West Yorkshire & Harrogate
Joint Committee of CCGs

Summary report			
Date of meeting: 6th April 2021		Agenda item: 18a/21	
Report title:		WY&H Healthy Hearts: Diabetes Treatment Guidance	
Joint Committee sponsor:		Dr Steve Ollerton (NHS Kirklees CCG)	
Clinical Lead:		Dr Youssef Beaini	
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Presenters:		Dr Steve Ollerton, Steph Potts	
Purpose of report: (why is this being brought to the Committee?)			
Decision	✓	Comment	
Assurance		For Information	

Executive summary

The purpose of this paper is to recommend to the Joint Committee of CCGs that it supports the introduction of standardised and simplified treatment guidance for Type 2 Diabetes patients (T2DM) with Cardiovascular Disease (CVD) or at high risk of CVD.

The Diabetes Treatment Guidance (Appendix A) has been developed for use in primary care and has been created following extensive stakeholder engagement across West Yorkshire and Harrogate. The guidance has been approved by the WY&H Area Prescribing Committee and Planned Care Board and will be considered by the WY&H Clinical Forum at its meeting on 6th April.

The proposed treatment guidance supports delivery of the third phase of the West Yorkshire and Harrogate Healthy Hearts project. This project was approved by the Joint Committee of CCGs on 5th June 2018. The project aims to reduce the chance of patients developing conditions affecting their heart or blood vessels, improve the outcomes of patients already living with these conditions, and improve outcomes for those living with diabetes.

Phase three of the Healthy Hearts project is focused on improving the treatment of T2DM patients with CVD or at high risk of CVD by introducing the addition of Sodium-glucose co-transporter-2 inhibitor (SGLT2i) medication if their current treatment is not controlling their glycated haemoglobin (HBA1c) levels. Cardiovascular disease (CVD) is a major complication and the most common cause of death in adults with type 2 diabetes. SGLT2i therapies have robust evidence for significantly reducing CVD outcomes in people with type 2 Diabetes who have either established CVD or are at risk of developing CVD.

The diabetes treatment guidance has been created following extensive review of the clinical evidence and engagement with over 70 stakeholders across West Yorkshire and Harrogate.

Recommendations and next steps	
The Joint Committee of CCGs is asked to: Agree the Diabetes Treatment Guidance to enable adoption across WY&H ICS.	
Delivering outcomes	
Health and Wellbeing: Decrease in deaths, decrease in heart attacks and strokes **Care and Quality:** Increase the number of people with, or at risk of developing, conditions affecting their heart or blood vessels, and diabetes receiving beneficial interventions **Finance and Efficiency:** Decrease the amount of resources spent on conditions affecting the heart or blood vessels and diabetes	
Impact assessment –	
Clinical outcomes:	As Health and Wellbeing above, see also appendices B (Diabetes Background Paper) and C (Quality and Equality Impact Assessment)
Public involvement:	See section 8
Finance:	See section 6
Risk:	Should the Joint Committee of CCGs not approve the simplified guidance, CCGs will be required to do so individually, which will be less efficient, and will delay implementation.
Conflicts of interest:	None

1. Introduction

1.1. This paper seeks to recommend to the Joint Committee of CCGs that it approves the introduction of standardised and simplified treatment guidance for Type 2 Diabetes (T2DM) patients with Cardiovascular Disease (CVD) or at high risk of CVD within West Yorkshire and Harrogate (WY&H) following extensive engagement with stakeholders and approval by the Area Prescribing Committee and Planned Care Board. The Directors of Finance agreed to the financial case on 26th March 2021, stressing that although the scheme was compelling in terms of balance between cost pressure and impact on health and quality of life, they believe the realisable financial benefits would not be as great as predicted in the modelling.

1.2. The proposed treatment guidance supports delivery of the third phase of the WY&H Healthy Hearts project. The third phase is focused on improving the treatment of T2DM patients with Cardiovascular Disease (CVD) or at high risk of CVD by introducing the addition of Sodium-glucose co-transporter-2 inhibitor (SGLT2i) medication if their current treatment is not adequately controlling their HBA1c levels.

1.3. It is important to support patients in controlling their HBA1c as high levels are a significant risk factor for diseases affecting blood vessels and the heart. HbA1c is a reliable risk factor of all-cause and cardiovascular mortality in both diabetics and non-diabetics[1].

1.4. This phase of the project is based on successful work carried out in phases one and two (Hypertension and Cholesterol) of WY&H Healthy Hearts. A key part of the success to date has been through creating standardised and simplified guidance for GPs, nurses, pharmacists and other members of the primary care team to use; as existing guidance, including that issued by NICE, is often complex to understand and more involved for the patient and their clinicians.

1.5. The Diabetes Treatment Guidance (Appendix A) has been developed for use in primary care and has been created following extensive stakeholder engagement across WY&H including with GP leaders from each of the seven Clinical Commissioning Groups. The evidence and rationale for the guidance is given at Appendix B.

2. Background

2.1. Following recommendation from the Clinical Forum, the Joint Committee of CCGs meeting of 5th June 2018 recommended that the WY&H CCGs adopt the Healthy Hearts project to reduce the chances of patients developing conditions affecting their heart or blood vessels; improve the outcomes of patients already living with these conditions, and improve outcomes for those living with diabetes.

[1] https://bmjopen.bmj.com/content/7/7/e015949

The project is being delivered in three phases:

- Phase One - Better identifying those with high blood pressure and controlling it more effectively
- Phase Two - Better identifying those with high cholesterol levels, and managing their cholesterol more effectively
- Phase Three - Better management of patients with diabetes

2.2. Problems of the heart and blood vessels account for one in four deaths in England. Yearly healthcare costs in England relating to poor health of the heart and blood vessels are estimated at £7.4 billion, with an annual cost to the wider economy of £15.8 billion.

2.3. The West Yorkshire and Harrogate Health and Care Partnership's (HCP) plan includes a target to 'Reduce the number of people experiencing a CVD incident *(such as a heart attack or stroke)* by 10% across the area by 2021.' If this target were met, there would be over 1,100 fewer of these incidents by 2021.

2.4. High HBA1c levels in T2DM patient is a significant risk factor for diseases of the heart and blood vessels. Positive lifestyle choices such as good diet, being physically active and maintaining appropriate body weight all contribute to reducing the incidence of high HBA1c levels and patients are supported by local projects supporting healthy living choices which support the prevention of high HBA1c levels.

2.5. When patients do have elevated HBA1c levels, the treatment guidance is clear that advice to patients as to how to reduce their HBA1c levels by improving their diets, losing weight, increasing their physical activity and stopping smoking is a key early intervention. For T2DM patients a blended approach of self-management and drug therapy will be required. SGL2ti therapy has shown[2] to reduce the risk of CV death by 38%, with a 35% reduction of hospitalisation for Heart Failure and overall reduction in mortality by 32%.

2.6. The estimated adult T2DM population across WY&H is c.150,000[3] with c.15,000 having higher than recommended HBA1c levels. This project aims to tackle around a third of these patients (see section 6) based on CVD risk.

