Implementation of Freestyle Libre® prescribing guidance across the NHS in London

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Additional supplementary paperwork to follow:
- Estimated numbers for the region and associated costings for each recommendation
- Shared care/transfer of care documentation and patient-prescriber agreement (as per section 3)
- Recommended additional information for patients (beyond user training) including sensor adhesion guide, what to do if a sensor falls off, disposal guidance, etc.
- Detailed training recommendations
Section 1 – Background to the document

1.1 Background to the London implementation recommendations

NHS London Procurement Partnership (LPP) were asked to facilitate the production of a pan-London clinical consensus for the use of FreeStyle Libre® in the NHS at the London Chief Pharmacist and CCG lead meeting on the 28th of September 2017.

An interim advice document was then written and agreed with senior members from the NHSE London diabetes clinical networks and the Children and Young People’s South East Coast & London Diabetes Network, as well as stakeholders within LPP’s Responsible Diabetes Prescribing Group (RDPG). This was published on the 13th of October 2017. The key recommendation from this was the following: Prescribers in primary care should not prescribe Freestyle Libre® sensors on an NHS prescription until the Freestyle Libre® device has been evaluated and approved for use through local governance processes.

On the 1st of November, a national position statement was issued by the NHSE Regional Medicines Optimisation Committee (RMOC): https://www.sps.nhs.uk/articles/regional-medicines-optimisation-committee-freestyle-libre-position-statement/

The diabetes clinical networks in London had several discussions regarding the use of Libre® in London both before and after the RMOC statement. Post publication, they met on the 3rd of November and discussed the statement and made a number of suggestions regarding how this could be implemented in London. This was fed back to the London RMOC on the 9th of November by Vicky Chaplin (LPP) and the broad scope of how this could work was agreed.

In the context of clinical priorities and the configuration of services within the London Region, London RMOC members identified that more detailed implementation guidance is essential and recommended that the London Diabetes Clinical Network, working in collaboration with LPP, be approached to develop guidance within the next 3 months to support the implementation of FreeStyle Libre®.

1.2 What is FreeStyle Libre®?

The FreeStyle Libre® flash glucose monitoring system is a device for the self-monitoring of glucose levels. Unlike traditional finger-prick devices (that measure the glucose level in the blood), Libre® measures the glucose level in the interstitial fluid, via a sensor that sits just under the skin.

It can provide a near-continuous record, which is produced by the patient scanning the sensor with their reader-device, as and when required.

Additional education and training is necessary for any healthcare professionals or patients who wish to use this system.

FreeStyle Libre® was listed in the Drug Tariff on the 1st of November 2017.
1.3 Quality assurance

Abbott were asked for relevant certification regarding quality assurance for the device and LPP are happy to forward these on to individual organisations, if required. EC certification (93/42/EEC Medical Device Directive) and Abbott’s declaration of conformity to the following was also sent:

- 92/42/EEC Medical Device Directive
- 2011/65/EU Restriction of Hazardous Substances Directive

1.4 How accurate is it?

Assessment of available evidence in the NICE Medtech Innovation Briefing 110 (July 2017) deemed the FreeStyle Libre® device to be clinically acceptable in terms of accuracy when compared to self-monitoring blood glucose measurement devices.

1.5 Is this a replacement for fingerprick blood glucose testing?

As FreeStyle Libre® measures glucose levels in the interstitial fluid, it is not a complete substitute for blood glucose testing. Self-monitoring blood glucose (SMBG) measurements are required in certain circumstances, including:

- during times of rapidly changing glucose levels when interstitial fluid glucose levels, may not accurately reflect blood glucose levels,
- when scanned glucose results do not correspond with the user’s symptoms,
- where the reader indicates a low glucose reading,
- to meet Driving and Vehicle Licensing Agency requirements,
- to use bolus calculators.

The average daily number required for the individual should be discussed and sufficient test strips should be provided in addition to FreeStyle Libre®, if Libre® is prescribed.

1.6 Notes on the use of SMBG testing alongside FreeStyle Libre®

The FreeStyle Libre® device has the option to use the handset as a SMBG and ketone meter, in conjunction with FreeStyle Optium blood glucose and ketone strips. Organisations are advised that it is not essential to use this functionality (and these strips) and patients can continue to use their current SMBG meter alongside the Libre® device. It is important to ensure that patients have enough SMBG testing strips as per their requirements, but the brand chosen should continue to reflect local formularies, the functionality required and patient choice.

1.7 Does this device have alarms?
Caution should be noted for those with hypoglycaemia unawareness and/or frequent (more than 2 episodes a week) asymptomatic hypoglycaemia that is causing problems with daily activities, as Libre® will not provide warnings or alarms about low or high glucose levels.

1.8 Who will be prescribing this?

Initiation should only be carried out by the local specialist diabetes team. Specialist centres available will vary locally and may comprise either secondary or both secondary and intermediate care services. Prescribing is expected to be transferred to primary care at 2 months (see later information on processes). Transfer of prescribing must be accompanied by clear monitoring responsibilities and information on ongoing review and it is suggested that the transfer of care documents (supplied separately) are used.

1.9 Which groups of patients are eligible?

The device is initially indicated for use in people with type 1 diabetes, under specialist care, using multiple daily injections (MDI - 4 or more doses of insulin a day) or insulin pump therapy, as per the RMOC statement released in November 2017. The specific cohorts of patients within this group are detailed in the recommendations below.

