

# Decision Aid Supporting Document – Type 1 Diabetes

Version 11.2 (Jan 2023) planned review (3 years)

This document is designed to give further information about how we made the Decision Support Tool (Decision Aid).

Each tool had an expert advisory group nominated by NHS England, who commissioned the tools, the involvement of relevant charities or support groups, and was designed through rounds of redesign and feedback from clinicians, patients and members of the public who might use it. These were one-on-one interviews, and the feedback was collated and acted on in multiple rounds.

EasyRead versions were then made through a similar process of iterative testing with experts and users.

Users (patients and the general public) are our focus, we include them from the beginning of the process and their views and feedback throughout are at the very heart of what we aim to do. The decision aids are for them.

Each tool is made to comply with the guidelines or criteria on decision aid development by [IPDAS](#) and [NICE](#). Very often they go beyond what many might consider as a ‘decision aid’ because our work with patients and clinicians has emphasised how much patients want ‘everything in one place’ and clinicians find it helpful to have ‘the perfect consultation’ laid out to support them.

Patients particularly appreciated the help that the documents gave them in preparing for an appointment (knowing what might happen in advance, and helping prompt questions they might want to ask), pages that help them when they talk to their doctor, and those that remind them what’s going on, what might happen, and what did just happen (what did the doctor tell me in the room). The extra information can make the documents seem long, but patients preferred this extra length, as long as the sections were easily navigable.

In this document you can find out more about who helped design the tool, some of the reasoning behind key decisions, and what reference sources were used. You can also see the answers to some of the questions we posed to the people we tested it with about how they might use the tool, which led to key decisions about its design. These are only examples designed to give you a sense of how they were made – the full process is too detailed to document.

In designing the graphical representations of the numbers, we use a large body of research into risk communication done over many years (some by us), plus the testing we do during the production of the tools. Graphic design was by the company Luna9.

## Who was involved?

	number	
<b>Expert Advisory Group Clinicians &amp; Patient Reps &amp; their Declarations of Conflicts of Interest (COI)</b>	<b>X 9</b>	<p><b>Prof Partha Kar OBE</b> (Consultant in Diabetes &amp; Endocrinology, National Specialty Advisor in Diabetes with NHS England and co-author of the national diabetes Getting It Right First Time report) No COI to declare.</p> <p><b>Dr Fulya Mehta</b> (Consultant in Paediatric Diabetes at Alder Hey Children’s Hospital, NHS England National Clinical Lead for Diabetes in Children and Young People) No COI to declare.</p> <p><b>Lesley Jordan</b> (Lived experience and Technology Access Lead at JDRF) No COI to declare.</p> <p><b>Dr Emma Wilmot</b> (Associate Professor at the University of Nottingham, Honorary Consultant Diabetologist in Derby and founder of the Diabetes Technology Network UK) COI: Previous recipient of personal fees from: Abbott, Astra Zeneca, Dexcom, Eli Lilly, Embecta, Insulet, Medtronic, Novo Nordisk, Roche, Sanofi, Ypsomed. Research support from: Abbott, Embecta, Insulet, Novo Nordisk, Sanofi.</p> <p><b>Liz Perraudin</b> (Lived Experience and Senior Policy Officer at Diabetes UK) No COI to declare.</p> <p><b>Charlotte Austin</b> (Lived experience and representing Diabetes UK) No COI to declare.</p> <p><b>Prof Pratik Choudhary</b> (Consultant Diabetologist, chair of the Diabetes Technology Network-UK) COI: Received personal fees from Abbot, Dexcom, Medtronic, Insulet, Ypsomed, Novo Nordisk, Lilly, Sanofi and Vertex. He has received research support from Abbott, Dexcom, Sanofi, Novo Nordisk.</p>