3. Proposal

3.1. The WY&H Healthy Hearts project aims to improve care beyond current levels by utilising the impact of existing primary care resource, and maximising engagement of clinicians with a large-scale improvement project. Phase three of the Healthy Hearts project is focused on improving the treatment of T2DM patients with CVD or at high risk of CVD by introducing the addition of Sodium-glucose co-transporter-2 inhibitor (SGLT2i) medication if their current treatment is not controlling their HBA1c levels.

[2] See Appendix B

[3] https://digital.nhs.uk/data-and-information/publications/statistical/national-diabetes-audit/care-processes-and-treatment-targets-2nd-quarter-january-september-2020-data-release

3.2. SGLT2i therapies have robust evidence for reducing CVD outcomes in people with type 2 Diabetes who have either established CVD or are at risk of developing CVD.

3.3. Feedback from GPs and nurses, particularly those involved in phase one and two of Healthy Hearts (high blood pressure and cholesterol) indicated that many clinicians liked the use of specific medicines and doses in guidance that streamlined the prescriber's approach.

3.4. This is also supported by NICE in *Type 2 diabetes in adults: management Evidence reviews for SGLT-2 inhibitors and GLP-1 which stated* "The [NICE] committee agreed that …. Historically, the focus has been on glucose control. The committee agreed that, of all the antidiabetic drugs and combination of drugs, healthcare professionals and patients do not know which drug or combination of drugs is best at improving macrovascular and microvascular outcomes".[4]

3.5. The WY&H Healthy Hearts Diabetes Treatment Guidance (Appendix A) and supporting information (Appendix B) seek to maximise the impact of existing primary care resource, and build on feedback from clinicians about the previous WY&H Healthy Hearts guidelines for treating high blood pressure and cholesterol, and to maximise engagement of clinicians with a large-scale improvement project.

3.6. The West Yorkshire and Harrogate Healthy diabetes project is not intended to cover, or duplicate, the full breadth of Diabetes care, which is part of the wider WY& Diabetes Programme; who have been involved in the design of this treatment guidance. This phase of the project is very specific to addressing those T2DM patients at high risk of CVD

4. Clinical Engagement

4.1. The Diabetes Treatment Guidance and supporting information has been developed following extensive consultation with clinicians and other stakeholders.

4.2. The engagement has been led in each of the CCGs by the lead Clinician for WYH Healthy Hearts; they have engaged with fellow GPs, nurses and pharmacists at primary care level, as well as secondary care colleagues. In total around 70 stakeholders have been involved in the preparation of the treatment guidance. .

4.3. A key outcome of the engagement was that consensus has been reached by lead clinicians across WY&H on what should be included and excluded from the Diabetes Treatment Guidance to ensure it is effective and clear.

4.4. This document was then presented to the Area Prescribing Committee in March, who approved the guidance, subject to minor changes.

[4] https://www.nice.org.uk/guidance/ng28/evidence/march-2018-evidence-reviews-for-sglt2-inhibitors-and-glp1-mimetics-pdf-4783687597

4.5. These changes included; strengthening the information around up-titration, making explicit the guidance only relates to oral therapy, revising eGFR levels, emphasizing the CVD benefits of SGLT2i regardless of HBA1c levels, along with adding extras supporting guidance on when SGLT2i should be prescribed with caution e.g. Elderly/Frail.

4.6. As with all the West Yorkshire and Harrogate Healthy Hearts guidance developed to date, clinical discretion and judgement can always be exercised

5. Quality and Equality Impact Assessment

5.1. A Quality and Equality Impact Assessment (QEIA) has been completed, and a summary is attached at Appendix C. This impact assessment has been shared and agreed by Quality and Equality Leads across the CCGs/ICS, following minor additions.

5.2. The Impact Assessment has concluded that there is a positive impact across Patient Experience, Patient Safety, Clinical Effectiveness, Equality & Health Inequalities and also Workforce. No negative impact is anticipated.

5.3. There is a positive impact on patient safety and clinical effectiveness by the introduction of simplified treatment guidance for Diabetes patients at risk of CVD. Evidence from NICE and also clinical trials shows the use of SGLT2i can lead to a 38% reduction in CVD death, a 35% reduction in hospitalisation for Heart Failure and also reduced overall mortality by 32%. Simplified treatment guidance is considered a strong way to improve pathways of care - making the information consistent and more accessible to health professionals.

5.4. The guidance will exclude a number of people on the grounds of clinical safety and not on their protected characteristics. e.g. drugs not being licensed for use in pregnant women / breastfeeding. It is anticipated that treatment guidance will have a positive impact on health inequalities and deprivation. The National Diabetes Audit provides a consistent way to measure any future equality impact.

5.5. There is a small positive impact anticipated in terms of workforce, as simplified treatment guidance helps health professionals with their management of patient caseloads i.e. by providing simple, consistent and easy to follow guidance.

6. Activity and Financial Impact

6.1 There have been numerous evaluations on the cost effectiveness of SGLT2i. Cost effectiveness of SGLT2 inhibitors has been demonstrated by NICE through technology appraisals. NICE[5] in 2018 suspended their planned appraisal of Empagliflozin stating "Empaglifozin is already recommended for people with type 2 diabetes (TA336) and the population for which this additional appraisal would be aimed at (poorly controlled diabetes plus cardiovascular risk) is already included in the population previously appraised."

6.2 The original Healthy hearts planning stated that "If all CCGs in the STP optimised the control of Hba1c in those with diabetes to the average of the best 5 in their group of similar 10, the RightCare data indicates that more than 4,200 people would benefit."

6.3 It is expected that the additional prescribing costs to the WY&H system for an SGLTi, in preference to a Dipeptidyl peptidase-4 (DPP4) inhibitor, will be offset by reductions in major cardiovascular adverse events, heart failure hospitalisation, and mortality. However, the figures below are for illustrative purposes and we would not want to mislead the Joint Committee into thinking that these were definite absolute savings expected.

6.4 Using the above assumptions, data from the national diabetes audit and also Public Health England; the following assumptions have been made:

- The additional cost of prescribing a SGLT2i above normal standard prescribing of DPP4 is around £600k for 3 years (4,200 patients) and would avoid an estimated 108 deaths. This could save the NHS an estimated £1.2m (not including societal savings / human impact) *Table 1*
- Bradford and Craven and Leeds CCG would have the biggest potential opportunity for initiation of SGLT2i; around 1240 patients at an additional cost of £115k p/a and a potential to prevent around 60 deaths within 3 years. *Table 2*
- For all CCGs, if patients who have a current history of CVD (Secondary prevention) were targeted first, this would be around 700 patients, at an additional cost of £32,000 p/a and a potential to prevent around 18 deaths within 3 years. (The targeting of secondary prevention may be a useful strategy when working with Primary Care to deliver this work i.e. providing a more manageable patient cohort). *Table 2*

[5] https://www.nice.org.uk/guidance/indevelopment/gid-ta10177

6.5 Whilst the financial investment in SGLT2i will not be insignificant, the reduction in personal cost to individuals, social cost to communities, and financially to the health and care system of not having to treat avoidable heart attacks and strokes could substantially outweigh the costs of the SGLT2i. The actual cost of the Healthy Hearts project to each place will depend on the intensity of implementation of the project.