The clinical networks acknowledge the potential benefit of this device in those with type 2 diabetes on MDI – particularly for recommendations 1 and 3 in this document – and we anticipate this will be reviewed by the summer of 2018.

1.10 How was this guidance formulated?

Expert opinion on local implementation of the RMOC statement was sought from the NHSE London diabetes clinical networks (Clinical Leadership Group and Type 1 Diabetes Network). Additional advice was sought from members of the South East Coast and London Children and Young Peoples Diabetes Network for paediatric patients. These groups contain a variety of clinician, commissioner and patient representatives and ongoing review regarding the practicalities and implementation of this document was facilitated by the input of external commissioner, formulary and primary care pharmacists via the NHS LPP Responsible Diabetes Prescribing Group.

The minutes of the RMOC meeting were not available at the time of writing this document, but the London diabetes clinical networks acknowledged the similarities between the North RMOC position statement and the formulary case from ABCD¹. This was therefore reviewed in order to gain an insight to the background of the RMOC recommendations, in addition to existing evidence where available (NICE MIB 110² (including trials referenced in this document), the Diabetes UK consensus guideline for Flash Glucose Monitoring³ and the Abbott Formulary Pack (available on request from Abbott and can be forwarded via email from NHS LPP/clinical networks if needed). Related NICE guidance for diabetes was also referred to as appropriate and is referenced throughout the document.

1.11 Summary of recommendations

Implementation of Freestyle Libre® prescribing guidance across the NHS in London 17th August 2018, version 1.4
Implementation of Freestyle Libre® prescribing guidance across the NHS in London
17th August 2018, version 1.4
Section 2 – Implementation guidance pathways

1. Recommended implementation of FreeStyle Libre® prescribing for patients with type 1 diabetes on MDI or insulin pump therapy who test frequently – pathway for specialist initiation

Identify patients where the use of Libre® may facilitate a safe reduction in test strip usage of 8 or more a day, being mindful of the Libre® license (see user manual), DVLA regulations and any other requirements*

Less than 3 months of high frequency testing**

More than 3 months of high frequency testing**

Consider in:
- pregnancy (including pre-conception period may be started pre-conception if under active pre-conception care, i.e. pre-conception clinic)
- elective surgery,
- cancer treatment,
- children aged 0-19 years (NB licensed for 4 years and above).

Consider reasons for frequent testing and discuss if the use of Libre® could significantly reduce this (by at least 8 strips a day for adults/at least 7 for children aged 0-19 years)**

If likely to reduce as above, start trial of FreeStyle Libre® in specialist care as detailed below.

If unlikely to reduce as above, consider alternative treatment options, as per local pathways.

*Please consider individual needs for SMBG blood testing, as per point 1.5

**confirm with data download from meter
1. **Recommended implementation of FreeStyle Libre® prescribing for patients with type 1 diabetes on MDI or insulin pump therapy who test frequently – further information, including transfer into primary care**

   a) **Outcome for review** - If FreeStyle Libre® is initiated for the above indication, the intention should be to reduce test strips by at least 8 strips a day (7 in children aged 0-19 years). If this is not achieved by 6 months prescribing may be discontinued and this should be discussed and agreed with the patient at initiation (see patient contract).

   b) **Suggested timeframe** – It is suggested that the reduction in the use of SMBG test strips is gradual and takes place over the initial 6 weeks, as familiarity with the system increases. Details of this will be agreed between the specialist and patient at initiation and detailed in the letter from the specialist team. The specialist will continue to review this item and the average reduction in SMBG test strip usage at future clinic appointments, but it is suggested that primary care practitioners also discuss self-monitoring requirements with the patient at around 6 weeks and take this opportunity to consider if the product will be placed on repeat prescription from 2 months. Please see further details of this process under “review and prescribing timelines”.

   c) **Key consideration** - If it is likely that a significant reduction (as detailed above) will not be achieved and a high number of SMBG tests will still be required (e.g. for frequent drivers) then this product is not suitable for prescribing under this recommendation (duplication of therapies). The primary outcome for review is the average reduction in test strips when considering cost-effectiveness, and this should be discussed as opposed to a “target” daily amount. It is important to make sure that sufficient SMBG test strips are prescribed for the individual’s needs as per the points detailed in point 1.5 (estimate average monthly usage); the recommended amount for retention on prescription will be detailed in the initiation letter, but may change depending on additional outcomes observed with the FreeStyle Libre®.

   d) **Information for self-funders who identify as coming under this recommendation** – Prior to review in specialist services, it is recommended that primary care prescribing data for SMBG test strips from the patient’s primary care clinical record is reviewed for the previous year (as well as recent meter download information, which can be reviewed in clinic) and that these are provided as evidence for continuation of FreeStyle Libre® on an NHS prescription (i.e. evidence of reduced usage of SMBG test strips as detailed above, following initiation of FreeStyle Libre®). Data for number of strips required prior to initiation (at least 6 months), date of initiation and information on SMBG testing 6 months post initiation should be considered, wherever possible. If patients fulfil criteria for NHS prescribing they will then continue to be reviewed as per the terms of this document.
2. **Recommended implementation of FreeStyle Libre® prescribing for patients with type 1 diabetes with HbA1c ≥ 8.5% (69.4 mmol/mol) or disabling hypoglycaemia who would be eligible for insulin pump therapy as per TA151** – pathway for specialist initiation

**Identify children under 12 where MDI therapy is considered to be impractical or inappropriate.**

**Identify adults and children 12 years and older with type 1 diabetes mellitus where:**

- attempts to achieve target haemoglobin A1c (HbA1c) levels with multiple daily injections (MDIs) result in the person experiencing disabling hypoglycaemia OR
- HbA1c levels have remained high (that is, at 8.5% [69 mmol/mol] or above) on MDI therapy (including, if appropriate, the use of long-acting insulin analogues as per local pathways) despite a high level of care. A high level of care is defined by the clinical networks as appropriate education and monitoring of capillary blood glucose with support from the diabetes team and regular attendance at clinic appointments.

