to, however, the recommendations are not ranked by importance as it may depend on the needs of the individual patient.
DS	Does this apply to those with a diagnosis of pre-diabetes, or only T2DM? I'm unsure as to why 6.1 is included as I don't know that we would carry out such an intervention with someone with pre-diabetes.	Prediabetes is a recognised condition related to obesity which we would treat with bariatric and metabolic surgery if appropriate.
ELC	Lilly agrees with the SIGN statement that "early in the course of type 2 diabetes, it is possible to reverse the disease through weight loss". However, Lilly would recommend that pharmacological treatment is included as an approach in addition to sections 6.1 and 6.2, especially as bariatric surgery is an invasive procedure. Among the patients in the SURMOUNT-1 clinical trial with prediabetes at baseline (N = 1032), 95.3% patients treated with tirzepatide reverted to normoglycemia at week 72, as compared with 61.9% of patients in the placebo group.	There is an insufficient level of evidence of efficacy for these medicines in the remission of type 2 diabetes at this time to recommend it as a specific and standalone treatment, although the group do acknowledge it is likely that any sufficient weight loss in the region of 10-15% will result in remission for some. At this point we cannot change the guideline to accommodate this until more published and peer reviewed evidence is available.
HD	<p>Within non-pharmacological approaches, it would be beneficial to be more specific (as has been done within the prevention section) on the behaviour change techniques that would be recommended, as well as the training and expertise required to do this.</p> <p>It states 'Younger patients may need to sustain weight loss to maintain remission.' This is true of all patients, so I feel this needs rewording. I wonder if it's about the support needed for younger patients to achieve remission over a longer period of time?</p>	<p>We haven't done an evidence review for this so cannot provide recommendations for specific behaviour change techniques.</p> <p>Sentence removed.</p>
JH	<p>The guideline for non pharmacological approach to remission is very clearly written and includes the additional information required to support implementation.</p> <p>It may be helpful to have a table summarising the meal replacement products and programmes considered to meet the recommendation (perhaps those included in the national digital pathway?)</p>	<p>Thank you</p> <p>The group felt this was out of scope of a clinical practice guideline and subject to change as the market develops. It is likely that any national procurement exercise would be the most robust way to obtain recommended products and programmes through a transparent specification and tender process.</p>

	<p>It would be helpful to have a short summary of the types of Bariatric Surgery available, as these have increased in type and have improved over recent years.</p> <p>The structure, presentation, language and content was easy to read and understand.</p>	<p>The group didn't think it was within scope of this guideline to go into further detail on bariatric and metabolic surgery and that there were other available guidelines (eg BOMSS guidance) that did this in a robust way that could be used for detail if required.</p> <p>Thank you</p>
JR	<p>Guideline does not cover whether people with very low HbA1c (ie remission) but who remain on SGLT2i or GLP1ag for cardiorenal benefit should be coded as 'diabetes in remission'. This has implications for follow up but also for life and travel insurance as well as patient self-understanding.</p>	<p>The following good practice point has been added:</p> <p>Upon achieving remission, ensure the patient is coded in GP systems correctly as being in remission of type 2 diabetes (READ code C10P1 Type II diabetes mellitus in remission). They should remain on the diabetes register for annual review despite their remission status. This should prompt routine diabetes checks for retinopathy, HbA1c and all other processes of care considered standard diabetes long-term condition management are carried out. This could be part of a comprehensive annual review for diabetes and other comorbidities, or prompted using the READ code 66AS.00 Diabetec annual review.</p>
JW	<p>The current level of remission being offered at diagnosis is very low. Can we make it stronger that people newly diagnosed with T2DM are provided with information on remission and supported into appropriate diet/lifestyle/weight management interventions. Should we give guidance on how to identify remission patients from historical primary care perspective?</p>	<p>We can strengthen message/best practice points to underline importance of this message across all services at diagnosis.</p> <p>Not within scope of guideline to recommend case finding or identification of patients in electronic record systems.</p>
KF	<p>Is there a reason why the published 5-year follow-up data for DIRECT is not discussed?</p> <p>It would also be nice to include some of Roy Taylor's ReTUNE data suggesting remission of T2D is possible even in people not living with overweight or obesity</p>	<p>It was not in scope of the guideline to undertake a full evidence review therefore we can't include detailed references to other studies here. The literature is now well established for remission and our hope is that the audience working in the area will seek out the source data from the Diabetes Canada guidelines and can explore these to better understand the wider evidence base.</p>
MC	<p>Individual motivation needs addressed</p>	<p>Psychological approaches for behavioural change and sustaining change are addressed in the section Preventing progression from prediabetes to type 2 diabetes.</p>
MCh	<p>This can put stress on people - not everyone can or will achieve remission.</p> <p>Focus should be on sustainable lifestyle changes.</p>	<p>Thank you, we have endeavoured to ensure that language throughout the guideline reflects that not everyone will achieve remission and that these programmes are not suitable for all. We have included the statement that it is critical to understand individual motivations and</p>