7. Governance

7.1. The development of the Diabetes Treatment Guidance is following the HCP's governance route for the approval of clinical guidance associated with the Healthy Hearts Project, as presented to the Joint Committee of CCG development session on 6th August 2019.

7.2. The Diabetes Treatment Guidance has been presented to the Area Prescribing Committee and the Planned Care Board (March 2021) who have supported the treatment guidance; subject to minor additions to strengthen the clarity of the treatment guidance, explore culturally appropriate patient information and gain agreement on the financial case by Directors of Finance. The Directors of Finance agreed to the financial case on 26th March 2021, stressing that although the scheme was compelling in terms of balance between cost pressure and impact on health and quality of life, they believe the realisable financial benefits would not be as great as predicted in the modelling. In line with the agreed governance process, the guidance will also be considered by the Clinical Forum on 6th April.

7.3. By adopting this HCP level governance process it avoids each of the CCGs having to take the decision through their own individual governance routes.

7.4. It should be noted that the use of the guidance will be at the discretion of individual clinicians. Agreement of the guidance by the APCs, Planned Care Board, Clinical Forum and Joint Committee of CCGs, will not mandate clinicians to use it. If clinically appropriate, flexibility can and should continue to be used by primary care clinicians at each treatment step, as would be expected as standard for all aspects of medical care.

7.5. The local guidance is simply proposed as a facilitator to quality improvement within a healthcare system that has limited capacity for extra workload. Clinicians will be expected to continue to use their clinical judgement on how best to treat their patients, drawing on this guidance and other relevant guidance to support them to make the best treatment decisions for their patients.

8. Patient engagement

8.1. As is standard practice, shared decision making remains the norm and multiple sources of information can help. As part of the project – patient engagement is taking place to design and shape any supporting information. A number of patient engagement sessions are scheduled in April. It is planned to explore the creation of culturally appropriate information, following the suggestion from the Planned Care Board. This is consistent with other phases of the project which has seen the creation of various supporting information resources which have been included on the WYH Healthy Hearts website.

8.2. The website has a range of features to support accessibility including; text-to-speech, translation support and easy read material for those with learning disabilities/low health literacy.

8.3. Localities will continue to also be supported and encouraged to use services such as local community lifestyle and pharmacy services.

8.4. Together these resources support patients to understand and use their medications effectively; provide information on what HBA1c and SGLT2i are and how they can help reduce CVD risk, as well as details of further advice and support.

9. Conclusion and Recommendations

9.1. Cardiovascular disease (CVD) is a major complication and the most common cause of death in adults with type 2 diabetes.

9.2. Sodium-glucose co-transporter-2 inhibitor (SGLT2i) therapies have robust evidence for significantly reducing CVD outcomes in people with type 2 Diabetes who have either established CVD or are at risk of developing CVD.

9.3. Evidence on cost effectiveness has been conducted through various trials and NICE technology appraisals.

9.4. The diabetes treatment guidance has been created following extensive review of the clinical evidence and engagement with over 70 stakeholders across West Yorkshire and Harrogate.

9.5. The WY&H Healthy Hearts Diabetes Treatment Guidance (Appendix A) and supporting information (Appendix B) seek to maximise the impact of existing primary care resource at scale, to support streamlining the management of cholesterol in patients with the aim of reducing diseases of the heart and blood vessels.

9.6. The Healthy Hearts project is aiming to have all resources available for health professionals and public by May/June 2021; ready for CCG/Primary Care local implementation.

9.7. The Joint Committee of CCGs is asked to:

- Agree the Diabetes Treatment Guidance to enable adoption across WY&H ICS.

Tables and Appendices

Table 1: Additional Costs of SGLT2i and potential savings
Table 2: Estimated Patients and Cost by CCG (per annum)

Appendix A: Diabetes Treatment Guidance
Appendix B: Diabetes Background Paper
Appendix C: Quality and Equality Impact Assessment Summary page

Table 1 *- Additional Costs of SGLT2i and potential savings*

			Patient Scenarios			
Cost of SGLT2i	*SGLT2i costs above DPP4		100	1000	2000	4200
1. Empagliflozin = £477 per year	£ 47.00	1 year	£ 4,700	£ 47,000	£ 94,000	£ 197,400
		3 years	£ 14,100	£ 141,000	£ 282,000	£ 592,200
2. Canagliflozin = £511 per year	£ 81.00	1 year	£ 8,100	£ 81,000	£ 162,000	£ 340,200
		3 years	£ 24,300	£ 243,000	£ 486,000	£ 1,020,600

**DPP4 cost per year = £430*

Deaths Avoided Number Needed to Treat (NNT)	39		3	26	51	108
CV Cost (Size of Prize Estimate) NNT	£ 11,500		£ 34,500	£ 294,872	£ 589,744	£ 1,238,462

Table 2 *- Estimated Patients and Cost by CCG (per annum)*

	All		Secondary Prevention		Primary Prevention	
	Estimated Patients	Estimated Cost	Estimated Patient	Estimated Cost	Estimated Patient	Estimated Cost
NHS CALDERDALE CCG	260	£ 12,202	42	£ 1,971	218	£ 10,231
NHS GREATER HUDDERSFIELD CCG	322	£ 15,151	52	£ 2,447	270	£ 12,704
NHS NORTH KIRKLEES CCG	391	£ 18,389	63	£ 2,970	328	£ 15,419
NHS NORTH YORKSHIRE CCG (Harrogate 38%) ^	179	£ 8,416	29	£ 1,359	150	£ 7,057
NHS WAKEFIELD CCG	591	£ 27,758	95	£ 4,484	495	£ 23,274
NHS LEEDS CCG	1174	£ 55,168	190	£ 8,911	984	£ 46,257
NHS BRADFORD DISTRICT AND CRAVEN CCG	1283	£ 60,315	207	£ 9,742	1076	£ 50,573
TOTAL	**4200**	**£ 197,400**	**678**	**£ 31,885**	**3522**	**£ 165,515**

**cost is additional cost above DPP4*

^NHS North Yorkshire (Harrogate) have been included due to previous participation in WY&H Healthy Hearts project.