**Confirm the following interventions are already included in management:**

- 4 or more SMBG tests a day and commitment to self-management.
- Strong engagement with specialist services, which have provided a high level of support including education provision covering (at a minimum): principles of insulin dose adjustment, appropriate management of hypoglycaemia and hyperglycaemia, self-management.

**Consider initiation of insulin pump therapy.**

If after discussion between the specialist and patient/carer, insulin pump therapy is not deemed practical or appropriate, consider a trial of FreeStyle Libre® as detailed below.


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The clinical networks also note that real-time CGM can be used as a strategy for the optimisation of HbA1c and/or reduction in hypoglycaemic episodes, as per NG17\(^1\) (type 1 diabetes in adults) and NG18\(^2\) (type 1 and type 2 diabetes in children and young people):

NG17\(^1\) states: “Consider real-time continuous glucose monitoring for adults with type 1 diabetes who are willing to commit to using it at least 70% of the time and to calibrate it as needed, and who have any of the following despite optimised use of insulin therapy and conventional blood glucose monitoring:

- More than 1 episode a year of severe hypoglycaemia with no obviously preventable precipitating cause.
- Complete loss of awareness of hypoglycaemia.
- Frequent (more than 2 episodes a week) asymptomatic hypoglycaemia that is causing problems with daily activities.
- Extreme fear of hypoglycaemia.
- Hyperglycaemia (HbA1c level of 75 mmol/mol [9%] or higher) that persists despite testing at least 10 times a day (see recommendations 1.6.11 and 1.6.12). Continue real-time continuous glucose monitoring only if HbA1c can be sustained at or below 53 mmol/mol (7%) and/or there has been a fall in HbA1c of 27 mmol/mol (2.5%) or more.”

NG18\(^2\) states: “Offer ongoing real-time continuous glucose monitoring with alarms to children and young people with type 1 diabetes who have:

- frequent severe hypoglycaemia or
- impaired awareness of hypoglycaemia associated with adverse consequences (for example, seizures or anxiety) or
- inability to recognise, or communicate about, symptoms of hypoglycaemia (for example, because of cognitive or neurological disabilities).

Consider ongoing real-time continuous glucose monitoring for:

- neonates, infants and pre-school children
- children and young people who undertake high levels of physical activity (for example, sport at a regional, national or international level)
- children and young people who have comorbidities (for example anorexia nervosa) or who are receiving treatments (for example corticosteroids) that can make blood glucose control difficult.

Consider intermittent (real-time or retrospective) continuous glucose monitoring to help improve blood glucose control in children and young people who continue to have hyperglycaemia despite insulin adjustment and additional support.”

Reference 1. Type 1 diabetes in adults: diagnosis and management NICE guideline [NG17] Published date: August 2015 Last updated: July 2016

Reference 2. Diabetes (type 1 and type 2) in children and young people: diagnosis and management NICE guideline [NG18] Published date: August 2015 Last updated: November 2016
FreeStyle Libre® may be considered as an option if traditional CGM devices are deemed not to be suitable or practical (including for patients already on an insulin pump). Particular caution is advised for prescribing where there is impaired awareness of hypoglycaemia, a history of severe hypoglycaemia (defined as requiring the assistance of another person, as per NICE guidelines such as NG17, TA151), or frequent asymptomatic episodes as the use of a device with warnings or alarms is strongly advised.
2. **Recommended implementation of FreeStyle Libre® prescribing for patients with type 1 diabetes with HbA1c >8.5% (69.4mmol/mol) or disabling hypoglycaemia who would be eligible for insulin pump therapy as per TA151** – further information, including transfer into primary care  
   a) **Outcome for review** - If FreeStyle Libre® is initiated for the above indication, the intention should be to reduce HbA1c by 0.6% (6.6mmol/mol) and/or reduce severe hypoglycaemic episodes by 75%, as detailed in TA151. The networks feel that if these outcomes are not achieved with Libre®, then consideration of other locally available and appropriate technologies should be revisited. Expected outcomes should be discussed by the specialist and patient at initiation and noted in the clinical records.

   b) **Suggested timeframe** – It is suggested that a review of outcomes should take place with the specialist team around 3-6 months after initiation. Primary care practitioners may be asked to issue acute prescriptions for sensors from month 2 onwards until this review has taken place and confirmation of long-term prescribing provided and accepted.

   c) **Key considerations** - The clinical networks discussed the place of FreeStyle Libre® in treatment pathways involving insulin pumps and CGM and considered where Libre® should feature. Whilst explicit commissioning policies are not in place across all of London, the need to comply with TA151 and provide the option to all eligible patients is clearly understood. They noted that the FreeStyle Libre® device is not a like-for-like alternative to pump therapy and patients eligible under TA151 should always be considered for an insulin pump if this is the most appropriate choice for the individual patient. There may be some circumstances where the patient and clinician feel that Libre® should be trialled prior to pump therapy.