	VLCD are not suitable for everyone and can lead to substantial weight gain when stopped.	social and personal circumstances, including comorbidities and access to services.
SF	Certainly the Ayrshire and Arran Diabetes remission programme has been successful with high referral rates and patient satisfaction. Expanding it to the levels needed to significantly adjust the projections in the introduction will be very expensive and need huge new investment.	The group agree that investment is required to meet scale but this is not something that is appropriate to detail within the guideline structure itself.
SW	<p>Add three words in capitals to: Early in the course of type 2 diabetes, it is possible FOR SOME PEOPLE to reverse the disease through weight loss.</p> <p>Suggest clarify follow-up for people who achieve remission in terms of frequency of HbA1c measurement, eye and foot screening and options for rescue approaches for people who relapse back to diabetes</p>	<p>We have changed the sentence to:</p> <p>Early in the course of type 2 diabetes, it is possible for some people to achieve remission from the disease through weight loss</p> <p>A new GPP has been added:</p> <p>Upon achieving remission, ensure the patient is coded in GP systems correctly as being in remission of type 2 diabetes (READ code C10P1 Type II diabetes mellitus in remission). They should remain on the diabetes register for annual review despite their remission status. This should prompt routine diabetes checks for retinopathy, HbA1c and all other processes of care considered standard diabetes long-term condition management are carried out. This could be part of a comprehensive annual review for diabetes and other comorbidities, or prompted using the READ code 66AS.00 Diabetec annual review.</p>
TD	<p>There is no mention of the role and evidence-based impact of education following diagnosis on both the self-management of T2D to improve outcomes and its contribution to achieving remission. Evidence from Best Practice in the Delivery of Diabetes Care in the Primary Care Network (Published April 2021) highlights the following:</p> <p>"Face to face structured education soon after diagnosis with type 2 diabetes is efficacious and well established; with demonstrable improvements in glycaemic control, quality of life and weight, and reduced cardiovascular risk after attendance. Furthermore there has been reported reduction of depression, improvement of empowerment, skills and confidence in self-management of diabetes; with cost-effective benefits."</p>	This is not in scope for this guideline as covered in other guidelines specific to type 2 diabetes management.

<https://diabetesonthenet.com/wp-content/uploads/Diabetes-in-the-Primary-Care-Network-Structure-April-2021.pdf>

Paragraph 2 - Only includes the 2 year follow up findings – it would be good to also include the the 5 year follow up findings from DiRECT study.

Would be good to include evidence of cost benefit over time with patients reduction in medication and reduced contact time with healthcare professionals. Health economics of remission would be good to include.

Paragraph 5 - Robust psychological screening in place with sufficiently trained clinicians to undertake the psychological screening. Where would those who are identified at screening to have additional psychology support access the correct support to undertake the programme? What additional resource will be required for screening? Can we be clearer on the focus here? What is the evidence for screening / links to other guidelines? / what intervention is required to enable a patient to receive service.... What are benefits of harm?