**cost is additional cost above DPP4 – based on Empagliflozin*

Treatment Guidance for T2DM Patients with established CVD / at high risk of CVD

West Yorkshire and Harrogate HEALTHY HEARTS

Appendix A

Offer lifestyle advice for all patients with newly diagnosed T2DM regardless of treatment options

Newly diagnosed T2DM or established T2DM but treatment naive

Metformin (if eGFR>30mL/min/ 1.73)

eGFR adequate*

Consider adding SGLT2i

Established T2DM on **oral** therapy only

HbA1c ≥58-75 mmol/mol On metformin monotherapy

eGFR adequate*

Add SGLT2i

HbA1c >58-75 mmol/mol and on 2 or 3 agents

eGFR adequate*

2 agents: add SGLT2i to existing therapy

3 agents: switch one existing agent to SGLT2i

SGLT2i Recommendation	
First choice	Empagliflozin 10mg od
Second choice	Canagliflozin 100mg od **First choice if Nephropathy**
Consider up-titration if required for HBA1c control	

Risk Stratification	
Primary Prevention	High risk of CVD: e.g DM >10 years Or other CVD risk factors
Secondary Prevention	Established CVD (Stroke / PAD / CHD)

IMPORTANT CLINICAL INFORMATION:

- Do not prescribe SGLT2i if previous history of diabetic ketoacidosis (DKA) / pregnant
- If any doubt about the diagnosis of T2DM do not start SGLT2i
- HbA1c thresholds above are for guidance only and therapy decisions should be individualized. SGLT2i are useful regardless of HBA1c levels
- Empagliflozin SPC advises avoid SGLT2i if eGFR levels below 60mmL/min/1.73m2. However Regional Expert guidance states appropriate to start >45 mL/min/1.73m2
- Canagliflozin SPC states can start >30mL/min/1.73m2

Supporting Clinical Support Information

- SGL2Ti reduce CVD risk regardless of HBA1 levels
- T1DM are excluded from this guidance due to the increased risk of Diabetic ketoacidosis
- HBA1c level of >58 mmol/mol are in line with NICE guideline [NG28] – section 1.6.8
- Use shared decision making with patient before changing therapy
- When starting SGLT2i Counsel risk of DKA/mycotic genital infections/UTI.
- Involve multidisciplinary diabetes team in more complex decisions

Supporting Guidance

West Yorkshire and Harrogate HEALTHY HEARTS

SGLT2i can be used in the following clinical conditions – but may require additional clinical monitoring / decision making – consult SPCs

- High HbA1c levels (>86 mmol/mol or 10%)
- History of PAD / Existing diabetic foot ulcers / Previous lower limb amputation / History of foot ulceration. If starting canaglifozin - counsel on MHRA increased risk of lower-limb amputation (mainly toes) and on good foot care.
- Receiving loop diuretics - Review the dose of diuretic after starting an SGLT2i (e.g. if frail, hypotensive, volume depleted, or high HbA1c)
- Canagliflozin not recommended in combination with loop diuretic
- Osteoporosis / History of fractures
- Frail / Cognitive impairment Increased risk of volume depletion, hypotension and falls.

Clinical Searches

A number of clinical searches have been created to identify patients who may be suitable for the application of this treatment guidance. The searches and full details on how to access can be found on the website link here

Criteria:

- T2DM with CVD or very high / high risk of CVD
- Excludes Active Foot Disease / Lower limb amputation
- Age: 40-79
- HBa1c: 58-75m mmol/mol
- On Metformin and/or 2-3 agents – Excluding Insulin
- eGfr: >60 mL/min/1.73
- Excluding clinical contraindications e.g. Red clinical situations

Further Information

This guidance document has been put together by the West Yorkshire and Harrogate Healthy Hearts project. It is has been adapted based on pathway work developed in Leeds and other regions. It has been endorsed for clinical use by the Joint Committee of CCGs (TBC) following appropriate clinical governance sign off.

**A background document summarising the evidence on SGLT2i can be found on the Healthy Hearts website. (insert link)

Other useful resources can also be found on the website, including information to use when communicating with patients.

www.westyorkshireandharrogatehealthyhearts/professionals-diabetes (TBC)

PLEASE NOTE THIS GUIDANCE DOCUMENT WILL BE GRAPHICALLY DESIGNED AND ALL HYPERLINKS INSERTED IN FINAL VERSION

Appendix B

West Yorkshire and Harrogate HEALTHY HEARTS

Improving CVD Outcomes in Diabetes Patients
Clinical Rationale Background Document

Contents

Summary

- Cardiovascular disease (CVD) is a major complication and the most common cause of death in adults with type 2 diabetes.

- CV death accounts for 52% of deaths in type 2 diabetes. Diabetes increases the risk of CVD by nearly 50% (reference: National Diabetes Audit UK 2012). Patients with diabetes are two and half times more likely to develop heart failure.

- Sodium-glucose co-transporter-2 inhibitor (SGLT2i) therapies have robust evidence for significantly reducing CVD outcomes in people with type 2 Diabetes who have either established CVD or are at risk of developing CVD.

1. Introduction

1.1. Cardiovascular disease is a major complication and the most common cause of death in adults with type 2 diabetes. CV death accounts for 52% of deaths in type 2 diabetes1 and patients with diabetes are two and half times more likely to develop heart failure[2]. Diabetes increases the risk of CVD by nearly 50% (reference, National Diabetes Audit, 2012)

1.2. Sodium/glucose cotransporter-2 inhibitors (SGLT2i) are a new type of glucose-lowering drug that can reduce blood glucose by inhibiting its reabsorption in proximal tubules and by promoting urinary glucose excretion. Evidence shows that they can lower HBA1c levels significantly, reduce weight and lower blood pressure[3]

1.3. Cardiovascular disease (CVD), including heart failure (HF), is a leading cause of morbidity and mortality in people with type 2 diabetes mellitus (T2DM). CVD and T2DM share common risk factors for development and progression, and there is significant overlap between the conditions in terms of worsening outcomes. In assessing the cardiovascular (CV) profiles of anti-diabetic drugs, sodium-glucose co-transporter-2 inhibitor (SGLT2i) therapies have emerged with robust evidence for significantly reducing the risk of adverse CVD outcomes in people with T2DM who have either established CVD or are at risk of developing CVD. [4]

1.4. There have been four major trials on SGLT2 inhibitors:

- EMPA-REG[5] (Empagliflozin)
- DECLARE–TIMI 58[6] (Dapagliflozin)
- CREDENCE[7] (Canagliflozin)
- CANVAS[8] (Canagliflozin)

1.5. These trials show various benefits for each of the SGLT2i across key areas, with Empagliflozin particularly showing good outcomes across: all-cause mortality, CVD mortality, MI, stroke and Heart Failure hospitalisation (see page 10)

2. Brief Background / Context

2.1. The West Yorkshire and Harrogate Healthy Hearts project met with key stakeholders across Primary, Community and Secondary Care (26th February 2020) to scope phase three of the project – improving CVD outcomes in Diabetes patients.