   The networks would also like to emphasise that if a patient is suitable for CGM as per NICE guidance this should be considered and eligibility reviewed in line with local commissioning policies. Libre® is not a like-for-like alternative in regards to all features of currently available CGM devices (e.g. Libre® device does not have alarms) and should not be automatically substituted where CGM was previously considered. This is especially the case for patients with impaired awareness of hypoglycaemia, a history of severe hypoglycaemia, or frequent (more than 2 episodes a week) asymptomatic hypoglycaemia that is causing problems with daily activities.

   d) **Information for self-funders who identify as coming under this recommendation** – Patients who have used FreeStyle Libre® with the intention to reduce HbA1c (from at least 8.5% (69.4mmol/mol)) or to reduce disabling hypoglycaemia, are expected to have these documented in historical clinical records (ideally within the last year) and should be able to demonstrate sustained improvements (as per the outcomes detailed above) post initiation of Libre® over a period of 6 months or more. The specialist team will review these with the patient and confirm if prescribing can be continued on the NHS.
3. Recommended implementation of FreeStyle Libre® prescribing for patients with type 1 diabetes on MDI or insulin pump therapy where conventional monitoring is not possible with SMBG testing – pathway for specialist initiation

Identify patients who have – or would be eligible for – third party monitoring and have multiple daily injections.

Is conventional monitoring possible?

Conventional blood testing is defined by the clinical networks as blood glucose testing taken at the appropriate time and frequency as required for the individual’s diabetes management. Factors that prevent conventional testing (such as those noted below) must be those that are outside of the patient or carer’s control.

Yes. Current and ongoing care facilitates appropriate testing for that individual.

FreeStyle Libre® not appropriate under this indication.

No. Due to factors outside of the patient or carer’s control, conventional monitoring would not be possible without third party assistance.

Examples include:

- Those with formally diagnosed needle phobia that interferes with their ability to perform SMBG monitoring as required.
- Those with physical impairment, dexterity issues or disabilities that reduce the ability to take multiple finger prick tests, e.g. missing limbs, clubbed fingers, poor peripheral circulation, arthritis.
- Those with resistance to conventional testing by a third party that results in suboptimal numbers of readings being taken, e.g. learning disabilities, dementia, severe mental illness.
- Children below the age of 8 (where current provision of third party monitoring at home/school is deemed to be suboptimal).

Consider trial of FreeStyle Libre® as detailed below.

NB It is not envisaged that those under community nursing services will be automatically eligible for FreeStyle Libre® under this indication. The clinical networks discussed how it was unlikely that monitoring would be a sole reason for any nursing visits and therefore the use of Libre® would not have a significant effect on reducing workload or enhancing monitoring, without the provision of additional training.
3. **Recommended implementation of FreeStyle Libre® prescribing for patients with type 1 diabetes on MDI or insulin pump therapy where conventional monitoring is not possible with SMBG testing – further information, including transfer into primary care**

   a) **Outcome for review** - If FreeStyle Libre® is initiated for the above indication, the intention should be to ensure appropriate monitoring of glucose levels is possible for the patient. The definition of appropriate monitoring is dependent on the individual and should be defined and noted following discussion between the specialist and patient at the initial consultation.

   b) **Suggested timeframe** – It is hoped that appropriate monitoring will be achieved relatively quickly after introducing the use of FreeStyle Libre®. The level of monitoring agreed at initiation will be detailed in the initiation letter and reviews may take place in primary care or at the specialist clinic, to determine continuation of prescribing in primary care at 6-8 weeks. Please note that if a primary care or clinic appointment is not organised before the end of 2 months some acute prescribing in primary care may be needed. A decision regarding continuation should be made as per the terms defined at initiation by 3 months.

   c) **Key consideration** – the FreeStyle Libre® would not be appropriate under this indication for those where adequate monitoring is already in place, even if via a third party. It is also not appropriate where adherence or compliance issues are the sole barrier to conventional monitoring (engagement with therapy should be addressed first-line).

   In regards to use in children, a defined age range is given of those below the age of 8, where current provision of third party monitoring at home/school is deemed to be suboptimal. The reasoning for this is that in many school situations there is full time support for children up to the end of Year 2 (infants). Glucose monitoring is undertaken for the child by the one to one carer, but provision of this will vary locally. After Year 2 (approximately the age of 8) care is gradually reduced so that by Year 6 the child is expected to be almost self-managing. In regards to continuation beyond 8 years, the specialist is expected to review progress regularly and communicate this with the GP practice. If Libre® is to be continued for reasons other than assisting monitoring beyond the age of 8 years (e.g. significant improvement in HbA1c) this may be considered for primary care prescribing, dependent on local agreement.

   d) **Information for self-funders who identify as coming under this recommendation** – Prior to review in specialist services, it is recommended that primary care prescribing data for SMBG test strips from the patient’s primary care clinical record is reviewed for the previous year (as well as recent meter download information, which can be reviewed in clinic) with consideration of monitoring prior (recommended 6 months) and post (recommended 6 months) initiation of FreeStyle Libre®. This data should inform discussions alongside considerations regarding the improvements seen in monitoring from the patient and/or carer’s perspective.
### Section 3 – Recommended review and prescribing timeline for all recommendations