		<p><b>Lisa Skinner</b> (Diabetes Specialist Nurse) COI: Received fees from Abbott and Lilly</p> <p><b>Geraldine Gallen</b> (Type 1 Service Lead, Senior diabetes specialist nurse, Kings College Hospital, Diabetes Technology Network) COI: Previous recipient of personal fees from: Abbott, Dexcom, Insulet, Medtronic.</p> <p><b>Dr Sam Finnikin</b> (GP and NHSE National Clinical Specialist Advisor in Personalised Care) No COI to declare.</p>
<p><b>Other clinicians (not part of the expert advisory group) who were interviewed or provided input or feedback</b></p>	x5	<p><b><u>Diabetes Specialist Nurse Forum UK</u></b></p> <p><b>Amanda Epps</b> (Lead Diabetes Specialist Nurse) COI: received honorarium both personally and on behalf of DSN Forum from Glooko, Menarini, Dexcom, Abbott, which are manufacturers of some of the products mentioned in the decision aid.</p> <p><b>Beth Kelly</b> (Lead Diabetes Specialist Nurse) COI: received honorarium both personally and on behalf of DSN Forum from Glooko, Dexcom, Abbott, which are manufacturers of some of the products mentioned in the decision aid.</p> <p><b>Tamsin Fletcher-Salt</b> (Lead Diabetes Specialist Nurse) COI: received honorarium both personally and on behalf of DSN Forum from Menarini, which are manufacturers of some of the products mentioned in the decision aid.</p> <p><b>Vicki Alabraba</b> (Diabetes Specialist Nurse) COI: received honorarium both personally and on behalf of DSN Forum from Dexcom, Abbott, NovoNordisk, which are manufacturers of some of the products mentioned in the decision aid.</p> <p>And <b>Alison Cox</b> (Clinical Nurse Specialist in Diabetes)</p>
<p><b>Patients and public involved in 4 rounds of testing and feedback</b></p>	x16	<p>5 male 11 female a range of ages, ethnicities, education levels</p> <p>Of the 15 interviewed: 9 have experience of Type 1 Diabetes</p>



		1 had English as not their native language
<b>Organisations involved</b>		Diabetes UK representative Charlotte Austin  JDRF representative Lesley Jordan  Diabetes Specialist Nurse Forum (specialist nurses)
<b>Who are the Winton Centre for Risk &amp; Evidence Communication?</b>		The Winton Centre was funded by a philanthropic donation from the David & Claudia Harding Foundation to help communicate evidence 'to inform, not persuade'. The team carried out research in how best to communicate numbers and uncertainty, created training courses to help professions who needed to communicate evidence in a balanced way, and produced tools to communicate evidence on different topics. They were commissioned, and funded, by NHS England to produce a series of printable decision support tools in 2022 and 2023. The funding for this work came from NHS England and the Winton Centre's own core funding.

## What questions do we ask of our expert group and user testers and why?

We interviewed the expert advisory group, regular patients and potential users of the decision aid and regular clinicians who might use the decision aid. We interviewed each tester (regular patients or users, and regular clinicians) via video call, usually for about an hour.

We need to understand which information to include and to what level of detail.

### **For users (patients):**

We always first asked about their experience of the condition or the decision to be made. We asked them what did they want to know at the time and what would they have liked to have known. We asked them what they would tell someone now who was making the decision.

We then asked for their feedback on the decision aid.

We ask if they would like a clinician to go through the document with them.

Then we ask them:

- Whether they understood the purpose of the document (that it is a decision aid, not an information sheet).
- Whether they would read it, if they would find it useful, would it help them make a decision?
- Whether, if they were handed the document by a clinician, they would read it.
- Whether, if they saw this document on a table, for example in a clinic waiting room, they pick it up, and *want* to read it.

The aim of these decision aids is to help people make a decision. But in order to be useful and used, they need to be read. And in order to be read, they need to be picked up. We therefore amend and refine the documents and retest them (with a mix of the same and different testers) until the answers to these questions are “yes”.

If people want a clinician to go through the document with them, we make sure it's clear in the document that this is what they can do and, on the front page, which pages are (most) useful to be used in a consultation with a healthcare professional.

### **For clinicians (both our expert group and regular clinicians):**

We ask:

- What is the decision being made? (what are the treatment options that are available)
- At which point in a patient's pathway/disease progression are they making the decision, and therefore what is the background knowledge of the potential user (what do they already know), and when and how would they physically receive this leaflet?

- Are there inclusion / exclusion criteria around the decision aid?
- How would the decision aid be used, e.g. by users 'on their own' before a consultation with a clinician, or always first with a clinician

The answers to these questions help us to understand which information to include in the leaflet, at what level of detail and language to use.

