Appendix B: Stakeholder consultation comments table

2022 surveillance of NG17 Type 1 Diabetes in Adults: Diagnosis and Management (2015)

Consultation dates: 26th May to 13th June 2022

	 Do you agree with the proposed changes to recommendation 1.13.8? Please could you let us know if you agree or disagree (yes/no) and provide your reasons if you disagree. 			
Stakeholder	Overall response	Comments	NICE response	
Diabetes UK	Yes	Yes	Thank you for your agreement.	
NICE Medicine Optimisation Team	Yes	Agree	Thank you for your agreement.	
Perspectum Ltd	No	(References included throughout text in parentheses, full list included in the final answer)	Thank you for your comment. With regards to the proposed wording:	

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We disagree with the following wording within the proposed changes to recommendation 1.13.8:"Use clinical judgement for adults with frailty, target organ damage or multimorbidity. See NICE's guidelines on chronic kidney disease, hypertension in adults, and multimorbidity."Use clinical judgement for adults with frailty, target organ damage or adults, and multimorbidity.
 This sentence was added to 1.13,8 to acknowledg situations which might not fit with the proposed target blood pressure threshold. This sentence was added to 1.13,8 to acknowledg situations which might not fit with the proposed target blood pressure threshold. The use of MRI for quantifying target organ damage is beyond the scope of this exceptional surveillance review which was only focussed on addressing the issues with inconsistency across the <u>chronic kidnee</u> disease guideline (NG203) the <u>type 1 diabetes in</u> adults guideline (NG17) in terms of blood pressure targets. We therefore propose including the use of multi-organ magnetic resonance imaging (MRI) techniques for the quantitative assessment of target organ damage in patients with type 1 diabetes (T1D) to inform blood pressure targets. Target organs with damage and concomitant hypertension include the heart, the kidney and arterial blood vessels, amongst others (1,2).
The prevalence of CVD in people with T1D has been reported as ranging from 6% in those aged 15-29, to 25% in those aged 45-59 (3) and is

	r
frequently reported as the leading cause of mortality (4–6). MRI	
technology has been proven to be a powerful technique to diagnose,	
monitor and stratify risk for CVD. For example, vessel wall MRI is a useful	
technique to examine the arterial wall to identify risk of CVD, characterise	
atherosclerosis in various regions of the cardiovascular system (7-12) and	
evaluate plaque composition and physiology to assess risk of severe acute	
cardiovascular events (13,14). In addition, cardiac MRI has proven useful	
to assess left ventricle structure and function, aortic stiffness and	
ventricular-arterial interaction to inform on risk of cardiovascular disease	
in patients with T2D (15). Cardiac MRI measures including carotid artery	
wall thickness are also accurate indicators of risk for CV events in	
asymptomatic patients (16). Non-contrast cardiac MRI techniques have	
been adopted in clinical guidelines for diagnosis of cardiac diseases (17-	
19). For example, T1 maps provide diagnostic information in the heart	
over a wide range of T1 values, so that increased T1 can be diagnostic of	
oedema (increased tissue water) or increased interstitial space (20-22),	
even before clinical symptoms develop (23,24); whilst shortening of T1	
characterises thrombus formation (25) and cardiac fat in lipomatous	
hypertrophy (26). T1 maps reliably diagnose a range of conditions,	
including acute myocardial infarction, myocarditis, amyloidosis, iron	
overload and Fabry disease (20,27–30), and the derived extracellular	
volume is a powerful independent predictor of mortality in patients with	
severe aortic stenosis (31). In support, the 2014 European Society of	
Cardiology guidelines for the diagnosis and treatment of aortic diseases	
state that MRI is well suited to diagnosing aortic disease due to the	
technical reliability of aortic measurements.	