[1] https://journals.lww.com/cardiovascularendocrinology/Fulltext/2017/03000/Epidemiology_in_diabetes_mellitus_and.4.aspx
[2] https://www.ncbi.nlm.nih.gov/pubmed/15277411
[3] https://care.diabetesjournals.org/content/37/6/1650
[4] https://link.springer.com/article/10.1007%2Fs13300-019-0657-8
[5] https://www.nejm.org/doi/full/10.1056/NEJMoa1504720
[6] https://www.thelancet.com/journals/landia/article/PIIS2213-8587(19)30180-9/fulltext
[7] https://www.nejm.org/doi/full/10.1056/NEJMoa1811744
[8] https://www.nejm.org/doi/full/10.1056/NEJMoa1611925

2.2. Discussion on the evidence for cardiometabolic drugs was presented[9] by Dr Rob Sapsford – Cardiologist (Leeds Teaching Hospitals NHS Trust) and Professor Stephen Wheatcroft - Professor of Cardiometabolic Medicine (University of Leeds) / Consultant Cardiologist (Leeds Teaching Hospitals NHS Trust).

2.3. Agreement was reached that it would be of benefit to Primary Care to develop simple treatment guidance, similar to that developed for Hypertension and Cholesterol as part of WY&H Healthy Hearts, and adapted from the work that has started to be developed in Leeds and other regions across the country.

2.4. A follow up meeting was arranged with representation from across Primary, Community and Secondary Care (18th December) to agree the treatment guidance. This will then be subject to robust governance through West Yorkshire and Harrogate in order to gain sign off.

3. Evidence

3.1. The evidence on the clinical effectiveness and safety of SGL2Ti has been increasing both internationally and nationally. These include randomised control trials, meta-analyses and evidence reviews. NICE have also carried out a number of reviews. One of the most significant trials is EMPA-REG.

3.2. *EMPA-REG, a large randomised controlled study…investigates empagliflozin compared with placebo on cardiovascular morbidity and mortality in people with type 2 diabetes at high risk for cardiovascular events who were receiving standard care …The results of this trial showed a showed a significant reduction in cardiovascular and all-cause mortality Based on extrapolation of EMPA-REG OUTCOME trial data using a participant-level simulation model, empagliflozin in addition to standard of care is projected to be highly cost-effective using UK healthcare costs*.[10]

3.3. Cardiovascular risk reduction using various drug interventions shows SGLT2i also as an effective method in terms of numbers needed to treat.

Table 1 CVD Risk Reduction from various drugs - Source Professor Stephen Wheatcroft (Leeds Teaching Hospitals NHS Trust)

Option	**Intervention**	**Trial**	**Number needed to treat to prevent one death**
Statins	Simvastatin for 5.4 years	4S	30
ACE inhibitors	Ramipril for 5 years	HOPE	53
SGLT2i	Empagliflozin for 3 years	EMPA-REG	39
GLP1 RA	Liraglutide for 3.8 years	LEADER	71

[9] Diabetes Scoping Event Feb 20 FINAL.pptx
[10] https://www.ncbi.nlm.nih.gov/pubmed/31295358

4. NICE Guidance

4.1. NICE have conducted various reviews of the evidence, with SGL2i being referenced in numerous guidance documents including (but not limited to):

- Canagliflozin, dapagliflozin and empagliflozin as monotherapies for treating type 2 diabetes Technology appraisal guidance [TA390] May 2016
- Empagliflozin in combination therapy for treating type 2 diabetes Technology appraisal guidance [TA336] March 2015
- Type 2 diabetes in adults: management Evidence reviews for SGLT-2 inhibitors and GLP-1 mimetics NICE guideline NG28 Evidence reviews March 2018

NG28 included a detailed assessment of the CVD data for SGLT2is. "The committee highlighted that in previous years, diabetes management was driven by the prescription of drugs on the basis of HbA1c benefits. However, diabetes management is now moving towards the prescription of drugs based on cardiovascular benefits"

NICE does recommend the use of SGLT2is as a second-line agent if HbA1c remains >58 with metformin

4.2. The current NICE guidance on SGLT2i is as follows:

4.3. Canagliflozin, dapagliflozin and empagliflozin as monotherapies are recommended as options for treating type 2 diabetes in adults for whom metformin is contraindicated or not tolerated and when diet and exercise alone do not provide adequate glycaemic control, only if:

- *a dipeptidyl peptidase-4 (DPP-4) inhibitor would otherwise be prescribed and*
- *a sulfonylurea or pioglitazone is not appropriate.*[11]

4.4. Empagliflozin in a dual therapy regimen in combination with metformin is recommended as an option for treating type 2 diabetes, only if:

- *a sulfonylurea is contraindicated or not tolerated, or*
- *the person is at significant risk of hypoglycaemia or its consequences.*

4.5. Empagliflozin in a triple therapy regimen is recommended as an option for treating type 2 diabetes in combination with:

4.6. metformin and a sulfonylurea or metformin and a thiazolidinedione.

4.7. *Empagliflozin in combination with insulin with or without other antidiabetic drugs is recommended as an option for treating type 2 diabetes.*[12]

11 https://www.nice.org.uk/guidance/ta390/chapter/1-Recommendations
12 https://www.nice.org.uk/guidance/ta336/chapter/1-Guidance

5. European Society Guidance

5.1. The European Society of Cardiology (ESC) (in collaboration with the European Association for the Study of Diabetes (EASD)) produced new guidelines in 201913 which have taken into account the CVD trials on SGLT2i and issued clear evidence-based guidance on their role in CVD prevention. The following recommendations are made in the new ESC guidelines

Glucose-lowering treatment
Empagliflozin, canagliflozin, or dapagliflozin are recommended in patients with T2DM and CVD, or at very high/high CV risk, to reduce CV events
Empagliflozin is recommended in patients with T2DM and CVD to reduce the risk of death
Liraglutide, semaglutide, or dulaglutide are recommended in patients with T2DM and CVD, or very high/high CV risk, to reduce CV events
Liraglutide is recommended in patients with T2DM and CVD, or at very high/high CV risk, to reduce the risk of death
Saxagliptin is not recommended in patients with T2DM and a high risk of HF

5.2. The recommendation on the use of Empagliflozin is concluded from the EMPA-REG trial evidence, and ESC interpretation is as follows:

In EMPA-REG OUTCOME….Empagliflozin significantly reduced the risk of the three-point composite primary outcome (CV death, non-fatal MI, or non-fatal stroke) by 14% compared with placebo. This reduction was driven mainly by a highly significant ***38% reduction in CV death*** *(P < 0.0001), with separation of the empagliflozin and placebo arms evident as early as 2 months into the trial….In a secondary analysis, empagliflozin was associated with a* ***35% reduction in hospitalization for HF*** *(P < 0.002), with separation of the empagliflozin and placebo groups evident almost immediately after treatment initiation, suggesting a very early effect on HF risk. Empagliflozin also* ***reduced overall mortality by 32%*** *(P < 0.0001), a highly significant effect, translating into a number needed to treat of 39 over 3 years to prevent one death*.