<p><b>What is the decision?</b></p> <p><b>And / or</b></p> <p><b>What are the treatment options available?</b></p>	<p>We included options guided by our expert group and NICE guidance (2023)</p> <ul style="list-style-type: none"> <li>- Methods of glucose testing (meter, CGM)</li> <li>- Methods of insulin delivery (pens, smart pens, pumps)</li> <li>- Hybrid closed loop system</li> </ul> <p>Users told us they wanted to know:</p> <ul style="list-style-type: none"> <li>- Am I eligible for technology, and if so, which?</li> </ul> <p>And then help with the decision:</p> <ul style="list-style-type: none"> <li>- Which of those technologies should I choose to manage my type 1 diabetes?</li> </ul>
<p><b>When in the pathway will it be used? (clinician answer)</b></p>	<p>e.g. Pre-primary care, primary care, secondary care</p> <p>Anyone who has been diagnosed with Type 1 Diabetes can choose technology to help manage their diabetes. This decision aid makes it clear who is eligible for which technologies and then gives them the details about each to support a decision between them.</p> <p>It should be used by those who have been newly diagnosed, or those who are not currently using the technology listed in the document, or those wishing to try a different technology.</p> <p>The decision aid would be used usually with a specialist diabetes nurse, or doctor.</p>
<p><b>When would it be useful? (patient answer)</b></p>	<p>Patients agreed that anyone with type 1 diabetes might be interested in this decision aid at any time.</p> <p>Example answers to the question 'at what point would you want the document?'</p> <ul style="list-style-type: none"> <li>- <i>"At diagnosis. It gives a really good overview of what your options are...At diagnosis you are given information but this is good, it's really clear: this is what I've got, this is how I can manage it. But it's also good for people who have had Type 1 for a while, like me, it's good to have all this in one document."</i></li> </ul>



	<ul style="list-style-type: none"> <li>- <i>"It's aimed at the newly diagnosed maybe but it will get in the hands of new people and old people. Anyone with type 1 will pick it up... and then again [I know] some GPs or non-specialists who would like this and find it useful."</i></li> <li>- <i>"You have a diabetes nurse at the GP, you have the diabetes nurse at the hospital clinic. I'd expect either of them to give it to me."</i></li> </ul>
<p><b>How would it be used?</b></p>	<p>e.g. patients to use it on their own before a consultation or always with a clinician</p> <p>Our decision aids are written where possible, in such a way as to be stand alone, the reader of any ability and any level of knowledge should be able to read it and understand their options. This document, more than other decision aids we have made, though had to start off at a certain level of knowledge otherwise the document would have been too long and unwieldy.</p> <p>We tried to include background about diabetes for those who would be new to the condition, but structured the document in such a way that if you have had T1DM for some time and don't need that information, it's not offputting.</p> <p>Testers agreed that we had achieved this, and that in the main the document could be used by patients on their own but there would always be a follow up meeting with their diabetes team to discuss.</p> <ul style="list-style-type: none"> <li>- (round 1) <i>"I'd hope that you'd write it so that I can read it myself"</i></li> <li>- <i>"It's quite nice because you can work through it, share it, and it can be a discussion piece. "</i></li> <li>- <i>"I was diagnosed as an adult. A diabetic nurse visited the house - it was all very daunting, overwhelming. I don't think I would have been able to take much information in at the time. A document like this could have been good to refer back to because I didn't take much in. I would have liked an appt with a nurse to talk through the document."</i></li> </ul>
<p><b>Are there any exclusion / inclusion criteria?</b></p>	<p>Who is the decision aid for? And who is it specifically not for?</p> <p>The development of the decision aid took a number of months and the answer to this question changed in that time. NICE guidance changed regarding eligibility of technology. This decision aid was finally produced aligning with NICE TA151 and NG17 and NG18.</p>