"More research is required on the contribution of physical activity (which offers other physical and mental health benefits) to remission. Similarly, health behaviour change approaches that do not have weight loss as a primary goal may be more appropriate." - Sentence structure is requires revision. Evidence that other behaviours support achievement of remission is required.

Paragraph 7 – “Important to support individuals who enter a formal programme.” What is the definition of a “formal programme” and how does it differ from a “structured programme”?

Paragraph 8 – “Younger patients may need to sustain weight loss to maintain remission.” - ALL patients – not just younger patients required to sustain weight loss.

Second tick – focus on Tier 3 but not mention of Tier 2 weight management services.

It was not in scope to do a full evidence review so we cannot include reference to all studies. The recommendation should make it clear what approaches work based on the strength of evidence available.

We have provided reference to the SHTG economic analysis on remission which is an up to date summary of the cost benefit to NHS in Scotland.

We have suggested that more research is needed to understand role of PA in the remission of type 2 diabetes and removed the sentence about health behaviour change.

We have changed all reference to ‘formal’ programme to ‘structured’ programme to ensure language us consistent.

	<p><b>6.2 Bariatric surgery</b> – reference National Forum Planning 2012 – bariatric surgery prioritised for T2DM with BMI over 35 – not living with obesity (BMI 30). NICE differs significantly from NHS Scotland guidance.</p> <p>Bariatric surgery section does not link to any monitoring guidance e.g. GP hub created by BOMSS</p>	<p>This has been changed to:</p> <p>Use standards for the delivery of tier 2 and tier 3 weight management services for adults in Scotland as a basis for design and delivery of structured weight management programmes (see Figure 3, in the section on Preventing progression: components of an effective prevention programme).</p> <p>The National Forum Planning guidance is no longer current so not applicable in Scotland. There is currently no national Scottish guideline on obesity.</p> <p>The group didn't think it was within scope of this guideline to go into further detail.</p>
<b>Section 7: Provision of information (now section 6)</b>		
AS	?Diabetes UK also added in	Diabetes UK is included alongside Diabetes Scotland, and with links to the booklet, Understanding diabetes.
BK	<p>While the focus of the guideline is clearly glycaemia and obesity it would be useful in section 7.3 and arguably in other parts of the guidance to re-emphasise the risk of premature CVD and in particular the need to take a person centred approach to CVD risk reduction. As such individuals should ensure they have their BP, lipids and smoking status checked and if appropriate have these risk factors optimised. The benefits of preventing T2DM while ignoring other major vascular risk factors will be limited. As such it would be ideal if such an important guideline emphasises this important aspect in an attempt to offer a more holistic approach to care.</p>	<p>We have added a link to the SIGN Cardiovascular prevention patient booklet</p> <p>We have added the bullet point to the Checklist for provision of information:</p> <p>Make people aware that type 2 diabetes increases the risk of other health conditions, such as cardiovascular disease, but that changes in diet and lifestyle, stopping smoking, along with regular check ups for blood pressure and cholesterol, can help to reduce the risk.</p> <p>We have added the following sentence to the introduction to section 3:</p> <p>Other risk factors that are not included are smoking, alcohol and sleep, although referral or signposting to relevant services to address these factors is encouraged.</p>
CC	How about adding other National re/sources	