<table>
<thead>
<tr>
<th>Month</th>
<th>Activity</th>
<th>Paperwork required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Month -1</td>
<td>Initial discussion regarding FreeStyle Libre® and agreement between prescriber and specialist clinician.</td>
<td>Patient-prescriber agreement to be read through and discussed. Referral to in-house training session.</td>
</tr>
<tr>
<td>Month 0</td>
<td>Group training session at specialist site. If patient wishes to continue, completion of training will result in supply of FreeStyle Libre® handset and sensor starter pack, plus one additional sensor. Complete and sign patient-prescriber agreement.</td>
<td>Notify GP of initiation of FreeStyle Libre®, by sending completed patient-prescriber agreement. Clinic to complete initiation data collection form (see later section on data and monitoring).</td>
</tr>
<tr>
<td>Month 1</td>
<td>Patient to attend specialist centre for initial usage review (recommended in original training group) to discuss any potential issues with the technology. If continuation agreed, one further month of sensors (2 sensors) to be supplied from specialist care. Request short-term prescribing from primary care using appropriate form.</td>
<td>Prescription for 2 sensors from specialist centre. Send short-term prescribing request (indication 2) or request for prescribing review (1/3). Patient to book primary care appointment for 6 weeks post initiation, if applicable.*</td>
</tr>
<tr>
<td>Month 2</td>
<td>If locally agreed - GP to inform clinic of progress of outcomes for recommendations 1 and 3 following primary care appointment at 6 weeks. Primary care is asked to supply acute prescriptions for up to a further 3 months. The clinic will confirm continuation and need for repeat prescribing after next scheduled clinic appointment (at 3-4 months).</td>
<td>Primary care prescriptions – acute – for up to 3 months if GP practice has agreed.</td>
</tr>
<tr>
<td>Month 3-4</td>
<td>Specialist review of outcome achievement (may be facilitated by information from GP for 1 and 3) and formal request for long-term prescribing.</td>
<td>If continuation confirmed send long-term prescribing agreement to primary care. Continuation data collection form by specialist care. Set up of repeat prescription in primary care, if applicable.</td>
</tr>
<tr>
<td>1 year</td>
<td>Review here and annually thereafter</td>
<td>Continuation data collection form by specialist care.</td>
</tr>
</tbody>
</table>

*Potential for GP practices to conduct an initial primary care review of outcomes at 6-8 weeks (recommendations 1 and 3) should be confirmed at a local level.


### Section 4 – Ordering information

FreeStyle Libre® readers (with one sensor) will be supplied to clinics free of charge by Abbott. Subsequent sensors should be supplied on prescription and the networks and LPP recommend that this is a further three from specialist care and then long-term continuation in primary care.

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The sensors are not available by standard wholesalers and pharmacies must set up a direct account with Abbott. Delivery is next day (if ordered before 5pm) via UPS. The prices are as follows:

Community pharmacies £35.00 - using pharmacy portal [https://www.freestylelibrepharmacyportal.co.uk/](https://www.freestylelibrepharmacyportal.co.uk/)

Outsourced outpatient pharmacies £35.00 - using pharmacy portal [https://www.freestylelibrepharmacyportal.co.uk/](https://www.freestylelibrepharmacyportal.co.uk/)

NHS Hospital Trust pharmacies £35.00 plus VAT - using pharmacy portal [https://www.freestylelibrepharmacyportal.co.uk/](https://www.freestylelibrepharmacyportal.co.uk/)

NHS LPP and the network have enquired regarding procurement of stock and have been informed that procurement teams can order at £48.29 plus VAT, via a Purchase Order should be sent to abbott.freestylelibre@nhs.net Abbott have confirmed they are not currently exploring discount schemes, either nationally or regionally.

Section 5 – Data collection

The clinical networks appreciate the need for real-life data to be collected on this and are grateful for the production of the ABCD audit material. These forms can be found here: [https://abcd.care/launch-abcd-nationwide-freestyle-libre-audit](https://abcd.care/launch-abcd-nationwide-freestyle-libre-audit)

The London diabetes clinical networks are keen to review data at a regional level and have therefore provided short forms to be completed for regional review. These are available on the website page with other associated documents.

Discussions regarding the collection of this highlighted a number of preferred formats and therefore both Word and PDF have been provided for in-clinic use, with an additional Excel master sheet for quarterly submission to the networks (further instructions can be found on this form).

All data collection will take place in specialist care. The time and resource pressure was noted but deemed to be unavoidable in order to contribute to increased data on this device to facilitate regional review. It was decided that the initiation form must be completed at the initial training session and then follow-up form completion is recommended at the next clinic appointment (3-6 months), at 12 months and then annually thereafter.

Section 6 - Expected outcomes

In order to gain maximum benefit from the device, sensors should be worn continuously (one sensor for each consecutive 14 day period) and ideally, scans should be undertaken to provide 24/7 readings (each scan provides 8 hours of data). At a minimum the sensor must be scanned at least four times per day for contemporaneous readings and it is anticipated that the scans taken will be at appropriate intervals to provide continuous glucose levels covering 20-24 hours per day, every day.