	<p>The expert group decided that the final version could then be used by anyone with type 1 diabetes, including children.</p>
<p><b>Would you prefer a printed version, online electronic version or both? (Patient answer)</b></p>	<p>We know from testing previous decision aids that most clinicians would prefer these were electronic online tools.</p> <p>NHS clinicians typically do say they have facilities to print (black and white only).</p> <p>Of the 9 patients and public who answered this question:</p> <ul style="list-style-type: none"> <li>- 6 wanted it as a printed piece of paper</li> <li>- 3 wanted it both online and printed</li> <li>- None wanted it online only</li> </ul>
<p><b>Any other comments?</b></p>	<p>It might be argued that this is not technically a decision aid. NICE defines a decision aid as something to: <i>“help people decide on healthcare options. They provide evidence-based information on the options available, along with likely outcomes, benefits, harms and uncertainties”</i>.</p> <p>The purpose of this T1DM decision aid is to help those with diabetes decide between different available technologies to manage their diabetes (‘available’ being which technologies they are eligible for on the NHS).</p> <p>This decision aid does:</p> <ol style="list-style-type: none"> <li>1. Give clear treatment and care options</li> <li>2. Help people in understanding and eliciting their own values when it comes to the decision. There are flow charts, spaces to think, and comparison pages about “choosing”.</li> </ol> <p>What this decision aid does not include are data-driven “risks and benefits” pages. We don’t have outcome measures with quantitative evidence for each options (e.g. ‘how many hypo periods am I likely to experience if I choose...?’). This information is not available and depends so much on individual factors.</p> <p>However, for each option we give qualitative information (e.g. the “Choosing” pages). These pages allow the patient to think through their personal preferences, practicalities of care and factor them into a decision regarding what system works best for them.</p> <p>Whether or not this falls under the definition of a Decision Aid, our testing suggests that the leaflet is a useful decision support tool.</p>
<p><b>Were there any key decisions</b></p>	<ul style="list-style-type: none"> <li>- The proposed purpose of the decision aid was to present the different technologies available to people with T1DM. As the</li> </ul>





<p><b>made when designing the document, and what was the reasoning behind them?</b></p>	<p>decision aid was being developed (during 2023), new NICE guidelines were published around eligibility (in Autumn 2023).</p> <ul style="list-style-type: none"><li>- Age range / eligibility – changed during the development of the tool such that it started as being relevant only for those over 12 years old, but the final version was relevant for anyone with type 1 diabetes.</li><li>- The expert group decided that there was a need to include the eligibility algorithm on page 2.</li><li>- Technology options to include changed during the development of the decision aid for example Flash’s new technology meant it could be classed as a CGM and incorporated into the CGM group.</li><li>- Detail of devices – the expert advisory group suggested higher classifications and groups of technology over detail of specific devices because the technology is changing all the time.</li><li>- The Diabetes Nurse Forum regularly review and update comparison charts of technology available. Clinicians suggested giving links to these, as well as printing the most recent versions as appendices to the decision aid, so that they could easily be updated as printouts in clinic.</li><li>- Patients agreed they would normally go through this decision aid with a clinician (usually a nurse specialist) who would explain the more detailed (DNF) charts so we included those without simplification or further explanation.</li><li>- Clinicians and patients all agreed that the user will come to the decision aid with a level of understanding about type 1 diabetes already. The level of information around diabetes and insulin was decided upon through testing. For example, we did not include a definition of ketones, or further detail about diabetes.</li></ul>
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Some example answers from our patient and regular clinician testers and actions we took on the basis of them (organised by testing round)	
<b>ROUND 1</b>	<p>Would you pick it up?</p> <ul style="list-style-type: none"> <li>- <i>"Yes! I've never seen anything like it"</i></li> </ul> <p>Wording (page 13):</p> <ul style="list-style-type: none"> <li>- <i>"I've never come away from diabetes appointment with a 'what do I need to do right now'. There's always time to change your mind. Change the wording to 'is there anything I need to do' I like that – works better"</i></li> </ul> <p><b>In response, we changed to the suggested wording.</b></p> <p>Thinking about including help to prepare for your appointment pages:</p> <ul style="list-style-type: none"> <li>- <i>"Preparing for your appt - I think it is almost the most important page, It's that point that changed to me 'owning' it from the clinician controlling it ....It's very important. We should be empowering the patient to go and ask questions"</i></li> </ul> <p>Language:</p> <ul style="list-style-type: none"> <li>- <i>"A lot of diabetics feel bad / guilt, but it's not always your fault or manage it well. Some days you just can't seem to get control"</i></li> <li>- <i>"It's a lifelong condition.... I'd take out 'if you manage it well'" (page 2)</i></li> </ul> <p><b>In response, we made this change.</b></p> <ul style="list-style-type: none"> <li>- <i>Its good you're keeping the language not too technical but not too 'sing song'</i></li> </ul> <p>PAGE 4 – choosing how to measure your glucose:</p> <ul style="list-style-type: none"> <li>- <i>"Found this page confusing. Not sure what I needed to do. Could the description be integrated into page 3 and the questions kept separate? Keep the questions all together, and all the descriptions together"</i></li> </ul> <p><b>In response, we made this change.</b></p>
<b>Round 2</b>	<p>What can we remove?</p> <ul style="list-style-type: none"> <li>- <i>"No – more is more! It's longish but targeted at newly diagnosed."</i></li> <li>- <i>"When I got into the document, I didn't mind the length so much; really useful prompts"</i></li> </ul>