	<p>1. British Dietetic Association - Food Facts - Type 2 Diabetes, Portion sizes, Carbohydrates, Glycaemic Index - What and how to see a dietitian</p> <p>e.g <a href="https://www.bda.uk.com/resource/diabetes-type-2.html">https://www.bda.uk.com/resource/diabetes-type-2.html</a>  <a href="https://www.bda.uk.com/resource/carbohydrates.html">https://www.bda.uk.com/resource/carbohydrates.html</a></p> <p>2.. British Nutrition Foundation Portion Guide  <a href="https://www.nutrition.org.uk/creating-a-healthy-diet/portion-sizes/">https://www.nutrition.org.uk/creating-a-healthy-diet/portion-sizes/</a>  &amp; 3. Diabetes UK -specifically: portions guide/food labelling and Weight Loss Planner  <a href="https://www.diabetes.org.uk/guide-to-diabetes/enjoy-food/eating-with-diabetes/whats-your-healthy-weight/lose-weight">https://www.diabetes.org.uk/guide-to-diabetes/enjoy-food/eating-with-diabetes/whats-your-healthy-weight/lose-weight</a></p> <p>4. NHS Lose Weight <a href="https://www.nhs.uk/better-health/lose-weight/">https://www.nhs.uk/better-health/lose-weight/</a></p>	<p>Thank you for the suggestions. We have added them to a new subsection: Weight management resources.</p> <p>We have not included the British Nutrition Foundation as it partners with the food industry which presents a conflict of interest here.</p>
CH	<p>Countering misinformation (lifestyle social media, peer pressure, and traditional, dysfunctional lifestyle habits) should shape the design of provision of information. Who do we wish to inform? How do they access information in their lives? Scandinavia intentionally destroyed their Dairy industry to minimize vascular disease; successfully switching population dietary habits from a high saturated fat dairy lifestyle to increased consumption of soft fruit. Healthy food has to be cheap, accessible, desirable and visible! Digital media aimed at the target population is key. Expensive gym memberships and Just Eat/Deliveroo dropping off cheap diabetogenic diets to the front door, need to be countered.</p>	<p>We agree, these are large public health issues that need to be addressed.</p> <p>The focus of this section of the guideline is what immediate advice does an individual need when they learn they have prediabetes.</p>
CW	<p>For individuals living with a heavier weight, they should be able to make an informed choice about the approach they are most likely to be successful with, therefore they should be provided with the most up to date evidence on what different non-surgical weight management programmes can achieve:</p> <p>10-20% Pharmacotherapy</p> <p>10 - 15% Total Diet Replacements</p>	<p>We have not conducted an evidence review for specific weight management programmes. The advice is to tailor it to the individuals personal preference, lifestyle and culture.</p>

	<p>5 – 7% Meal Replacements</p> <p>3 – 5% Food Based Approaches e.g. Low Carbohydrate, Low Fat etc.</p> <p>There were some learnings on best language for use with patients and health professionals supporting those eligible for remission services in NHS England. This has come from the NEWDAWN study and preliminary findings were presented at DUK conference in April 24.</p> <p>Odd that you are recommending a companies website- Diabetes My Way. Does this create a conflict of interest?</p>	<p>We have used terminology which is currently in use. Any published advice on changes to language will be taken into consideration in the next update of this guideline.</p> <p>We have removed this resource from the list.</p>
DM	<p>Very useful to have a list of trusted/ approved web sites for reference.</p>	<p>Thank you</p>
JH	<p>The structure, presentation, language and content is easy to understand in this section. The links to national support are useful. The checklist for resources for people at risk fits the brief identified at the top of the section - it provides signposting information for patients and carers.</p> <p>The checklist for people with type 2 diabetes contains text which does not fit with the brief. It may be useful to include this in a separate and additional table as it is relevant for all in a different context.</p> <p>This includes all of the information under the title "patients are sometimes left to find their own information", and the final 2 points under "Employment issues" which ask questions about the need for organisational policy, rather than address signposting options. It would be helpful to outline the points at which to alert patients about insurance, or to replace that bullet point with "include information about insurance based on the circumstances of your individual patient".</p> <p>The information provided is feasible and easily implemented, particularly if available in a Once for Scotland format to which local signposting may be added.</p>	<p>Some of the recommendations are relevant for people with type 2 diabetes, working towards remission, so we have included advice. The section has been revised and some points removed.</p> <p>Thank you. The guideline and plain language version will be available on the Right Decision Support platform.</p> <p>We have highlighted the need for a Once for Scotland approach in the Implementation section.</p>