For the first time in the history of DM, we have data from several "Cardiovascular Outcome Trials" (CVOTs) that indicate CV benefits from the use of glucose-lowering drugs in patients with CVD or at very high/high CV risk….. The recommendation for empagliflozin is supported by a recent meta-analysis which found high heterogeneity between CVOTs in mortality reduction. [I.e. each SGLT2i has different results]

6. Cost Effectiveness

6.1. There have been numerous evaluations on the cost effectiveness of SGLT2i. Cost effectiveness of SGLT2 inhibitors has been demonstrated by NICE through technology appraisals. NICE in 2018 suspended their planned appraisal of "Empagliflozin for reducing the risk of cardiovascular events in type 2 diabetes". They state 'Empaglifozin is already recommended for people with type 2 diabetes (TA336) and the population for which this additional appraisal would be aimed at (poorly controlled diabetes plus cardiovascular risk) is already included in the population previously appraised14.

6.2. However in one cost effectiveness evaluation the use of empagliflozin was shown to have a positive cost effectiveness ratio:

6.3. The model predicted an 18% relative increase (by 2.1 life-years) in survival for empagliflozin (14.0 life-years) vs. standard of care (11.9 life-years), attributable to direct treatment effect on cardiovascular mortality, and to indirect effect via reductions in other events. Participants treated with empagliflozin may experience improved quality of life (1.0 QALY) … yielding an incremental cost-effectiveness ratio (ICER) of £4083/QALY15.

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[13] https://academic.oup.com/eurheartj/article/41/2/255/5556890#191172082

[14] https://www.nice.org.uk/guidance/indevelopment/gid-ta10177

[15] https://pubmed.ncbi.nlm.nih.gov/31295358/

7. Rationale for the Local Clinical Guidance

Although there have been numerous trials and studies on SGLT2i, it is not always clear to health professionals which is the most appropriate drug for an individual or a particular group of patients.

7.1. The [NICE] committee agreed that evidence showed a clinically significant reduction in cardiovascular and all-cause mortality with empagliflozin but not with canagliflozin. Therefore, benefits on cardiovascular and all-cause mortality cannot be assumed for all SGLT-2 inhibitors as a class until more evidence is available.

7.2. *The committee [also] agreed that …. historically, the focus has been on glucose control. The committee agreed that, of all the antidiabetic drugs and combination of drugs, healthcare professionals and patients do not know which drug or combination of drugs is best at improving macrovascular [heart attacks and strokes] and microvascular outcomes [eye, kidney and foot disease]*.[16]

7.3. In addition to this, across each of the CCGs within West Yorkshire and Harrogate, there are no consistent prescribing recommendations for SGLT2i. *Appendix 2 - SGLT 2 Formulary choices in West Yorkshire* shows the current prescribing recommendations for SGLT2i.

7.4. This highlights the need to create local treatment guidance which, similar to the work already conducted on the West Yorkshire and Harrogate Healthy Hearts project for Hypertension and Cholesterol, has proved welcome.

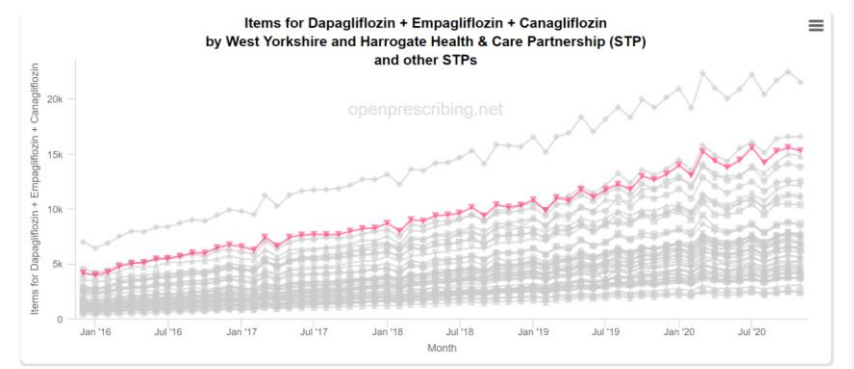
7.5. This treatment guidance will be targeted at specific patient cohorts – for example, those who are going on to a second line drug with HBA1c levels >58- 75 . This will be achieved by creating clinical searches to help Primary Care identify only suitable patients for this treatment regime. A list of the inclusion and exclusion criteria can be found (Appendix 2)

7.6. A copy of the draft treatment guidance can be found Appendix A. This will be taken through the appropriate clinical governance routes across West Yorkshire and Harrogate in order to gain sign off. As with previously developed guidance – clinical discretion can always be used.

[16] https://www.nice.org.uk/guidance/ng28/evidence/march-2018-evidence-reviews-for-sglt2-inhibitors-and-glp1-mimetics-pdf-4783687597

8. Current Local Prescribing

8.1. Current prescribing of SGLT2i is increasing, and across WY&H it is the third highest of all STPs[17] across the country, with Leeds CCG and Bradford and Craven CCG having higher prescribing numbers[18] – reflecting population sizes. However, further work to improve CVD outcomes in diabetes patients is needed and so the further use of SGLT2i is considered an important strategy to achieve this objective.



Total prescribing for *Dapagliflozin + Empagliflozin + Canagliflozin* across West Yorkshire and Harrogate Health & Care Partnership (STP)

	Nov '20	Financial YTD (Apr—Nov '20)	Last 12 months (Dec '19—Nov '20)
Cost (£)	555,907	4,316,230	6,374,984
Items	15,237	118,136	173,397

Figure 1 - SGLT2i prescribing by STP - source www.openprescribing.net

Table 2 - Figure 2 - Figure 1 - SGLT2i item prescribing by CCG - source www.openprescribing.net

	2015	2016	2017	2018	2019	2020
NHS BRADFORD DISTRICT AND CRAVEN CCG	1060	18122	22539	27412	32755	39813
NHS CALDERDALE CCG	505	7735	10927	12591	15185	16713
NHS GREATER HUDDERSFIELD CCG	2661	4155	7187	9630	11898	12275
NHS LEEDS CCG	1229	17750	23633	31310	41465	50399
NHS NORTH KIRKLEES CCG	550	8579	11705	14452	16302	16867
NHS WAKEFIELD CCG	533	8254	12999	17597	21785	24191
Grand Total	**4143**	**64595**	**88990**	**112992**	**139390**	**160258**

17 https://openprescribing.net/analyse/#org=stp&orgIds=E54000005&numIds=0601023AN,0601023AG,0601023AM,0601023AR,0601023AL,0601023AP&denom=nothing&selectedTab=map

18 https://openprescribing.net/analyse/#org=CCG&orgIds=03J,15F,02W,02R,03R,03E,02T,03A,02N&numIds=0601023AN,0601023AG,0601023AM,0601023AR,0601023AL,0601023AP&denom=nothing&selectedTab=chart

9. Clinical Searches

In order to target the most appropriate patients for the locally developed treatment guidance, a number of clinical searches have been developed based on a safety and clinical effectiveness. These searches will also help ensure that Primary Care are not overwhelmed with high numbers of patients and can therefore target those with the greatest risk. Existing treatment guidance and care will therefore apply to any patients outside of the following criteria.