	<p>What's missing?</p> <ul style="list-style-type: none"> <li>- <i>"Psychological support – you have to fill out a 'diabetes distress score' – living with diabetes can be tough, there are people who can help you – something about mental / psychological strain"</i></li> </ul> <p><b>In response, we added a support group link on the back page for psychological help, a reflective question about mental health on the 'what's important to you' page, and notes about feeling overwhelmed and help that's available.</b></p> <p>What's missing?</p> <ul style="list-style-type: none"> <li>- <i>"Include contents page - If you have a contents page then if you only want the technical stuff then you turn to that, If you're new, you know to read the intro pages"</i></li> </ul> <p><b>In response, we included a contents page on page 2.</b></p> <p>What's missing?</p> <ul style="list-style-type: none"> <li>- (specialist nurse feedback) <i>"You get the specifics [of the devices] from the nurses, you don't need to be too detailed"</i></li> </ul>
<b>Round 3</b>	<ul style="list-style-type: none"> <li>- <i>"Have somewhere that this is an extremely personal decision with no right or wrong treatment choice"</i></li> </ul> <p><b>In response, we added this to the 'choosing how to manage' pages.</b></p> <ul style="list-style-type: none"> <li>- <i>"Really good to be able to make notes"</i></li> <li>- <i>"I'd take it to the doctors with me filled in"</i></li> <li>- <i>"I like having it printed especially here because you can write on it, even though normally I'm all electronic, but with this one I think printed so I can make notes and get to grips"</i></li> </ul>
<b>Round 4</b>	<ul style="list-style-type: none"> <li>- <i>"very visual &amp; easy to follow"</i></li> </ul>
<b>Reading age range</b>	<p>Using <a href="https://readabilityformulas.com/readability-scoring-system.php">https://readabilityformulas.com/readability-scoring-system.php</a> Average Reading Age Consensus Calculator</p> <p>Average reading age 9-10</p>



<b>Easy Read development</b>	
<p>When making the first Easy Read version of a decision aid (for Heavy Periods) we were able to create a basic structure and set of illustrations for the other easy read decision aids (see 'notes and lessons learned'). From this basis, we then made and tested each other decision aid in Easy Read version.</p> <p><b>This Easy Read was tested in 3 rounds of testing with x 14 easy readers and specialist clinicians</b></p>	
<b>Number of Rounds of testing</b>	x 3 rounds of testing
<b>Professionals</b>	<p>x 9 professionals</p> <ul style="list-style-type: none"> <li>- Writers of easy reads and groups for those with learning difficulties</li> <li>- Type 1 Diabetes nurses and nurses who work specifically with those with learning difficulties</li> </ul>
<b>Easy Read users</b>	<p>5 Easy Read users including 2 who have type 1 diabetes from:</p> <ul style="list-style-type: none"> <li>- Thameside People First</li> </ul>
<b>Notes and lessons learned from previous development</b>	<p>To our knowledge there were no other decision aids / decision support tools in Easy Read format (i.e. documents helping readers make a treatment decision informed by evidence).</p> <p>Usually Easy Read users would be using the leaflets with a carer or clinician. We aimed for the language and illustrations to be as simple as possible but in some instances need to rely on carers or others to explain some concept. If users have profound disability such that they need help to understand they would always have someone with them to advocate for them or explain to them.</p> <p>Some feedback about images came from clinicians, for example, we initially showed a GP in a white coat. GPs (and other clinicians) pointed out that they do not wear white coats. We tested with the Easy Read users and asked 'what we could draw to show a doctor?' They suggested a desk, a monitor and a stethoscope.</p> <p>We developed and tested ways of expressing the concept of a 'choice' and presenting different options and</p>