KF	Again i apologise for signposting my own work however I have independently made a series of person-facing social media videos (YouTube & TikTok) based on the 5 S's / importance of 24 hours physical behaviours for people living with T2D - stepping/sweating/sitting/strengthening/sleep. These have been well received by my patients and many colleagues to discuss the importance of lifestyle intervention They are also very applicable to people at risk of developing T2D. The videos are all independently made by myself with no industry/pharmaceutical involvement	Thank you for the suggestion. SIGN guidelines focus on links to resources from national organisations.
MC	Comprehensive	Thank you
MCh	Comprehensive list - how does a patient choose what is best ?	We have removed some of the organisations listed and added a new section directing people to weight management resources, so hopefully they can find a link which is tailored to their needs.
CH	The Couch to 4K App had celebrities encouraging people in their ear buds. Elaine C Smith successfully encouraged women to attend for mammography. Find role model(s) that people relate to. Make any change in diet and lifestyle rewarding (incentivized). The Hollyhealth App and similar free platforms may be one element, but rather than opportunistic reactive healthcare (99% of NHS Scotland activities), proactive anticipatory interventions are more likely to have longer term sustained benefit and impact for the future.	Rather than listing individual apps we have added a link to the NHS Lose Weight website which includes links to a range of useful apps such as the Couch to 5K.
SW	There are links to diabetes tech in pregnancy and to Joint British Diabetes Societies for Inpatient Care Group but no specific links to resources for diabetes prevention and remission!	The link to the tech in pregnancy has been removed. We have signposted to the patient version of the diabetes in pregnancy guideline for advice during pregnancy. We have removed the link to the diabetes inpatient care group. We have added resources for weight management.
TD	As above, in the checklist for provision of information post-diagnosis, additional information on the role and evidence-based impact of education should be included. People should be encouraged to engage with education as a first line intervention and not simply as an optional additional management tool.  Good practice guide regarding accessible patient information considerations should be included here.	The advice in the section Preventing progression from prediabetes to type 2 diabetes incorporates educating and encouraging people to alter their eating and activity habits to achieve remission. This section is a list of points to include that are supportive but not necessarily evidence based.

		<p>The following sentence has been added to the introduction of the checklist for provision of information</p> <p>Advice should be provided in a format suitable to the person's learning needs.</p>
<b>Section 8: Implementing the guideline</b>		
AS	I do think that in this current climate we will struggle to identify and access people who will require risk assessment making this part of the guideline difficult to implement	We have expanded the implementation section to acknowledge the challenges and what is currently in place to support implementation.
CC	<p>Need to engage key stakeholders such as primary care front line staff GP, nurses, pharmacists - key is communication/dissemination and also the public - use experts in communication to do this?</p> <p>GP in North Berwick Dr Kevin Fernando is working with Medscape and has put out out info on YouTube &amp; Social media and has a special interest in type 2 diabetes and communication in primary care.</p>	<p>Agree</p> <p>SIGN focus on links to resources from national organisations</p>
CH	As mentioned repeatedly, informed by the success of where reversing diabetes strategies have worked elsewhere, this should not be Scotland reinventing the wheel, but copying and pasting nationally without HSCP nor HB variation. Too many SIGN guidelines have merely served to augment CVs. To have a population-level impact, this will need investment in Apps, media promotion, and changing the lifestyle characteristics of the 18-30s to prevent T2DM in the 40 to 65s.	We have added further information to the implementation section to outline what is in place currently and what is needed in the future.
DM	This should emphasise how we need to prioritise prevention and early intervention rather than dealing with the even more expensive complications of poorly controlled diabetes further down the line. This should recommend high level, high profile SG adopted targets (via annual delivery plans) that will force change and implementation of this Guideline. This is important in getting Health Boards to prioritise this approach. Some kind of costing tool might be useful to show where Health Boards are likely to get the most impact for investment.	We have added further information to the implementation section to outline what is in place currently and what is needed in the future.
JH	The expectation is clearly outlined.	Thank you. Further information has been added.