Inclusion Criteria:

- Type 2 Diabetes with existing CVD or high / very high risk of CVD
- No history of PAD / Lower limb amputation
- Age: 40-79 (the expert advisory committee suggested avoiding prescribing in younger patients who were more likely to have type 1 diabetes and suggested avoiding routine searches in the elderly since this group was less represented in the studies and there would be an increased risk of polypharmacy and frailty. Standard medical care would remain for these age groups, as would individual clinician discretion)
- HBa1c: 58-75mmol
- On Metformin and/or 2-3 agents – Excluding Insulin
- eGfr:60+
- Excluding all Amber and Red clinical situations (see Appendix 2)

10. Author

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- Clinical Lead - Cardiovascular Disease, NHS Bradford District and Craven CCG
- Honorary Senior Lecturer, University of Bradford
- Primary Care Lead, National Rapid Uptake Products (RUP) programme for Lipid Management, NHS England & Accelerated Access Collaborative
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January 2021

Programme Support provided by: Yorkshire and Humber Academic Health Science Network

Contact: Pete Waddingham (Programme Manager)

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5. Empagliflozin in combination therapy for treating type 2 diabetes Technology appraisal guidance [TA336]Published date: 25 March 2015 https://www.nice.org.uk/guidance/ta336
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7. Fan, Wenjun Epidemiology in diabetes mellitus and cardiovascular disease Cardiovascular Endocrinology & Metabolism: March 2017 - Volume 6 - Issue 1 - p 8-16
8. Kansal A, Reifsnider OS, Proskorovsky I, Zheng Y, Pfarr E, George JT, Kandaswamy P, Ruffolo A. Cost-effectiveness analysis of empagliflozin treatment in people with Type 2 diabetes and established cardiovascular disease in the EMPA-REG OUTCOME trial. Diabet Med. 2019 Nov;36(11):1494-1502. doi: 10.1111/dme.14076. Epub 2019 Jul 23. PMID: 31295358; PMCID: PMC6851686. https://pubmed.ncbi.nlm.nih.gov/31295358/
9. Häring HU, Merker L, Seewaldt-Becker E, et al. Empagliflozin as add-on to metformin in patients with type 2 diabetes: a 24-week, randomized, double-blind, placebo-controlled trial. Diabetes Care 2014;37:1650-1659.

Appendix 1 - EMPA REG Trial – Graphs and Tables

Table 3 - All cause mortality

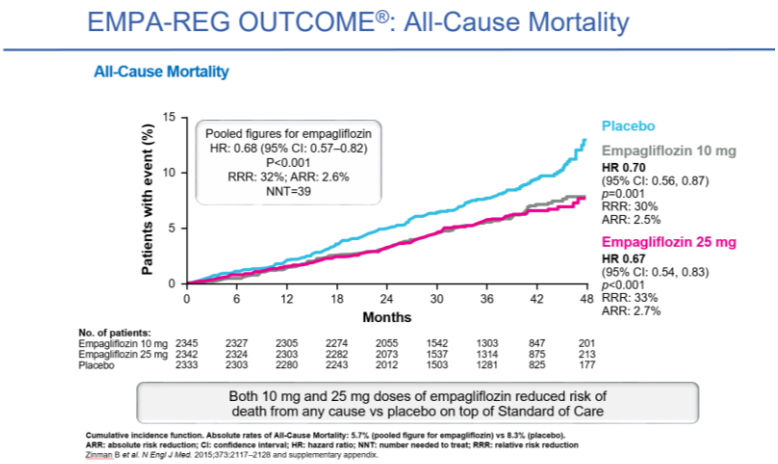


Table 4 - Cardiovascular Death

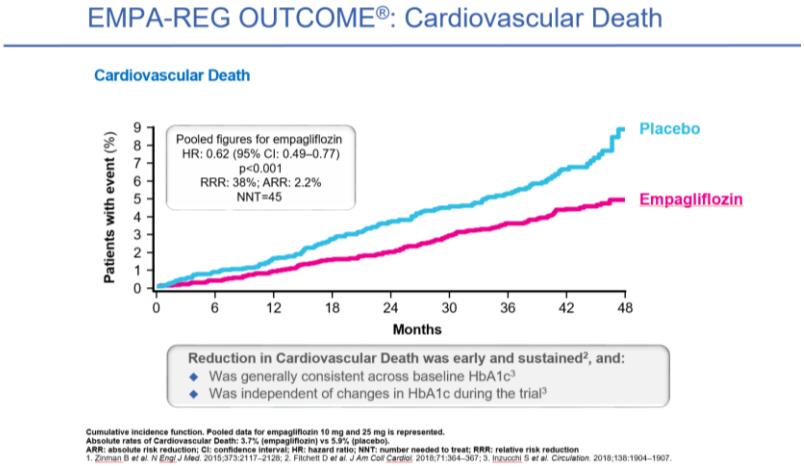
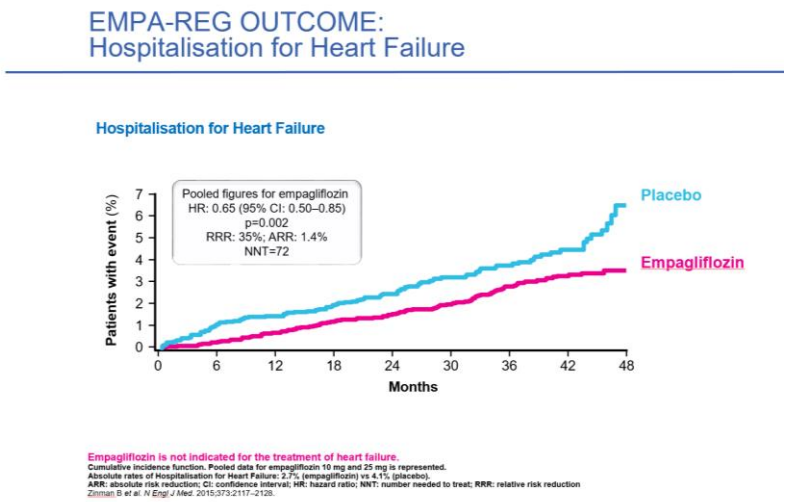


Table 5 - Heart Failure Hospitalisation



Appendix 2 - Prescribing Safety – Clinical Situations

The following tables are taken from the SGLT2i Prescribing Tool which has been prepared by the UK Improving Diabetes Steering Committee. To see the full document please see https://adisjournals.figshare.com/articles/dataset/SGLT2_Inhibitors_in_Type_2_Diabetes_Management_Key_Evidence_and_Implications_for_Clinical_Practice/6621683?file=24683327

- T2DM
- Age: above 40-80
- HBa1c = 58-75
- On Metformin and/or 2-3 agents (BNF groups of Diabetes) Exclude Insulin
- eGfr – 60+
- Include Red (do not prescribe below)