		COVID-19, with liver volume, fat accumulation in the liver and pancreas and pancreatic inflammation displaying a positive association with hospitalisation, whilst severe PCS was associated with evidence of myocarditis. In support, a separate study also revealed multi-organ impairment in the lungs, brain, heart, liver and kidneys in 58 PCS patients in the UK by use of multi-organ MRI technology (46).		
Healthy.io	Yes	Yes	Thank you for your agreement.	
Royal College of Nursing	No comment	We do not have comments on this consultation. Thank you for the opportunity to contribute.	Thank you for responding.	
Royal College of Physicians	No comment	We have liaised with our experts in diabetes and have no concerns.	Thank you for responding.	
Royal College of General Practitioners	Yes	This appears more clinically pragmatic and relevant and overall better phrased.	Thank you for your agreement that this seems more clinically pragmatic.	
 Do you agree with the proposed deletion of recommendation 1.13.13? Please could you let us know if you agree or disagree (yes/no) and provide your reasons if you disagree. 				
Stakeholder	Overall response	Comments	NICE response	
Diabetes UK	Yes	Yes	Thank you for your agreement.	

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NICE Medicine Optimisation Team	Yes	Agree	Thank you for your agreement.
Perspectum Ltd	Yes	We agree	Thank you for your agreement.
Healthy.io	Yes	Yes	Thank you for your agreement.
Royal College of Nursing	No comment	We do not have comments on this consultation. Thank you for the opportunity to contribute.	Thank you for responding.
Royal College of Physicians	No comment	We have liaised with our experts in diabetes and have no concerns.	Thank you for responding.
Royal College of General Practitioners	Yes	Yes	Thank you for your agreement.

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3. Do you agree with the proposed changes to recommendation 1.15.14?

Please could you let us know if you agree or disagree (yes/no) and provide your reasons if you disagree.

Stakeholder	Overall response	Comments	NICE response
Diabetes UK	Yes	Yes	Thank you for your agreement.
NICE Medicine Optimisation Team	Yes	Agree	Thank you for your agreement.
Perspectum Ltd	Yes	We agree	Thank you for your agreement.
Healthy.io	Yes	Yes	Thank you for your agreement.
Royal College of Nursing	No comment	We do not have comments on this consultation. Thank you for the opportunity to contribute.	Thank you for responding.
Royal College of Physicians	No comment	We have liaised with our experts in diabetes and have no concerns.	Thank you for responding.

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Royal College of General Practitioners	Yes	Yes	Thank you for your agreement.
		comments on equality issues related to these recommendations? urces of information on equality issues if available.	
Stakeholder	Overall response	Comments	NICE response
Diabetes UK	No answer given	None	Thank you for responding.
NICE Medicine Optimisation Team	No answer given	None	Thank you for responding.
Perspectum Ltd	Yes	As mentioned earlier in our response to the changes to recommendation 1.13.8, by relying solely on clinical judgement for assessing patients for target organ damage, multimorbidity or frailty, there will be an inherent bias in clinicians' assessment towards clinical experience gained from treating and serving a particular population that might adversely affect the correct diagnosis for those from underserved or minority backgrounds.	Thank you for your comment. Please see the above response for the rationale of why the sentence was added to 1.13.8. The use of MRI for quantifying target organ damage is beyond the scope of this exceptional surveillance review which was only focussed on addressing the

		Standardised, quantitative metrics such as those provided by mpMRI could therefore provide a key diagnostic tool to aid clinicians in making optimum treatment decisions.	issues with inconsistency across the <u>chronic kidney</u> <u>disease</u> guideline (NG203) the <u>type 1 diabetes in</u> <u>adults guideline</u> (NG17) in terms of blood pressure thresholds. However, this issue has been noted for future surveillance of the guideline.
Healthy.io	No	No	Thank you for responding.
Royal College of Nursing	No Comment	We do not have comments on this consultation. Thank you for the opportunity to contribute.	Thank you for responding.
Royal College of Physicians	No comment	We have liaised with our experts in diabetes and have no concerns.	Thank you for responding.
Royal College of General Practitioners	No	No	Thank you for responding.

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5. Do you know of any other ongoing research in this area that may impact on the recommendations? (Yes/No)

If yes, could you please provide sources of information.