JW	The variation and unmet need currently is large and this guideline will be a challenge for some to implement. Each stage of the patient pathway will be difficult to implement in some Board areas. Should we mention emerging technology such as the Right Decision Service? This would support once for Scotland patient information and implementation of the guideline. Once for Scotland, digital prevention and remission services will also help support the implementation of this guideline.	We have added information on digital technologies. The guideline and plain language version of the guideline will be published on the Right Decision Service platform.
MCh	Timescale? When? Who? What? Why?	We have added further information to the implementation section to outline what is in place currently and what is needed in the future.
SF	I think there is a danger if this is issued without agreed resource much of this work is 'dumped' on primary care as an expected 'gold standard' without realistic resource to deliver on it. At present there is only so much resource in practices to provide care for diabetics so there is a risk this further dilutes this if no new resource comes with these guidelines.	We acknowledge that there are pressures on primary care and have added further information in a subsection in Implementation.
SW	<b>8.1</b> – suggest add guidance on primary care coding at all stages eg identification/prioritisation of eligible individuals for recall, referral and collection of follow-up/outcome data in this section and refer to it in earlier sections	We have added the following good practise point to the section on Achieving remission: Upon achieving remission, ensure the patient is coded in GP systems correctly as being in remission of type 2 diabetes (READ code C10P1 Type II diabetes mellitus in remission). They should remain on the diabetes register for annual review despite their remission status. This should prompt routine diabetes checks for retinopathy, HbA1c and all other processes of care considered standard diabetes long-term condition management are carried out. This could be part of a comprehensive annual review for diabetes and other comorbidities, or prompted using the READ code 66AS.00 Diabetec annual review.
TD	Publication of a guideline may raise expectation of care against a backdrop of no additional resources or review of national strategy to implement the guideline.  <b>8.2</b> The threshold of resource impact of implementation not exceeding £5m requires to be challenged. The current population data relating to T2DM prevalence and overweight and obesity prevalence would suggest the size and scale of implementation would far exceed this figure.	We have added more detail to this section to provide an overview of current policy and future needs.  Because resourcing is now discussed in the Implementation section we have removed the old section 8.2.

Section 9: Guideline development (now section 8)		
CC	Good use of existing guidelines eg NICE and international guidelines	Thank you
CH	Aim to end up with something deliverable at a population level in Scotland, not simply collecting recommendations based on the published evidence base. The overweight sedentary 55 year olds of Cumnock, Bellshill, Twechar and Pumpherston can currently access McDonalds via JustEat, cheap booze via home delivery and stream entertainments to their device; all on a sofa. As a Public Health intervention to anticipatorily stop prediabetes or reverse T2DM, how does Scotland want to make exercise and a better diet both attractive & cheap?	<p>The focus of the guideline is on the area where we can support people at risk who attend primary care services. We agree that the issue is a wider public health issue.</p> <p>This is a clinical guideline aimed at improving outcomes for individual people not a public health guideline.</p> <p>It is hoped that the implementation of the recommendations, along with the Framework and development of services can support a wider impact.</p>
DM	This will be a significant issue for Scotland for decades to come. More research is needed.	Agree
JH	The development process is clearly outlined	Thank you
SW	<p>In my opinion the order of research recommendations should be changed to</p> <ol style="list-style-type: none"> <li>1. prioritise robust evaluation of proposed interventions so that they can be refined to be most cost-effective</li> <li>2, to move bariatric surgery to the bottom of the list with the priority for research relating to surgical interventions being updated cost-effectiveness analyses to include long-term complications of bariatric surgery and comparisons with other approaches to achieving weight-loss including short-term outcomes of newer approaches</li> </ol>	We have restructured the recommendations as suggested and added points for long-term complications of BMS. Cost effectiveness studies have already been conducted.
TD	<p><b>9.2</b> The guideline should reflect the context and the scale/ scope of the at risk and T2D populations.</p> <p>In addition to the specialist clinical interventions, the guideline and research considerations should look beyond specialised clinical interventions, to programmes and interventions that can be adaptable and implementable at a population level e.g. impact of Tier 2 weight management programmes on remission outcomes.</p>	This is outside the remit of the guideline.