Do not prescribe SGLT2i

Clinical Situation	**Potential Implications**
Stage 3 CKD/eGFR <60 mL/min/1.73m2	Outside of licensed indication
DKA (or previous episode of DKA)	DKA risk
Eating disorders	DKA risk
Rapid progression to insulin (within 1 year)	DKA risk
Latent autoimmune diabetes	DKA risk
Excessive alcohol intake	DKA risk/outside of licensed indication
Diabetes due to pancreatic disease	DKA risk/outside of licensed indication
Genetic diabetes	Outside of licensed indication
Acute illness	Outside of licensed indication
Pregnancy (or suspected pregnancy), planning pregnancy or breastfeeding	Outside of licensed indication
Recent major surgery	Outside of licensed indication
Past history of necrotising fasciitis of the perineum (Fournier's gangrene)	Fournier's gangrene risk

Appendix 2 - SGLT 2 Formulary choices in West Yorkshire

CCG	1st choice	2nd choice
Bradford Districts and Craven	Canagloflozin Empagloflozin	None listed
Calderdale (CHFT)	Ertugloflozin	Dapagloflozin Canagloflozin Empagloflozin
Greater Huddersfield	No information available	No information available
Kirklees	No information available	No information available
Harrogate	Dapagloflozin Canagloflozin Empagloflozin Ertugloflozin (no preference)	
Leeds	Empagloflozin	None listed
Wakefield (MYHT)	Dapagloflozin Canagloflozin Empagloflozin Ertugloflozin (no preference)	

Correct as of 6/3/2020 Complied by Tracey Gaston (Head of Optimisation – NHS Bradford District and Carven CCG)

Summary

APPENDIX C

West Yorkshire and Harrogate
Combined Impact Assessment

Title of Scheme/Project:	West Yorkshire and Harrogate Healthy Hearts - Phase 3 Diabetes Treatment Guidance

Project Manager:	Pete Waddingham
Clinical Lead:	Dr Youssef Beaini
Programme Lead:	Steph Potts
Senior Responsible Officer (SRO):	Shane Hawyard Giles
Quality Lead:	Dr Youssef Beaini
Equality Lead:	Pete Waddingham

Proposed change:

The West Yorkshire and Harrogate Healthy Hearts project has developed clinical resources for phase three of the project which aims to target Type2 diabetes (T2DM) patients who are at high risk of CVD. New treatment guidance, focussed on sodium glucose Cotransporter-2 inhibitors (SGLT2i), has been developed following engagement with primary, community and secondary care colleagues. SGLT2 inhibitors are tablets that can help lower blood glucose (sugar) levels and have robust evidence for significantly reducing Cardiovascular disease in people with type 2 Diabetes who have either established CVD or are at risk of developing CVD. Following sign off by WY&H Joint Committee of CCGs this treatment guidance will be promoted across Primary Care for Diabetes patients at high risk of CVD.

Which areas are impacted:

NHS Airedale, Wharfedale and Craven CCG	☑	NHS Harrogate and Rural Districts CCG	☑	Acute services	☐
NHS Bradford City CCG	☑	NHS Leeds CCG	☑	Yorkshire Ambulance Service	☐
NHS Bradford Districts CCG	☑	NHS North Kirklees CCG	☑	Independent Sector	☐
NHS Calderdale CCG	☑	NHS Wakefield CCG	☑	Primary Care	☑
NHS Greater Huddersfield CCG	☑	Community services	☐	Mental Health services	☐
				Third sector	☐

Summary of engagement activity:

The West Yorkshire and Harrogate Healthy Hearts project met with key stakeholders across Primary, Community and Secondary Care (26th February 2020) to scope phase three of the project – improving CVD outcomes in Diabetes patients. Due to COVID19 the preparation of this guidance was put on hold. A follow up meeting was arranged, again with representation from across Primary, Community and Secondary Care (18th December 2020) to review the work to date and agree the treatment guidance. This treatment was then presented to the Area Prescribing Committee and Planned Care Board (March 21) In total more than 70 stakeholders have been involved in the preparation of the treatment guidance.

Summary of impacts graph - This will automatically populate from the impact score on each tab

Note that scores above zero indicate positive impact and below zero indicate negative impact

Links to each area for further detail:

Patient Experience

Patient Safety

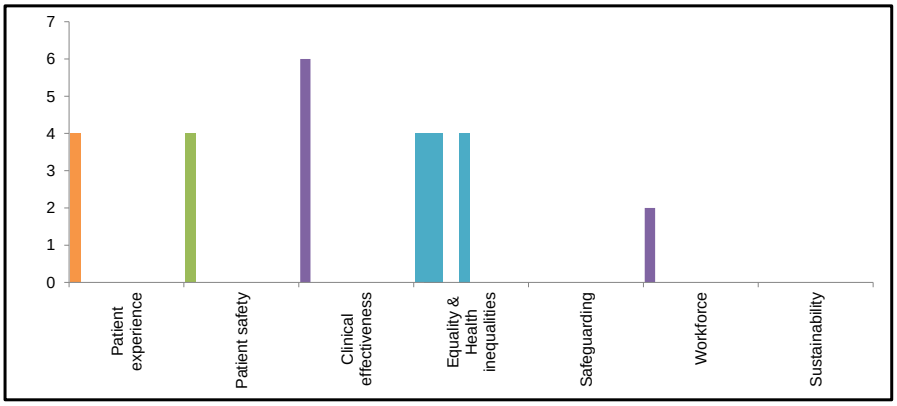
Clinical Effectiveness

Safeguarding

Equality and Health Inequality

Workforce

Sustainability



Summary of findings:

The Impact Assessment has concluded that there is a positive impact across Patient Experience, Patient Safety, Clinical Effectiveness, Equality & Health Inequalities and also Workforce. No negative impact is anticipated.

There is a positive impact on patient safety and clinical effectiveness by the introduction of simplified treatment guidance for Diabetes patients at risk of CVD. Evidence from NICE and also Clinical trials shows the use of SGLT2i can lead to a 38% reduction in CVD death, a 35% reduction in hospitalisation for Heart Failure and also reduced overall mortality by 32%. Simplified treatment guidance is considered a strong way to improve pathways of care - making the information consistent and more accessible to health professionals. CVD and its risk factors (hypertension and diabetes) are also closely related to fatal outcomes in COVID-19 for patients across all ages.

This guidance will exclude a number of people on the grounds of clinical safety and not on their protected characteristics. e.g. drugs not being licensed for use in pregnant women / breastfeeding. It is anticipated that the treatment guidance will have a positive impact on health inequalities and deprivation. The National Diabetes Audit provides a consistent way to baseline and measure any future equality/health inequalities impact.

There is a small positive impact anticipated in terms of workforce, as simplified treatment guidance helps health professionals with the management of their patient caseloads i.e. by providing simple, consistent and easy to follow guidance.

QEIA completed by (name, role and organisation):	Pete Waddingham (Programme Manager) Y&H AHSN
Date QEIA completed:	01/02/2021

QEIA signed off by:	**Name**	**Date**
On behalf of WY&H HCP	Michelle Turner - Strategic Director of Quality and Nursing John Hartley Senior Head of Quality Improvement NHS Bradford District and Craven Clinical Commissioning Group (CCG)	25-Mar-21