Following review, continuation of therapy is only indicated if predetermined outcomes have been observed (depending on initial indication and agreement between the patient and

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clinician at initiation), which are summarised below. This will ensure that treatment is appropriate and tailored to individual patients:

- A substantial reduction in test strip usage must be seen if the device has been initiated under recommendation 1.
- An improvement in clinical outcomes (as defined for individual) must be seen if initiated under recommendation 2.
- Appropriate monitoring of glucose levels for the individual patient must be observed if initiated under recommendation 3.

Other benefits or outcomes that may be observed include:

- improved quality of life,
- better glycaemic control during acute periods (e.g. pregnancy, surgery)
- improved monitoring for parents (e.g. during school, sleep)

The use of FreeStyle Libre® may result in improved management, which can theoretically lead to a reduced HbA1c, a reduction in hypoglycaemic episodes, reduction in admissions, etc. Initiating specialist centres must ensure data collection forms are completed as appropriate to ensure that these can be reviewed at a later date to facilitate a review of this implementation guidance. NB Please note, a reduction in the use of test strips does not automatically result in improved clinical outcomes.

If the agreed benefits and outcomes have not been achieved by 3-6 months, the initiating team and patient should have a discussion as to why this may not be. If it is agreed that it is unlikely any further improvements will be seen, then the use of Libre® should be discontinued, as per the terms in the patient-prescriber agreement.

As more data is collected, this guidance may be reviewed at a later date to include further information on expected clinical outcomes.

Section 7 - Exclusions for prescribing of FreeStyle Libre®

FreeStyle Libre® may NOT be suitable in some circumstances, even if the patient meets the requirements of the listed indications. Consider alternatives to monitoring with Libre® for the following patients:

- Those who will not realistically reduce their test strip usage by the amount specified above (if initiated under recommendation 1), leading to a significant cost pressure.
- Those with no hypoglycaemia awareness (including where CGM had been deemed not suitable or practical).
- Those with an allergy to medical grade adhesive.
- Children and young people on CSII who need to test their blood glucose frequently to make insulin dosing decisions, including with pump algorithms. A reasonable number of SMBG strips will be required for this as many require blood glucose measurements. Some pump devices (e.g. Medtronic 640G) can use glucose levels from interstitial fluid for these calculations but blood glucose is deemed to be more appropriate. If interstitial glucose levels are to be measured and used with pumps where the algorithm supports this, ideally this should be from a CGM device.
Patients (or carers, where appropriate) who have not had appropriate basic diabetes education to date, covering at the very least: principles of insulin dose adjustment, appropriate management of hypoglycaemia and hyperglycaemia, and general self-management. These must be completed first, including follow-up, before considering introducing FreeStyle Libre®.

Those not under the care of a specialist team with skills to support the initiation of Libre® for the first 6 months.

**NB the use of Libre® must be associated with sufficient training and engagement in order to ensure that its use is safe and effective for ongoing measurement of glucose levels. Please see training recommendations below.**

**Section 8 – Training recommendations**

There are currently 27,145 people with type 1 diabetes in London (NDA 16/17). NHSBSA prescribing data suggests around 1400 of these test 8 or more times a day, but the number eligible under recommendations 2 and 3 is uncertain. Regardless of total numbers, the need for a controlled and supported rollout is recognised.

One of the most important parts of implementation is adequate training for clinicians (who will then provide this to patients). The clinical networks have liaised with Abbott to ensure this is provided in a fair and timely manner (as well as reviewing content). This device must only be initiated in specialist care and therefore clinic resources will stagger uptake across the region. It is recommended that services attempt to offer at least one session per month (approximately 1 hour) for 12-16 patients at a time; this must take place before the device is provided. The networks and NHS LPP will liaise with primary care in order to ensure that primary care practitioners receive adequate information about this device and feel supported in prescribing the sensors when care is continued. Detailed transfer of prescribing documentation and patient contracts are also provided to support care across the treatment pathway.

We will learn from current and successful training programmes and recommended training competencies have been published as supplementary documents. As an overview:

- The clinical networks have discussed and agreed key topics for inclusion in training sessions at each level.
- The content for specialist training by Abbott have been agreed between Abbott and clinical network leads and details of this will be available in supplementary documentation.
- This will be rolled out over localities as guidance is approved.
- Once members of the specialist centres have been trained for initiation and patient training, it is advised each centre holds 1-3 sessions for 12-16 patients at a time (1 hour) each month (depending on capacity of clinic).
- Minimum content of patient training and additional resources have been advised in supplementary documentation.
- Basic information for primary care prescribers (how to use device is covered in a supplementary sheet, with links to instructional videos that are publically available from Abbott. Additional online material is available via Abbott’s website.
Supplementary documentation on training recommendations includes:

- Initiating clinicians must be able to:
- Continuing prescribers must be able to:
- Patients must be able to:

All documents highlighted above can be found here: http://www.londonscn.nhs.uk/networks/cardiovascular/diabetes/freestyle-libre/

Section 9 - Future reviews and recommendations

The London diabetes clinical networks recognise that FreeStyle Libre® is a novel and innovative device and encourage local organisations to consider the recommendations above for the benefit of groups of patient, as specified previously.

The networks are also aware that there are other potential groups of patients who may benefit that are not included in these recommendations. The networks would emphasise that this guidance is suitable for the initial roll-out of Libre® prescribing, and later reviews may include additional groups, as and when more data becomes available. The groups highlighted below are also dependent on ensuring sufficient and appropriate training has been rolled out into primary care and community services.