YI	<p>Re: recommendation of research <b>9.2</b></p> <p>I wonder if improvement of eGFR for remission with or without hypertension (or AECi) should be included ?</p>	This would be best placed in a renal guideline.
<b>Section 10: Stakeholder involvement (now section 9)</b>		
CC	<p>Would Primary care involvements GPs and specialist practice nurses be helpful? or BDA specialist Diabetes group?</p>	<p>Thank you. This section reflects the multidisciplinary input throughout the development of the guideline. We have made this clearer by amending the section heading to 'stakeholder involvement in the guideline'. The guideline will be relevant to the professionals you have listed.</p>
CH	<p>Behavioural scientists, the Media, and Public Health are the key stakeholders. What motivates a change in Scots' behaviour? How does Scotland make healthier choices easier, more convenient and safer (when vested interests will politically lobby for outcomes that preserve their profits, using the disingenuous Libertarian's Trojan Horse of "protecting personal choice", individual responsibility and "free will")? Focus groups can take you so far. What are the specific characteristics of services that have worked elsewhere? How can they be implemented at scale in Scotland (not variably from HSCP to HSCP)?</p>	<p>Thank you. This section explains the multidisciplinary input into producing the guideline.</p>
JH	<p>The consultation process is clearly outlined and details those involved. A wide range of professionals have been involved in the development or external consultation, which should highlight many of the enablers and barriers to implementation which local HB and HSCP stakeholders might face.</p>	<p>Thank you</p>
MCh	<p>Important to consider wide range of views</p>	<p>We have endeavoured to gather a wide range of views through the open consultation.</p>
<b>Additional comments</b>		
AR	<p>Could my details be as below</p> <p>Mr Andrew G Robertson Consultant Bariatric Surgeon, NHS Lothian, British Obesity and Metabolic Surgery Society Council Member</p>	<p>Amended</p>

AS	Overall a helpful guideline, I just feel that as a pharmacist I would struggle to turn the drug recommendations into a local process/guideline currently	We recognise the challenges and have added further information to the section on Implementation.
DK	<p>I think, in general, the guidelines are clear and easily readable. Language is accessible and not too jargonistic.</p> <p>I do, however, have two main areas of concern:</p> <p>1) I had thought, when asked to do this, that comments were being sought before the recommendations had been finalised. I would have had more to say on some of the recommendations had they not already been a done deal. These would have been in relation to the realistic hopes of putting them into practice. With apologies to Ms Austen it is a truth universally acknowledged that it is now almost impossible to see a GP, whether online or face to face. The worthy and good practice conversations implied in these recommendations are extremely important but in a five minute appointment, if you can get one, how likely to happen? For example, I was diagnosed with Type 2 almost 2 years ago and have not once, including at diagnosis have I had a conversation with my GP about it. Two appointments with the practice nurse have been all that has happened. Similarly I have just come through an operation and a course of radiotherapy for breast cancer, ongoing since last September and not once have I spoken to my GP or Practice Nurse about that. Care from specialists has been exemplary but nothing from primary care. I know that this is a common experience.</p> <p>2) My other concern is about accountability. If the guidelines are simply that and have no regulatory status, how are HCPs held to account for their implementation. How are they measured, how do you know what is working and what's not and why not? I would be very keen to comment on the QUOF guidelines as I believe that is where more impact can be made in the success of the recommendations!</p>	<p>Thank you.</p> <p>Thank you. SIGN will take these comments into consideration when evaluating the methodology used to develop the guideline.</p> <p>The recommendations set out best practice. We acknowledge the considerable strain on primary care and have added a subsection highlighting this in the Implementation section.</p> <p>SIGN guidelines are intended to inform protocols and pathways at national and local level. It is the responsibility of boards and HSCPs to implement.</p>
DM	Critical guideline. Should be reviewed in 5 years. Needs to help support Health Boards prioritise investment decisions to increase the scale and pace of health improvement.	Thank you. SIGN will take your feedback into consideration when reviewing our methodology and processes.