Stakeholder	Overall response	Comments	NICE response
Diabetes UK	No answer given	None	Thank you for responding.
NICE Medicine Optimisation Team	No answer given	None	Thank you for responding.
Perspectum Ltd	Yes	(References included throughout text in parentheses, full list included in the final answer)	Thank you for your comment. Please see the above response for the rationale of why the sentence was added to 1.13.8.
		Studies both at a population level (38) and on a cellular level (47,48) have shown that contracting COVID-19 can lead to development of T1D, either as an acute effect of SARS-CoV-2 infection or as result of persistent, prolonged symptoms, commonly referred to as 'long COVID'. One of the mechanisms by which people with COVID-19 can develop T1D is as a by- product of systemic inflammation in the body. The other is that pancreas cells can become infected by SARS-CoV-2 and cause beta-cell dysfunction (47,48). In a large US study (38) that followed up ~27 million people, researchers found that patients who were infected with SARS-CoV-2	is beyond the scope of this exceptional surveillance review which was only focussed on addressing the issues with inconsistency across the <u>chronic kidney</u> <u>disease</u> guideline (NG203) the <u>type 1 diabetes in</u>

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were 42% more likely to develop T1D than those who did not contract COVID-19 during the study period. The potential consequences of this effect of COVID-19 on development of T1D is shown by the establishment of the CoviDIAB Project, a global registry of people with new-onset COVID-19-related diabetes (49).	future surveillance of the guideline. The list of references has also been retained, thank you. With regards to the comments related to Covid-19 infection, we have passed these across to the NICE Covid-19 team for consideration.
There is a clear need therefore to identify early on the extent, if any, of pancreatic damage, fibrosis or inflammation so that patients can be appropriately risk-stratified for presence of T1D.	
Evidence on the applicability of multi-organ MRI techniques to examine multi-organ abnormality is provided as described above. In particular, mild pancreatic impairment was found in 40% of patients following infection with SARS-CoV-2 (median 141 days post infection)45. In the follow-on, longitudinal study, multi-organ imaging was able to estimate the prevalence of organ impairment in Long COVID patients at 6 and 12 months post initial infection, reporting increased pancreatic fat content in 15% of patients at baseline, and multi-organ impairment in 23% of patients at 6 months and 27% of patients at six months, reporting that 3 in 5 people with PCS had impairment in at least more than one organ (50).	
Pancreatic and renal fibro-inflammation as measured by T1 correlates well with histological markers / histology and standard of care markers of disease (42,51–56).	

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Patients that develop pancreatic damage, either as a symptom of long COVID, or for other reasons such as pancreatitis, can be identified using multiorgan MRI, which can detect inflammation and fibrosis in the aforementioned six organs, including the pancreas. Early identification and risk stratification of these patients with pancreatic damage could therefore enable them to be referred for early diagnostic testing for T1D, which can help avoid the onset devastating episodes of diabetic ketoacidosis. With current management of long Covid not standardised, and driven by disparities between locations, being able to identify and diagnose at-risk patients early, will greatly benefit patients and the NHS.
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Healthy.io	Yes	Regarding recommendation 1.13.8, NICE should include within the recommendation that clinicians may consider semi-quantitative ACR, as well as the quantitative ACR test currently detailed. The NHS National Diabetes Audit shows that completion of ACR tests for people with type 1 diabetes is the lowest performing of all eight care processes in England. In 2021, only 52.8% of type 1 diabetes patients had an ACR test. This presents a challenge for clinicians in complying with recommendation 1.13.8. Expanding the recommendation so that clinicians can consider alternative approaches, such as home-based testing, can support increased adherence of ACR testing and in turn can support compliance with this recommendation.	Thank you for your comment. Neither the type 1 diabetes NICE guideline nor the chronic kidney disease NICE guideline found sufficient evidence of semi-quantitative ACR and thus no recommendations were made for this. We do note that NICE already has a Medtech Innovation briefing on <u>Healthy.io test</u> for home testing of urine albumin to creatinine ratio (MIB221). However, we will note this issue for future surveillance of the guideline.

Royal College of Nursing	No Comment	We do not have comments on this consultation. Thank you for the opportunity to contribute.	Thank you for responding.
Royal College of Physicians	No comment	We have liaised with our experts in diabetes and have no concerns.	Thank you for responding.
Royal College of General Practitioners	No	No	Thank you for responding.

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