Future groups for review include:

- People with type 2 diabetes on MDI, as detailed earlier in this document.
- Those under district nurse services where the readings provided by Libre® can be integrated into enhanced patient care.

These reviews are anticipated to take place shortly after implementation of this document. A review of the current recommendations will be initiated no later than April 2019, against the data collected by the local and national audits on the use of Libre® in practice; this and consideration of any future cost-effectiveness models produced may or may not widen the list of outcomes considered for each indication (dependent on the results published).

The networks also recognise that if the price falls, or other similar devices come to market, then the place of Libre® in the pathways above should be reviewed in line with any new information.
The Regional Medicines Optimisation Committee (North) reviewed the use of the flash glucose monitoring system, Freestyle Libre®, at its meeting on October 26th 2017.

The advice of this group to Area Prescribing Committees is as follows:

Until further trial data is available, it is recommended that audit data on the use of Freestyle Libre® is collected through its use in limited and controlled settings where patients are attending for Type 1 diabetes care.

It is recommended that Freestyle Libre® should only be used for people with Type 1 diabetes, aged four and above, attending specialist Type 1 care using multiple daily injections or insulin pump therapy, who have been assessed by the specialist clinician and deemed to meet one or more of the following:

1. Patients who undertake intensive monitoring ≥8 times daily
2. Those who meet the current NICE criteria for insulin pump therapy (HbA1c >8.5% (69.4mmol/mol) or disabling hypoglycaemia as described in NICE TA151) where a successful trial of FreeStyle Libre® may avoid the need for pump therapy.
3. Those who have recently developed impaired awareness of hypoglycaemia. It is noted that for persistent hypoglycaemia unawareness, NICE recommend continuous glucose monitoring with alarms and Freestyle Libre does currently not have that function.
4. Frequent admissions (>2 per year) with DKA or hypoglycaemia.
5. Those who require third parties to carry out monitoring and where conventional blood testing is not possible.

In addition, all patients (or carers) must be willing to undertake training in the use of Freestyle Libre® and commit to ongoing regular follow-up and monitoring (including remote follow-up where this is offered). Adjunct blood testing strips should be prescribed according to locally agreed best value guidelines with an expectation that demand/frequency of supply will be reduced.

Freestyle Libre® is an innovative new device that has the potential to improve quality of life for patients and support self-management. However, at the present point in time there are significant limitations in available clinical trial data and economic analysis that make it difficult to make an appropriate judgment as to its place in therapy.

The following concerns were noted with regard to the clinical evidence and costing information supplied:

- Trials contain only small numbers (n=700) of patients with well controlled Type 1
Implementation of Freestyle Libre® prescribing guidance across the NHS in London
17<sup>th</sup> August 2018, version 1.4

diabetes.

- Limited trial duration (9-12 months only)
- Limited data comparing to Continuous Glucose Monitoring
- Limited or no data of use in unstable patients, pregnancy, young people and children.
- Projected reductions in finger-prick testing are unrealistic given the need to test before driving (current DVLA requirement) and during illness.
- Costing information with regard to testing strips does not recognize significant reductions that have already been achieved in this area of prescribing.

The RMOC is aware that clinics using Freestyle Libre® are already collecting audit data and would strongly support all clinics to work collaboratively (potentially through the Association of British Clinical Diabetologists) to maximize learning about this new intervention and measure its impact in individual patients. We suggest information is collected on the following:

1. Reductions in severe/non-severe hypoglycaemia
2. Reversal of impaired awareness of hypoglycaemia
3. Episodes of diabetic ketoacidosis
4. Admissions to hospital
5. Changes in HbA1c
6. Testing strip usage
7. Quality of Life changes using validated rating scales.
8. Commitment to regular scans and their use in self-management.

We recommend that if no improvement is demonstrated in one or more of these areas over a 6 month trial then the use of Freestyle Libre® should be discontinued and an alternative method of monitoring used.

References:


ABC Type 1 Diabetes Clinical Collaborative: Information to help a formulary case for Freestyle Libre System October 2017. Available at [https://abcd.care/getting-freestyle-libre-your-formulary](https://abcd.care/getting-freestyle-libre-your-formulary)

Appendix 2 – Considerations by London in reaching the three implementation pathways

1. Recommended implementation of FreeStyle Libre® prescribing for patients with type 1 diabetes on MDI or insulin pump therapy who test frequently

Recommendation 1 from the RMOC statement is: “Patients who undertake intensive monitoring ≥8 times daily”.

SMBG testing will still be required for certain situations, as detailed in section 1.5, and therefore some SMBG testing strips should still be supplied for these circumstances. This will vary daily depending on individual requirements, but an average should be estimated between the clinician and the patient and regularly reviewed (e.g. at follow-up appointments).

The reasoning behind the RMOC recommendation is interpreted as meaning that if 8 or more test strips are being used a day, then using the Libre® to cover the majority of blood glucose testing (and concomitantly reducing finger prick tests by 8) will be cost neutral. Any additional perceived or observed benefits should be noted, but the ultimate aim of this indication is to reduce finger prick testing (other potential benefits are covered within other indications) and this should be borne in mind throughout initiation and continuation reviews. Therefore, a suggested reduction in total test strips is given below, as opposed to a target for a specific number.

Discussion within the clinical networks agreed that it was unlikely an average of less than two a day would not be plausible for the majority of patients. In children and young people, it is likely the baseline number will be higher (4-5). The relative cost benefit/pressure following initiation of Libre® and subsequent reduction in SMBG testing depends on the price of the testing strips and lancets prior to initiation.