ED	SIGN guidance development is welcomed to help highlight and push these priorities forward but current financial climates to support them are concerns.	Thank you. We have now acknowledged this in the section on Implementation
JH	When reading these guidelines, I really welcome the clarity of the pathway, the inclusion of person centred care and an acknowledgment of the social determinants of health. NHS Scotland, HSCPs and Local Authorities are all experiencing funding and delivery challenges which mean that we cannot implement every recommendation within these guidelines. I would like to see the recommendations prioritised according to impact, or a set of recommendations which are all implementable within current systems and funding structures. Of particular interest, is the process by which we can introduce drug treatments to the Formulary, and equitable HbA1c testing across Primary and Secondary Care, whereby capacity meets demand.	We have added further detail in the section on Implementation.
JMF	Helpful to have a guideline	Thank you
JW	I look forward to seeing the final version of this important guideline. Well done to everyone who has been involved in the development of the guideline to the stage.	Thank you
MCh	Too many words and layout could be clearer. Bullet points are helpful.	The guideline and the plain language version will be published on the right decision platform so will be presented in smaller sections.
RCN	Overall good flow and style, main point is to consider definition of 'pre-diabetes' due to interchangeably in the guidance with high risk diabetes and non-diabetic hyperglycaemia	The group have considered this and hope to have provided more consistency in the move to advise on one Read code that is inclusive of all dysglycaemic states.
TD	This comes across very much as implementation guidance rather than clinical guidance and implementation would need be tailored within each individual board.  Throughout the guideline, reference is made where recommendations have been adapted from previous NICE guidelines. However, what is not clear is what, if any, further evidence since the publishing of these NICE guidelines has been considered and how these recommendations have been adapted. The evidence for all adapted recommendations and	Thank you for your feedback. Your comments will be taken into consideration by SIGN to review our methodology and processes.  We used the NICE guideline rather than conducting an evidence review. In order to keep the guideline concise we prefer to link to the original NICE evidence review.

	<p>the adaptations themselves should be explicit within this guideline.</p> <p>Gestational Diabetes is mentioned as a risk factor and there are some recommendations in relation to this group. However, there is insufficient focus on this population given the evidence around their risk of T2D.</p> <p>The information presented comes across as two very specific separate issues – prevention of developing type 2 diabetes and remission. The evidence regarding remission is drawn from one programme as an intervention and the potential that this may be effective if delivered remotely but lacks strong evidence to back this. We would suggest the inclusion of the remote delivery focus as currently presented is ahead of the evidence for the intervention. We acknowledge the evidence relating to remote delivery more widely.</p> <p>The strong emphasis on a prediabetes/diabetes prevention specific programme seems to ignore that the general advice diet and lifestyle advice for the prevention of diabetes is shared for the most part with the prevention of other conditions that develop as a consequence of overweight/obesity and in many cases reflects wider multiple co-morbidities. Appropriate signposting to condition specific support within the existing lifestyle and weight management services as a discreet ‘add ons or modules’ complimenting generic weight management or behavioural change approaches might maximise the impact of limited resources rather than condition specific programme delivery models.</p> <p>The focus on achieving remission through TMR or bariatric surgery leaves a significant gaps in the early intervention of T2D, including the role of evidence based education and other weight management interventions.</p>	<p>SIGN have recently published SIGN 171: Management of diabetes in pregnancy. Further information has in the section on Testing form prediabetes.</p> <p>We have added a section about digital technologies to the implementation section to highlight that this is a growing resource.</p> <p>In the section Diet and weight management, we have added a recommendation based on the Scottish Obesity Standards which provides advice on approaches to weight management.</p> <p>To keep within a manageable remit we focused on areas where we knew there was robust evidence, and used the NICE evidence review and recommendations.</p>
YI	<p>Would there be any information about the percentage of T2DM being seen by the renal team prior to starting HDx or approaching ESRF?</p>	<p>Both of these are outwith the remit of this guideline.</p>

	Is there any supporting evident to show the benefits (both financially and clinically) of setting up a renal/DM clinic ?	
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