	<p>outcomes in a way that the readers could make a decision (by themselves, if necessary).</p> <ul style="list-style-type: none"><li>- Easy Read users preferred photographs when a specific kind of medication or treatment was being referred to and they wanted to know what it looked like. Otherwise, cartoons were OK. There were several poses that they were used to seeing.</li><li>- If using a colour key (e.g. purple is always medicine in the leaflet), they asked us to explain this. For example, say clearly “medicines are always purple in this leaflet” - explaining what we were doing instead of assuming a key, colour code, shape etc would ‘speak for itself’.</li><li>- Because the leaflets are long, we clearly split them into sections, explaining at the start that you might not want to read it all at once. And that you don’t need to.</li></ul> <p>Risks and benefit visualisations</p> <ul style="list-style-type: none"><li>- We experimented with ways of showing the potential risks and benefits of the different options. In the standard versions of the same tools these are generally expressed as expected frequencies (number out of 100 expected to show each outcome), plus a bar to show the number visually; e.g. 20 in every 100 who have this treatment have this effect.</li><li>- We usually present ranges around the numbers to encompass the quantified uncertainty in the data available.</li><li>- We also usually present the evidence in the past tense (out of 100 people who HAD/CHOSE...) to emphasise that the numbers are not a prediction but are a summary of past numbers.</li></ul> <p>For Easy Read users</p> <ul style="list-style-type: none"><li>- For the Easy Read audience, these bars were not clear, and nor were the ranges. They also found the past tense more difficult than present tense.</li></ul>
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- We also could not present outcomes 'out of 100' because this high number wasn't so easily imagined by the audience.
- Testing revealed that 'out of 10' outcomes were understandable for the audience, and generally provided as precise a number as they needed to inform their decision. So we present the risks and benefits out of 10.
- This of course means 'rounding' - sometimes in quite an extreme way. However, our testers felt that it gave them enough information to make comparisons.
- Easy Read users told us they were used to 'faces' as icons, to help them know which represented positive and which represented negative outcomes without having to check. This was useful on the 'amount of bleeding' outcome on heavy periods (even though we are describing a continuous outcome, not a frequency). For most other outcomes (frequencies), anthropomorphic icons were fine.
- They also told us that they were used to having the number that had a 'positive' outcome on the right hand side, and those that had a 'negative' outcome on the left hand side of an icon array, and to be consistent with that (rather than putting the number that 'had' the described outcome always on the left).
- Testers were very happy to see the information and have it presented so clearly. They were very engaged and happy to have been consulted.

It would not have been possible to make these Easy Read versions without multiple testing rounds. We consistently found language or images that we felt were clear, but did not make sense at all to the groups.

**Example feedback and decisions specific to T1DM**

We tested the leaflet with diabetic people with learning difficulties and other easy readers who did not have diabetes.

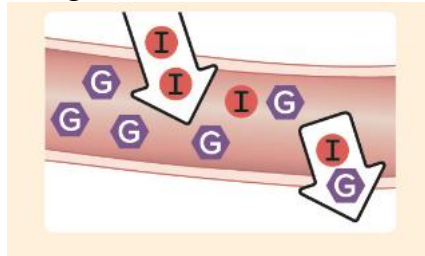
The T1DM decision aids, both standard and easy read versions will always be used with a clinician at some point. For this reason, some feedback was considered with this in mind, such as illustrations of the devices being described not being immediately obvious to non-diabetics. To diabetics, and ‘in the moment’ when the leaflet would be used, users would either have had access to these, or the device would be available to look at the time.

Diabetic easy readers prefer “blood sugar” to “blood glucose”.

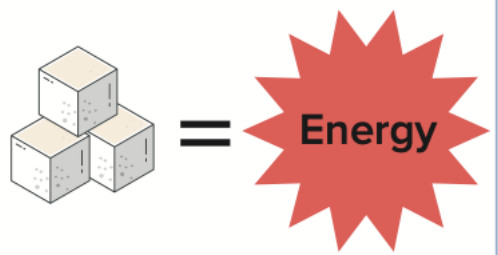
Some of the illustrations were too abstract or ‘science-y’, for example

“Insulin helps your body use sugar for energy”

Changed from



To



Because at time of printing, some people are eligible for some technology and not others, and because throughout the document the user is required to make a choice, think about a decision, we added reflective ‘yes / no’ prompts to most options.

“Your diabetes nurse will tick this box if you can choose...Y/N”

Or



	<p>“Do you want to try a pump? Y/N”</p> <p>In order to help the reflective choice element of the decision throughout.</p>
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