The attached Excel sheet provides the potential ranges of cost-benefit/pressure depending on total reduction in average daily test strip usage and the lowest and highest cost testing strips and lancets. It may not always be possible to guarantee no cost pressure but the suggested reduction in this document aims to minimise the impact of this across the London population.

Libre Costings plus London.xlsx

Due to the individual and day to day variations in test strip usage it is not possible to calculate an exact figure for prescribing costs, but the networks feel that the calculations that follow are a fair assessment in order to ensure minimal impact financially for this particular indication.

Firstly, potential minimum and maximum cost pressures were calculated (if all patients used lowest cost and highest cost strips and lancets, respectively):
The average cost per strip in those testing 8 or more times a day was then compared across the 32 CCGs. This was taken from 16/17 ePACT2 data and cannot be differentiated by type. The networks feel that patients should not be penalised for being on cheaper strips and therefore a suggested reduction for all patients (regardless of original strips and lancets) has been suggested, based on a likely cost neutral point for the majority of patients, using the average cost per strip for each CCG in London across 2016/17.

The mean cost per strip for those with diabetes testing 8 or more times a day in London was 27p; at this cost, a reduction of 8 a day with Libre® is cost neutral. Further calculations are available in the supplementary paperwork that will follow this document.

<table>
<thead>
<tr>
<th>Reduction in test strips per day</th>
<th>Max cost pressure</th>
<th>Max cost benefit</th>
</tr>
</thead>
<tbody>
<tr>
<td>11</td>
<td>n/a</td>
<td>£561.17</td>
</tr>
<tr>
<td>10</td>
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<tr>
<td>4</td>
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</table>

The networks would also like to emphasise that if a patient is suitable for CGM as per NICE guidance this should be considered and eligibility reviewed in line with local commissioning policies. Libre® is not a like-for-like alternative in regards to all features of currently available CGM devices (e.g. Libre® device does not have alarms) and should not be automatically substituted where CGM was previously considered. This is particularly the case for patients with hypoglycaemia unawareness and/or with frequent (more than 2 episodes a week) asymptomatic hypoglycaemia that is causing problems with daily activities.

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Specialist clinicians in London felt it was important to emphasise that a high level of care was a prerequisite to technological interventions, in order to ensure that all relevant treatment options had been considered. A high level of care is defined as appropriate education and monitoring of capillary blood glucose with support from the diabetes team and regular attendance at clinic appointments.

**Recommendation 3 from the RMOC statement is: “Those who have recently developed impaired awareness of hypoglycaemia. It is noted that for persistent hypoglycaemia unawareness, NICE recommend continuous glucose monitoring with alarms and Freestyle Libre does currently not have that function.”**

This is not included as a standalone pathway in the London implementation guidance, because:

- Patients with intact hypoglycaemia awareness with frequent biochemical hypoglycaemia that interferes with daily activities are covered in pathway for recommendation 2.

- For those with hypoglycaemia unawareness, we recommend consideration of NICE guidance for the use of CGM (NG17 and NG18) in order to facilitate the appropriate use of CGM with alarms, as per the further notes to the pathway for recommendation 2.

**Recommendation 4 from the RMOC statement: “Frequent admissions (>2 per year) with DKA or hypoglycaemia.”**

This is not included as a standalone pathway in the London implementation guidance, because:

- The networks would like to emphasise that first-line support for recurrent DKA should include psychological support and management of any underlying causes. In some exceptional cases appropriate interventions may not have been successful and in these rare cases, technological interventions may be considered as per revised recommendation 2 (e.g. those with > 2 episodes of DKA per year may be eligible for Libre® if their HbA1c is > 8.5%, as per recommendation 2).

- Those with > 2 admissions of hypoglycaemia should be reviewed as per revised recommendation 2.

**3. Recommended implementation of FreeStyle Libre® prescribing for patients with type 1 diabetes on MDI or insulin pump therapy where conventional monitoring is not possible with SMBG testing**

**Recommendation 5 from the RMOC statement is: “Those who require third parties to carry out monitoring and where conventional blood testing is not possible”**.

The reasoning behind this recommendation is interpreted as the use of FreeStyle Libre® being an option to facilitate regular and appropriate (for the individual) glucose monitoring for patients who have previously not been able to test conventionally due to factors beyond their control, and therefore would require third parties to test appropriately for their individual needs.
Interpretation of this statement within London considers the following points:

- If third party monitoring is carried out and conventional monitoring IS possible via this, then Libre® is NOT necessary.

- If people are unable to carry out conventional blood testing but do not have access to third party monitoring, this does not exclude them (as they would require a third party in order to conventionally test).

At this stage, this indication does not apply to all housebound patients, patients in residential care or those under district nursing services.

Examples where Libre® is not currently recommended for prescribing include:

- District nursing where regular care is needed for other interventions (e.g. insulin injections) at the same or greater frequency than monitoring is required.

- Residential or nursing home services where staff regularly see and care for patients throughout the day.

The ultimate aim of this indication is to ensure that all eligible patients have access to a device that allows them to monitor appropriately. As many patients may previously have tested less than the recommended amount, it is likely that the prescribing of Libre® will result in a cost pressure, which should be taken account of within local budgets, using local population figures and estimated cost differential per patient where known (highly dependent on individual and previous testing frequency).